HRI Good Mood Tablets

Asda St John’s Wort Tablets

Power Health St John’s Wort Tablets

Bettermood Tablets

Food Supplement Company Herbal Mood Relief Tablets

Superdrug St John’s Wort Tablets

THR 02231/0002

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted The Herbal Research Company Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal products HRI Good Mood Tablets, Asda St John’s Wort Tablets, Power Health St John’s Wort Tablets, Bettermood Tablets, Food Supplement Company Herbal Mood Relief Tablets and Superdrug St John’s Wort Tablets (Traditional Herbal Registration number: THR 02231/0002). These products are identical to each other in all respects apart from their product names and will collectively be referred to as St John’s Wort Tablets in the remainder of this report. St John’s Wort Tablets are available without prescription and can be bought from pharmacies and other outlets.

The active ingredient in St John’s Wort Tablets comes from the aerial parts of the St John’s Wort plant, which is also known as *Hypericum perforatum* L. St John’s Wort is a traditional herbal medicine used to relieve the symptoms of slightly low mood and mild anxiety. This registration is based exclusively upon the longstanding use of St John’s Wort as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration Scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
HRI GOOD MOOD TABLETS
ASDA ST JOHN’S WORT TABLETS
POWER HEALTH ST JOHNS WORT TABLETS
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SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration certificate for the traditional herbal remedy St John’s Wort Tablets (THR 02231/0002) to The Herbal Research Company Limited on 28 September 2010. This product is on the general sales list (GSL).

This application was submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme. St John’s Wort Tablets is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety, based on traditional use only.

The data supplied by the applicant demonstrate 30 years of traditional use of St John’s Wort in the European Community. A satisfactory review of the available safety data on St John’s Wort has also been provided, together with an Expert Report supporting the proposed product.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: ST JOHN’S WORT AERIAL PARTS
Latin name: Hypericum perforatum L.
Plant family: Hypericaceae

Manufacture of Herbal Substance
The plants are harvested manually from the wild in Chile in July and August. Following harvesting, the plants are dried in the sun. The plants are harvested during the flowering stage and in accordance with Good Agricultural and Collection Practice (GACP) guidelines. It is also stated that the plants are not treated with chemicals or irradiation following harvesting.

Assurance has been provided that the herbal substance is collected from the wild in a sustainable manner.

Control of Herbal Substance
An appropriate specification based on the Ph Eur monograph is applied and is acceptable. The specification is supported by the batch data provided.

Container Closure System
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Confirmation is given that the herbal substance will be tested prior to being used to make the herbal preparation. A shelf-life for the herbal substance is not appropriate because it is only a precursor of the active substance, the herbal preparation. The actual guideline requires stability testing data for the herbal preparation and the herbal product in the application documents and not for the herbal substance.

HERBAL PREPARATION: ST JOHN’S WORT AERIAL PARTS DRY EXTRACT
Extraction solvent: Ethanol 60% (v/v)
Drug extract ratio (DER): 5-7:1

Manufacture
A satisfactory description of the manufacturing processes of the herbal preparation has been provided.

The in-process controls are satisfactorily detailed. There are no critical steps identified as the manufacture of the herbal preparation is considered to be a standard procedure.

Certificates of Analysis for all materials used in the manufacture of the herbal preparation have been provided.
Control of Herbal Preparation
Satisfactory specifications with appropriate tests and limits have been provided for the herbal preparation.

Satisfactory analytical procedures are used to control the quality of the herbal preparation. Analytical procedures have been validated, as appropriate.

Certificates of Analysis have been provided for production batches of the herbal preparation, demonstrating satisfactory compliance with the proposed specifications.

The proposed specifications have been justified satisfactorily.

Reference Standards or Material
Suitable details have been provided for the reference standards used.

Container Closure System
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Stability studies have been carried out under ICH conditions. The results support the proposed shelf life of the herbal preparation.

HERBAL PRODUCT:  ST JOHN’S WORT TABLETS

Description and Composition of the Herbal Product
The product is presented as a pale yellow, oval shaped, biconvex film coated tablet. The tablets contain the excipients dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, silicon dioxide, magnesium stearate, stearic acid, hypromellose, iron oxide yellow (E172), titanium dioxide (E171) and purified talc. The choice of excipients is based on experience and compatibility of the chosen excipients with the active substance and is confirmed by stability testing. All excipients used comply with their respective Ph Eur monograph.

The magnesium stearate used is of vegetable origin and a suitable statement from the supplier is provided confirming this.

Manufacture
A description and flow-chart of the manufacturing method has been provided. The manufacturing method is a standard uncomplicated procedure.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on product batches and the results are satisfactory.
Control of Herbal Product
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

Reference Standards or Materials
Suitable details have been provided for the reference standards used.

Container Closure System
The finished product is packed into either HDPE bottles with a CRC heat sealed cap or PVC/PVDC blister strips. Pack sizes are 30, 60 or 90 tablets. The bottles or blister strips are inserted into a cardboard outer carton with a patient information leaflet.

Specifications and certificates are provided from the manufacturers and confirmation that all components are safe for use in contact with foodstuffs and conform to Ph Eur standards is also provided.

Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a product shelf-life of 2 years is appropriate. The special precautions for storage are “Do not store above 25°C” and “Store in the original packaging”. These precautions are appropriate.

PRODUCT LITERATURE
All product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) is satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

OVERALL CONCLUSIONS ON QUALITY
The grant of a Traditional Herbal Registration is acceptable.
NON-CLINICAL ASSESSMENT

NON-CLINICAL ASPECTS
A review of non-clinical safety data has been provided. Details of controlled and non-controlled clinical trials in humans and drug interactions have also been submitted.

Due to a shortage of published data on St John’s Wort, it is not possible to assess if the safety package for the phytochemical constituents of St John’s Wort is acceptable to the standards of today’s GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and thus the lack of provision of a complete standard safety package is acceptable and in compliance with guideline EMEA/HMPC/32116/05.

The applicant also refers to the published HMPC assessment report and monograph for St John’s Wort; these documents adequately cover the non-clinical safety issues for St John’s Wort.

The HMPC assessment report for St John’s Wort describes a mutagenicity test that was carried out on an extract similar to that in St John’s Wort Tablets and is accepted in the monograph adopted by the HMPC. Therefore, it is considered that no further testing of the extract is required.

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)
The SmPC for this product is satisfactory from a non-clinical point of view.

ENVIRONMENTAL RISK ASSESSMENT
An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

CONCLUSION
The information supplied demonstrates the traditional use of St John’s Wort and an adequate literature review of St John’s Wort has been carried out by the applicant. In addition, the applicant also refers to the published HMPC assessment report and monograph for St John’s Wort. Granting of a THR is acceptable.
CLINICAL ASSESSMENT

LEGAL STATUS
St John’s Wort is currently on the General Sales List for internal use.

INDICATION
The applicant has proposed the following:

“A traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety based on traditional use only.”

The indications sought comply with the Community monograph for St John’s Wort adopted by the HMPC and other granted THRs containing St John’s Wort extract. The proposed indication is acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has proposed the following:

“Adults and the elderly: the recommended dosage is 1 or 2 tablets daily.

The tablets should be swallowed whole with a little water or other liquid. The tablets should not be chewed.

This product is not recommended for children or adolescents under 18 years of age (See Section 4.4. Special Warnings and precautions for use).

If symptoms worsen during the use of the product or persist for more than 6 weeks, a doctor or a qualified healthcare practitioner should be consulted.”

This is acceptable.

EFFICACY
No clinical efficacy data is required for registration of Traditional Herbal Medicinal Products (THMP).

EVIDENCE OF LONG-STANDING USE
Article 16 c 1 (c) requires the applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the EU.

The information provided is adequate to demonstrate that St John’s Wort has been in use for at least 30 years, of which at least 15 years have been in an EU Member State. The requirements of the Directive are therefore satisfied.

SAFETY REVIEW
The applicant has provided a summary of the clinical safety issues associated with St John’s wort. The applicant also refers to the published HMPC assessment report and
monograph for St John’s Wort; the documents fully cover the clinical safety issues for St John’s wort.

**PRODUCT LITERATURE**
The product literature for this product is medically satisfactory.

**RECOMMENDATION**
A Traditional Registration may be granted.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

EFFICACY AND SAFETY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

There are no safety concerns about this product.

RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The risk: benefit balance is, therefore, acceptable.
HRI GOOD MOOD TABLETS
ASDA ST JOHN’S WORT TABLETS
POWER HEALTH ST JOHN’S WORT TABLETS
BETTERMOOD TABLETS
FOOD SUPPLEMENT COMPANY HERBAL MOOD RELIEF TABLETS
SUPERDRUG ST JOHN’S WORT TABLETS

THR 02231/0002

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Traditional Herbal Registration application on 4 November 2009
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 22 December 2009
3. Following assessment of the application the MHRA requested further information relating to the quality dossier on 4 January 2010 and the clinical dossier on 16 April 2010
4. The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 18 March 2010 and the clinical dossier on 25 May 2010
5. Following assessment of the response the MHRA requested further information relating to the quality dossier on 19 April 2010
6. The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 25 May 2010
7. Following assessment of the response the MHRA requested further information relating to the quality dossier on 14 June 2010 and the clinical dossier on 3 August 2010
8. The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 31 August 2010 and the clinical dossier on 28 September 2010
9. A THR was granted on 28 September 2010
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

- HRI Good Mood Tablets
- Asda St John’s Wort Tablets
- Power Health St John’s Wort Tablets
- Bettermood Tablets
- Food Supplement Company Herbal Mood Relief Tablets
- Superdrug St John’s Wort Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (*Hypericum perforatum* L.) (5-7:1) (equivalent to 1670mg – 2338mg of St John’s Wort.)
Extraction solvent: Ethanol 60% V/V

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Film coated tablet
Pale yellow, oval shaped, biconvex film coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety based on traditional use only.

4.2 Posology and method of administration

*Adults and the elderly:* the recommended dosage is 1 or 2 tablets daily.

The tablets should be swallowed whole with a little water or other liquid. The tablets should not be chewed.

This product is not recommended for children or adolescents under 18 years of age (See Section 4.4. Special Warnings and precautions for use)

If symptoms worsen during the use of the product or persist for more than 6 weeks, a doctor or a qualified healthcare practitioner should be consulted.

4.3 Contraindications
Hypersensitivity to the active substance or any of the excipients.
Patients with known dermal photosensitivity or patients undergoing phototherapy or other photodiagnostic procedures.

This product should not be taken concomitantly with the medicines included in Section 4.5. This is because St John’s wort (*Hypericum perforatum*) has been shown to induce the cytochrome P450 isoenzymes CYP1A2, CYP2C9, CYP2C19 and CYP3A4 as well as transport protein P-glycoprotein. This results in pharmacokinetic interactions with a large number of medicines including leading to a possible decrease in the effectiveness of those medicines.

In addition, pharmacodynamic interactions have also been identified with antidepressants, particularly the SSRI antidepressants and with the triptan group of medicines.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If the condition worsens during the use of the product or if symptoms persist for more than 6 weeks, consult a doctor or qualified healthcare practitioner.

The use of this product in children or adolescents under 18 years of age is not recommended because data are not sufficient and medical advice should be sought.

This product is intended for the relief of symptoms of slightly low mood and mild anxiety. Patients with signs and symptoms of depression should consult a doctor for appropriate treatment.

In very rare cases, particularly in fair-skinned persons, sun burn type reactions on skin areas exposed to strong sunlight may occur due to photosensitisation by St John’s wort. Persons using this product should avoid excessive sunbathing or the use of sunbeds or solariums.

This product should be discontinued at least 10 days prior to elective surgery due to the potential for interactions with medicinal products used during general and regional anaesthesia (see Section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Substances in St John’s Wort (*Hypericum perforatum*) have been shown to induce the cytochrome P450 isoenzymes CYP1A2, CYP2C9, CYP2C19 and CYP3A4 as well as the transport protein P (type glycoprotein). This results in pharmacokinetic interactions with a large number of medicines leading to a potential decrease in the effectiveness of those medicines.

The concomitant use of ciclosporin, tacrolimus for systemic use, Amprenavir, indinavir and other protease inhibitors, irinotecan and warfarin is contraindicated. Special care should be taken in case of concomitant use of all drug substances the metabolism of which is influenced by CYP1A2, CYP3A4, CYP2C9, CYP2C19 or P-glycoprotein (e.g. amitriptyline, fexofenadine,
benzodiazepines, methadone, simvastatin, digoxin, finasteride), because a reduction of plasma concentration is possible.

Users of oral contraceptives taking St John’s Wort (*Hypericum perforatum*) may experience intracyclic menstrual bleeding and risk of contraception failure is increased.

Clinically significant pharmacodynamic interactions have also been identified with the SSRI antidepressants, and the triptan group of medicines used to treat migraines. Due to the increased risk of undesirable effects associated with these interactions this product should not be used concomitantly with these types of medicines. Therefore this product should not be taken concomitantly with the medicines included in Table below:

<table>
<thead>
<tr>
<th>Co-Administered Drug</th>
<th>Interaction</th>
<th>Recommendations concerning co-administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetics/pre-operative medicines</td>
<td>Fentanyl, propofol, sevoflurane, midazolam</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Analgesics</td>
<td>Tramadol</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Antianginals</td>
<td>Ivabradine</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Anti-arrhythmics</td>
<td>Amiodarone</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Antibacterials</td>
<td>Erythromycin, clarithromycin telithromycin</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>Warfarin, acenocoumarol</td>
<td>Reduced anticoagulant effect and need for increased dose.</td>
</tr>
<tr>
<td>Antidepressants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
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<td>------------------</td>
</tr>
<tr>
<td><strong>Tricyclics eg.</strong></td>
<td>Increased serotonergic effects with increased incidence of adverse reactions.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>amitriptyline, clomipramine</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MAOIs eg.</strong></td>
<td></td>
<td></td>
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<tr>
<td>moclobemide</td>
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</tr>
<tr>
<td><strong>SSRIs eg.</strong></td>
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<tr>
<td>citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Others eg.</strong></td>
<td></td>
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<tr>
<td>duloxetine, venlafaxine</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Antiepileptics</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>All drugs in this class including: carbamazepine phenobarbitalone phenytoin primidone sodium valproate</td>
<td>Reduced blood levels with increased risk of frequency and severity of seizures.</td>
<td>Do not take with this product.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antifungals</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Itraconazole, voriconazole</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antimalarials</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Artemether, lumefantrine</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anti-parkinsons</th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Rasagiline</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Antipsychotics</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Aripiprazole</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antivirals</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV protease inhibitors: amprenavir, atazanavir, darunavir, fosamprenavir, indinavir,</td>
<td>Reduced blood levels with possible loss of HIV suppression.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Medication Classes</td>
<td>Example Medications</td>
<td>Effects</td>
</tr>
<tr>
<td>--------------------</td>
<td>---------------------</td>
<td>---------</td>
</tr>
<tr>
<td>HIV nonnucleoside reverse transcriptase inhibitors:</td>
<td>lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir</td>
<td></td>
</tr>
<tr>
<td>Anxiolytics</td>
<td>Buspirone</td>
<td>Increased serotonergic effects with increased incidence of adverse reactions.</td>
</tr>
<tr>
<td></td>
<td>Aprepitant</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>Butobarbital, phenobarbital</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>Amlodipine, nifedipine, verapamil, felodipine</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Cardiac glycosides</td>
<td>Digoxin</td>
<td>Reduced blood levels and loss of control of heart rhythm or heart failure.</td>
</tr>
<tr>
<td>CNS Stimulants</td>
<td>Methylphenidate</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Cytotoxics</td>
<td>Irinotecan, dasatinib, erlotinib, imatinib, sorafenib, sunitinib,</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
</tr>
<tr>
<td>Medications</td>
<td>Interaction</td>
<td>Advice</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Hormonal contraceptives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td>Reduced blood levels with risk of unintended pregnancy and breakthrough bleeding.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Emergency hormonal contraception</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hormonal implants, injections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transdermal patches, creams etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-uterine devices with hormones</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hormone Replacement Therapy</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Hormone Replacement Therapy: Oral Transdermal patches, gels, Vaginal rings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hormone antagonists</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Exemestane</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diuretics</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Eplerenone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5HT agonists</td>
<td>Increased serotonergic effects with increased incidence of adverse reactions.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunosuppressants</td>
<td>Reduced blood levels with risk of transplant rejection.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Ciclosporin, tacrolimus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipid regulating drugs</td>
<td>Reduced blood levels with risk of</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Simvastatin, atorvastatin</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

etoposide, mitotane
<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Interaction Description</th>
<th>Precaution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Proton pump inhibitors</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Theophylline</td>
<td>Reduced blood levels and loss of control of asthma or chronic airflow limitation.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Thyroid hormones</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
<tr>
<td>Oral hypoglycaemic drugs</td>
<td>Reduced blood levels with risk of therapeutic failure.</td>
<td>Do not take with this product.</td>
</tr>
</tbody>
</table>

4.6 Pregnancy and lactation
Safety of the product during pregnancy and lactation has not been established. In the absence of sufficient data the use in pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects
Gastrointestinal disorders including dyspepsia, anorexia, nausea, diarrhoea or constipation; allergic skin reactions such as rash, urticaria, pruritus, fatigue and restlessness have been reported. The frequency is not known.

Fair skinned individuals may react with intensified sunburn-like symptoms under intense sunlight or strong ultra-violet (UV) irradiation.

Other adverse reactions that have been reported include headaches, neuropathy, anxiety, dizziness and mania.

If other adverse reactions not mentioned above occur, a doctor, pharmacist or a qualified healthcare practitioner should be consulted.
4.9 Overdose
No case of overdose has been reported. There are no data on human overdose with St.John’s Wort.

After the intake of up to 4.5g dry extract per day for 2 weeks and additionally 15g dry extract just before hospitalisation seizures and confusion have been reported.

When a large overdose has occurred, phototoxic reactions may occur. The skin of the patient should be protected for 1-2 weeks from UV irradiation and sunlight. Outdoor activities should be restricted and clothes and/or sun block preparations used to protect the skin from sunlight. Symptomatic and supportive measures should be taken as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
The active constituents of St. John’s wort have not been definitively established. However, hypericin, pseudohypericin, hyperforin and the flavonoids are considered to play a role in its activity.

5.2 Pharmacokinetic properties
No relevant pharmacokinetic data are available.

The active ingredients of St John’s wort can interact with other medicinal agents in two ways. Firstly, active ingredients in St John’s wort that themselves are metabolised in the liver by the CYP3A4 isoenzyme, increase (induce) the activity of this enzyme so that it accelerates the elimination of other medicinal agents which are degraded by the same pathway. This leads to a consequent reduction in the plasma concentration and effectiveness of these other substances. Secondly, the active ingredients in St John’s wort, like other type SRI or SSRI medicinal agents with an antidepressant action, can raise the concentration of serotonin in certain parts of the central nervous system so that this neurotransmitter can sometimes reach toxic levels, particularly when drugs containing St John’s wort are combined with other antidepressants.

5.3 Preclinical safety data
Not required as per Article 16c (1) (a) (iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.

Studies on acute toxicity and repeated dose toxicity did not show signs of toxic effects.

The weak positive results of an ethanolic extract in the AMES-test (Salmonella typhimurium TA 98 and TA 100 with and without metabolic activation) could be assigned to quercetin and are irrelevant to human safety.
No signs of mutagenicity could be detected in further in-vitro and in-vivo test systems.

Tests on reproductive toxicity revealed equivocal results.

Tests on carcinogenic potential have not been performed.

Phototoxicity:
After oral application of dosages of 1800mg of an extract per day for 15 days the skin sensitivity against UVA was increased, and the minimum dose for pigmentations was significantly reduced. In the recommended dosage, no signs of phototoxicity are reported.

Tests on reproductive toxicity and on carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Dicalcium Phosphate
Microcrystalline Cellulose
Croscarmellose Sodium
Silicon Dioxide
Magnesium Stearate
Stearic Acid

Film Coating
Hypromellose
Iron Oxide Yellow (E172)
Titanium Dioxide (E171)
Purified Talc

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25 °C. Store in the original packaging.

6.5 Nature and contents of container

Tablets are packed into HDPE bottles with a CRC heat sealed cap containing 30, 60 or 90 Tablets and packed into a Carton.

Tablets are packed into PVC/PVDC blister strips of 15 tablets in the following pack sizes; 30, 60, 90 Tablets and packed into a Carton.
Not all pack sizes may be marketed

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
The Herbal Research Company Limited
(trading as Jessup Marketing)
27 Old Gloucester Street
London
WC1N 3XX

8 MARKETING AUTHORISATION NUMBER(S)
THR 02231/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
28/09/2010

10 DATE OF REVISION OF THE TEXT
17/05/2012
HRI GOOD MOOD™ TABLETS
St John’s Wort extract 334 mg

Please read this information carefully before you start taking these tablets.
It contains some important information about this product. Keep this leaflet with the tablets.
You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet?
1. What HRI Good Mood is and what it is used for
2. Before you take HRI Good Mood
3. How to take HRI Good Mood
4. Possible Side Effects
5. How to store HRI Good Mood
6. Further Information

1. What HRI Good Mood is and what it is used for

What HRI Good Mood is

This product is a traditional herbal medicinal product containing St John’s Wort extract. Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5:7:1) (equivalent to 1670mg - 2353mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v.

Why HRI Good Mood is used for

HRI GOOD MOOD is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety. This is based on traditional use only.

Suffering from depression?

Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, appetite or weight changes, sleep changes, loss of energy and difficulty concentrating, thoughts of self-harm or suicide. If your doctor has told you that you are suffering from depression do not use this product. If you think that you may be suffering from depression you should tell your doctor before taking this product.

2. Before you take HRI Good Mood

Do not take this product if:

- Your skin is exceptionally sensitive to sunlight (photosensitive)
- You are having light treatment (phototherapy) for any condition
- You are suffering from depression (see above)
- You are pregnant or breastfeeding

While you are taking this product:

- avoid excessive sunbathing or the use of sunbeds/solariums
- stop using it at least 10 days prior to undergoing any surgery

Driving and operating machinery

- In rare cases St John’s Wort may make you feel dizzy or sleepy. If affected do not drive or use machines.

Taking other medicines

St John’s Wort can affect the way some medicines work and reduce their effectiveness. Medicines that can be affected by St John’s Wort include prescription medicines, and those that you may have bought without a prescription. Therefore it is important that you do not take St John’s Wort if you are using any of the medicines in the following list.

All hormonal contraceptives: The birth control ‘pill’, emergency contraception (also known as the morning after pill), hormonal implants, coils, patches, intra-uterine devices with hormones.

All medicines for depression/anxiety: Amitriptyline, clomipramine, moclobemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine.

All hormonal replacement therapy (HRT) treatments: HRT tablets, patches, gels, vaginal rings

All medicines for thinning the blood (anticoagulants): Warfarin, acenocoumarol

All medicines for epilepsy: Carbamazepine, phenobarbital, phenytoin, primidone, sodium valproate

All immunosuppressant medicines: Ciclosporin, tacrolimus

All medicines for HIV infections: Amprenavir, stavudinav, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tenofovir, efavirenz, nevirapine, delavirdine

Some medicines for cholesterol: Simvastatin, atorvastatin

Some medicines for cancer: Imatinib, dasatinib, erlotinib, imatinib, sometinib, sunitinib, etoposide, nitotane

Some medicines for heart disease: Digoxin, furosemide, amiodarone

Some medicines for migraines: Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan

Some medicines for high blood pressure: Amlodipine, nifedipine, felodipine, verapamil

A medicine for regulating mood: Lithium

A thyroid hormone: Thyroxine

St John’s Wort may also affect the following medicines. Therefore do not take this product with these medicines unless a doctor has said it is safe to do so:

- fentanyl, propofol, sevoflurane, and midazolam (anaesthetics/pre-operative medicines)
- tramadol (en analgescs)
- erythromycin, clarithromycin and telithromycin (antibiotics)
- irtraconazole and voriconazole (antifungals)
- artemether and lumefantrine (antimalarials)
- rasagiline (an anti-Parkinson’s medicine)
- aripiprazole (an antipsychotic medicine)
- bupropion (an anti-depressant)
- acipimox (used to treat post-operative vomiting)
- butobarbitral and phenobarbitral (barbiturates)
- methylphenidate (a central nervous system or CNS stimulant)
- exemestane (a hormone antagonist)
- epalrestat (a diuretic)
- lanisorazole and omeprazole (proton pump inhibitors)
- theophylline (a bronchodilator)
- gliclazide (an antidiabetic medicine)

3. How to take HRI Good Mood

Adults and the elderly
Take 1 or 2 tablets a day. Swallow the tablets whole with some water or other liquid. Do not chew the tablets.
Do not exceed the stated dose.

If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.

If your condition worsens or if symptoms persist for more than 6 weeks after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects

Like all medicines, this product can have side effects. The following side effects have been reported:
- gastrointestinal disorders such as indigestion, loss of appetite, nausea, diarrhoea, constipation; fatigue and restlessness.
- allergic skin reactions such as rash, hives or itching of the skin. If you experience allergic skin reactions, stop taking the product and consult your doctor.
- Also sunburn-like reactions on skin exposed to strong sunlight or strong ultraviolet (UV) irradiation e.g. solarium have been reported, particularly in fair skinned individuals. Other side effects that have been reported include headaches, nerve pain or tingling, anxiety, dizziness and mania.
- If any of the above side effects become serious or if other side effects not mentioned above occur, a doctor or pharmacist should be consulted.

5. How to store HRI Good Mood

- Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste.
- Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.
- The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original packaging.
- Keep the tablets out of reach of children.
- Keep your tablets in the blister pack until it is time to take them.

6. Further Information

Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L) (5-7:1) (equivalent to 167mg - 2338mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v.

This product also contains the following ingredients:
- Tablet core: Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate, Stearic Acid
- Tablet coating: Hypromellose, Iron Oxide Yellow (E172), Titanium Dioxide (E171), Purified Talc.
- What these tablets look like
- HRI Good Mood are pale yellow oval biconvex Film coated tablets. This product is available in 30, 60, 90 pack sizes.
- Not all pack sizes may be marketed.

Traditional Herbal Registration Number: THR 02231/0002
Registration holder for this product:
The Herbal Research Company Limited (trading as Jessup Marketing), 27 Old Gloucester Street, London WC1N 3XX
Manufacturer of this product:
Honeywood Ltd, Edmonds Close, Dennington Industrial Estate, Wellingborough, Northants, NN8 2QY
If you would like further information about this product please contact: Jessup Marketing
Email: info@jessup.co.uk
You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper yellow card form from your GP’s surgery or pharmacy, or call free phone 0808 100 3352 (available 10am - 2pm Monday to Friday).
For a large print, Braille or audio version of this leaflet call 01932 854825.
This leaflet was last revised in May 2012.
**PATIENT INFORMATION LEAFLET**

**ASDA ST JOHN’S WORT TABLETS**

**St John’s Wort extract 334 mg**

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**Please read this information carefully before you start taking these tablets.**

It contains some important information about this product. Keep this leaflet with the tablets. You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

**What is in this leaflet?**

1. What ASDA St John’s Wort is and what it is used for
2. Before you take ASDA St John’s Wort
3. How to take ASDA St John’s Wort
4. Possible Side Effects
5. How to store ASDA St John’s Wort
6. Further Information

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**1. What ASDA St John’s Wort is and what it is used for**

**What ASDA St John’s Wort is**

This product is a traditional herbal medicinal product containing St John’s Wort extract. Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (S-7-1) (equivalent to 167mg - 233mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v.

**What ASDA St John’s Wort is used for**

ASDA St John’s Wort is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety. This is based on traditional use only.

**Suffering from depression?**

Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, appetite or weight changes, sleep changes, loss of energy and difficulty concentrating, thoughts of self harm or suicide. If your doctor has told you that you are suffering from depression do not use this product. If you think that you may be suffering from depression you should tell your doctor before taking this product.

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**2. Before you take ASDA St John’s Wort**

Do not take this product if:

- Your skin is exceptionally sensitive to sunlight (photosensitive)
- You are having light treatment (phototherapy) for any condition
- You are suffering from depression (see above)
- You are pregnant or breastfeeding

While you are taking this product:

- Avoid excessive sunbathing or the use of sunbeds/solariums
- Stop using it at least 10 days prior to undergoing any surgery

Driving and operating machinery

In rare cases St John’s Wort may make you feel dizzy or sleepy. If affected do not drive or use machines.

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**Taking other medicines**

St John’s Wort can affect the way some medicines work and reduce their effectiveness. Medicines that can be affected by St John’s Wort include prescription medicines, and those that you may have bought without a prescription.

Therefore it is important that you do not take St John’s Wort if you are using any of the medicines in the following list.

- All hormonal contraceptives: The birth control pill, emergency contraception (also known as the morning after pill), hormonal implants, creams, patches, intra-uterine devices with hormones.
- All medicines for depression/anxiety: Amitriptyline, clomipramine, moclobemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, dlooxetine, venlafaxine.
- All hormonal replacement therapy (HRT) treatments: HRT tablets, patches, gels, vaginal rings.
- All medicines for thinning the blood (anticoagulants): Warfarin, acenocoumarol.
- All medicines for epilepsy: Carbamazepine, phenobarbital, phenytoin, primidone, sodium valproate.
- All immunosuppressant medicines: Ciclosporin, tacrolimus.
- All medicines for HIV Infections: Amprinonavir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir, efavirenz, nevirapine, delavirdine.
- Some medicines for cholesterol: Simvastatin, atorvastatin.
- Some medicines for cancer: Imatinib, dasatinib, erlotinib, imatinib, somafenib, sunitinib, cetuximab, panitumab, erlotinib.
- Some medicines for heart disease: Digoxin, irbasimod, amiodarone.
- Some medicines for migraine: Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan.
- Some medicines for high blood pressure: Amodipine, nifedipine, felodipine, verapamil.
- A medicine for regulating mood: Lithium.
- A thyroid hormone: Thyroxine.

St John’s Wort may also affect the following medicines. Therefore do not take this product with these medicines unless a doctor has said it is safe to do so:

- Fentanyl, propofol, sevoflurane, and midazolam (anaesthetics/pre-operative medicines)
- Tranquillisers (an analgesic)
- Ceftriaxone, clarithromycin and telithromycin (antibiotics)
MHRA PAR; HRI GOOD MOOD TABLETS, ASDA ST JOHN’S WORT TABLETS, POWER HEALTH ST JOHN’S WORT TABLETS, BETTERMOOD TABLETS, FOOD SUPPLEMENT COMPANY HERBAL MOOD RELIEF TABLETS AND SUPERDRUG ST JOHN’S WORT TABLETS, THR 02331/0002

3. How to take ASDA St John’s Wort

Adults and the elderly
Take 1 or 2 tablets a day. Swallow the tablets whole with some water or other liquid. Do not chew the tablets.
Do not exceed the stated dose.
If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.
If you forget to take this product
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.
If your condition worsens or if symptoms persist for more than 6 weeks after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur; consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects
Like all medicines, this product can have side effects. The following side effects have been reported:
- Gastrointestinal disorders such as indigestion, loss of appetite, nausea, diarrhoea, constipation: fatigue and restlessness.
- Allergic skin reactions such as rash, hives or itching of the skin. If you experience allergic skin reactions, stop taking the product and consult your doctor.
Also sunburn-like reactions on skin exposed to strong sunlight or strong ultraviolet (UV) irradiation e.g. solanum have been reported, particularly in fair skinned individuals. Other side effects that have been reported include headaches, nervous pain or tingling, anxiety, dizziness and mania.
If any of the above side effects become serious or if other side effects not mentioned above occur, a doctor or pharmacist should be consulted.

5. How to store ASDA St John’s Wort
✓ Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste.
✓ Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.
✓ The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.
✓ Do not store above 25°C. Store in the original packaging.
✓ Keep the tablets out of the reach and sight of children.
✓ Keep your tablets in the blister pack until it is time to take them.

6. Further Information
Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5-7:1) (equivalent to 1670 mg - 2338 mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v.
This product also contains the following ingredients:
Tablet core: Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate, Stearic Acid
Tablet coating: Hypromellose, Iron Oxide Yellow (E172), Titanium Dioxide (E171), Purified Talc.
What these tablets look like
ASDA St John’s Wort are pale yellow oval biconvex film coated tablets. This product is available in 30, 60, 90 pack sizes. Not all pack sizes may be marketed.
Traditional Herbal Registration Number: THR 02331/0002
Registration holder for this product:
The Herbal Research Company Limited, 27 Old Gloucester Street, London WC1N 3XX
Manufacturer of this product:
Honeywood Ltd, Edmonds Close, Denington Industrial Estate, Wellingborough, Northants, NN8 2QY
If you would like further information about this product please contact: ASDA Stores Limited, Leeds, LS11 5AD
You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.yellowcard.gov.uk/yellowcard. Alternatively you can get a paper yellow card form from your GP’s surgery or pharmacy, or call free phone 0808 100 3352 (available 10am - 2pm Monday to Friday).
For a large print, Braille or audio version of this leaflet call 01932 854825.
This leaflet was last revised in May 2012.
PATIENT INFORMATION LEAFLET

powerhealth st john's wort tablets
St John's Wort extract 334 mg

Please read this information carefully before you start taking these tablets. It contains some important information about this product. Keep this leaflet with the tablets. You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet?
1. What power health st john's wort is and what it is used for
2. Before you take power health st john's wort
3. How to take power health st john's wort
4. Possible Side Effects
5. How to store power health st john's wort
6. Further Information

1. What power health st john's wort is and what it is used for

What power health st john's wort is
This product is a traditional herbal medicinal product containing St John's Wort extract. Each film-coated tablet contains 334 mg of St John's Wort extract (as dry extract) from St John's Wort aerial parts (Hypericum perforatum L.) (5:7:1) (equivalent to 1670mg - 2338mg of St John's Wort). Extraction solvent: Ethanol 60% v/v.

What power health st john's wort is used for
power health st john's wort is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety. This is based on traditional use only.

Suffering from depression?
Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, appetite or weight changes, sleep changes, loss of energy and difficulty concentrating, thoughts of self harm or suicide. If your doctor has told you that you are suffering from depression do not use this product. If you think that you may be suffering from depression you should tell your doctor before taking this product.

2. Before you take power health st john's wort

Do not take this product if:
- Your skin is exceptionally sensitive to sunlight (photosensitive)
- You are having light treatment (phototherapy) for any condition
- You are suffering from depression (see above)
- You are pregnant or breastfeeding

While you are taking this product:
- Avoid excessive sunbathing or the use of sunbeds/solariums
- Stop using it at least 10 days prior to undergoing any surgery

Driving and operating machinery
In rare cases St John's Wort may make you feel dizzy or sleepy. If affected do not drive or use machines.

Taking other medicines
St John's Wort can affect the way some medicines work and reduce their effectiveness. Medicines that can be affected by St John's Wort include prescription medicines, and those that you may have bought without a prescription. Therefore it is important that you do not take St John's Wort if you are using any of the medicines in the following list.

All hormonal contraceptives: The birth control 'pill', emergency contraception, hormonal implants, creams, patches, intrauterine devices with hormones.
All medicines for depression/anxiety: Amitriptyline, clomipramine, moclobemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine
All hormonal replacement therapy (HRT) treatments: HRT tablets, patches, gels, vaginal rings
All medicines for thinning the blood (antiocoagulants): Warfarin, acenocoumarol
All medicines for epilepsy: Carbamazepine, phenobarbital, phenytoin, primidone, sodium valproate
All immunomodulatory medicines: Ciclosporin, tacrolimus
All medicines for HIV infections: Amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nefavir
ritonavir, saquinavir, tipranavir, clavirenic, nevirapine, delavirdine
Some medicines for cholesterol: Simvastatin, atorvastatin
Some medicines for cancer: Irinotecan, dasatinib, erlotinib, imatinib, sorafenib, sunitinib, etoposide, mitotane
Some medicines for heart disease: Digoxin, ivabradine, amiodarone
Some medicines for migraine: Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
Some medicines for high blood pressure: Amlodipine, nifedipine, felodipine, verapamil
A medicine for regulating mood: Lithium
A thyroid hormone: Thyroxine

St John's Wort may also affect the following medicines. Therefore do not take this product with these medicines unless a doctor has said it is safe to do so:
- fentanyl, propofol, secobarbital, and midazolam (anaesthetics/pre-operative medicines)
- tramadol (an analgesic)
- erythromycin, clarithromycin and telithromycin (antibiotics)
3. How to take power health st john’s wort

Adults and the elderly
Take 1 or 2 tablets a day. Swallow the tablets whole with some water or other liquid. Do not chew the tablets. Do not exceed the stated dose.
If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.
If you forget to take this product
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.
If your condition worsens or if symptoms persist for more than 6 weeks after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects

Like all medicines, this product can have side effects. The following side effects have been reported:
- gastrointestinal disorders such as indigestion, loss of appetite, nausea, diarrhoea, constipation, fatigue and restlessness.
- allergic skin reactions such as rash, hives or itching of the skin. If you experience allergic skin reactions, stop taking the product and consult your doctor.
Also sunburn-like reactions on skin exposed to strong sunlight or strong ultraviolet (UV) irradiation e.g. solarium have been reported, particularly in fair skinned individuals. Other side effects that have been reported include headaches, nerve pain or tingling, anxiety, dizziness and mania.
If any of the above side effects become serious or if other side effects not mentioned above occur, a doctor or pharmacist should be consulted.

5. How to store power health st john’s wort

Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste.
Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.
The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.
Do not store above 25°C. Store in the original packaging.
 Keep the tablets out of the reach and sight of children.
Keep your tablets in the blister pack until it is time to take them.

6. Further Information

Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5-7:1) (equivalent to 1670mg = 2338mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v.
This product also contains the following ingredients:
Tablet core: Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate, Stearic Acid
Tablet coating: Hypromellose, Iron Oxide Yellow (E172), Titanium Dioxide (E171), Purified Talc.
What these tablets look like
Power health st john’s wort are pale yellow oval biconvex film coated tablets. This product is available in 30, 60, 90 pack sizes. Not all pack sizes may be marketed.
Traditional Herbal Registration Number: THR 0231/0002
Registration holder for this product:
The Herbal Research Company Limited, 27 Old Gloucester Street, London WC1N 3XX
Manufacturer of this product:
Honeywood Ltd, Edmonds Close, Denington Industrial Estate, Welvingborough, Northants, NN8 2QY
If you would like further information about this product please contact:
Power Health Products Ltd., Pocklington, York YO42 1NR. Email: enquiries@power-health.co.uk. Tel: 01759 302595.
You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.yellowcard.gov.uk.
Alternatively you can get a paper yellow card form from your GPs surgery or pharmacy, or call free phone 0808 100 3352 (available 11am – 2pm Monday to Friday).
For a large print, Braille or audio version of this leaflet call 01759 302595. This leaflet was last revised in September 2010.

MHRA PAR; HRI GOOD MOOD TABLETS, ASDA ST JOHN’S WORT TABLETS, POWER HEALTH ST JOHN’S WORT TABLETS, BETTERMOOD TABLETS, FOOD SUPPLEMENT COMPANY HERBAL MOOD RELIEF TABLETS AND SUPERDRUG ST JOHN’S WORT TABLETS, THR 02331/0002
1. What bettermood is and what it is used for

What bettermood is
This product is a traditional herbal medicinal product containing St John’s Wort extract. Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5:7:1) (equivalent to 1670mg - 2235mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v.

What bettermood is used for
bettermood is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety. This is based on traditional use only.

Suffering from depression?
Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, appetite or weight changes, sleep changes, loss of energy and difficulty concentrating, thoughts of self harm or suicide. If your doctor has told you that you are suffering from depression do not use this product. If you think that you may be suffering from depression you should tell your doctor before taking this product.

2. Before you take bettermood

Do not take this product if:
- You are allergic to any of the ingredients (see section 6)
- You are due to have an operation in the next 10 days
- You are under the age of 18 years
- You are pregnant or breastfeeding
- You have liver disease
- You have any other medical condition or are taking any other medicines
- You have any other medical condition or are taking any other medicines

While you are taking this product:
- Avoid excessive sunbathing or the use of sunbeds/solariums
- Stop using it at least 10 days prior to undergoing any surgery

Driving and operating machinery
In rare cases St John’s Wort may make you feel dizzy or sleepy. If affected do not drive or use machines.

Taking other medicines
St John’s Wort can affect the way some medicines work and reduce their effectiveness. Medicines that can be affected by St John’s Wort include prescription medicines, and those that you may have bought without a prescription. Therefore it is important that you do not take St John’s Wort if you are using any of the medicines in the following list.

All hormonal contraceptives: The birth control “pill”, emergency contraception (also known as the morning after pill), hormonal implants, creams, patches, intra-uterine devices with hormones.

All medicines for depression/anxiety: Amitriptyline, clomipramine, moclوبemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine.

All hormonal replacement therapy (HRT) treatments: HRT tablets, patches, gels, vaginal rings

All medicines for thinning the blood (anticoagulants): Warfarin, acenocoumarol

All medicines for epilepsy: Carbamazepine, phenobarbital, phenytoin, primidone, sodium valproate

All immunosuppressant medicines: Ciclosporin, tacrolimus

All medicines for HIV infection:amprenavir, azidanosavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, nitoavir, saquinavir, tipranavir, efavirenz, nevirapine, delavirdine

Some medicines for cholesterol: Simvastatin, atorvastatin

Some medicines for cancer: irinotecan, dasatinib, erlotinib, imatinib, sorafenib, sunitinib, etoposide, mitotane

Some medicines for heart disease: Digoxin, ivabradine, amiodarone

Some medicines for migraines: Almotripitant, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan

Some medicines for high blood pressure: Amlodipine, nilodipine, felodipine, verapamil

A medicine for regulating mood: Lithium

A thyroid hormone: Thyroxine

St John’s Wort may also affect the following medicines. Therefore do not take this product with these medicines unless a doctor has said it is safe to do so:
- Fentanyl, propofol, sevoflurane, and midazolam (anaesthetic/pre-operative medicines)
- Tramadol (an analgesic)
- Erythromycin, clarithromycin and tetracycline (antibiotics)
MHRA PAR; HRI GOOD MOOD TABLETS, ASDA ST JOHN’S WORT TABLETS, POWER HEALTH ST JOHN’S WORT TABLETS, BETTERMOOD TABLETS, FOOD SUPPLEMENT COMPANY HERBAL MOOD RELIEF TABLETS AND SUPERDRUG ST JOHN’S WORT TABLETS, THR 02331/0002

3. How to take bettermood

Adults and the elderly
Take 1 or 2 tablets a day. Swallow the tablets whole with some water or other liquid. Do not chew the tablets.
Do not exceed the stated dose.
If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.
If you forget to take this product
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.
If your condition worsens or if symptoms persist for more than 6 weeks after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects
Like all medicines, this product can have side effects. The following side effects have been reported:
- gastrointestinal disorders such as indigestion, loss of appetite, nausea, diarrhoea, constipation: fatigue and restlessness.
- allergic skin reactions such as rash, hives or itching of the skin. If you experience allergic skin reactions, stop taking the product and consult your doctor.
- also sunburn-like reactions on skin exposed to strong sunlight or strong ultraviolet (UV) irradiation e.g. solarium have been reported, particularly in fair skinned individuals. Other side effects that have been reported include headaches, nerve pain or tingling, anxiety, dizziness and mania.
If any of the above side effects become serious or if other side effects not mentioned above occur, a doctor or pharmacist should be consulted.

5. How to store bettermood
- Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste.
- Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.
- The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original packaging.
- Keep the tablets out of the reach and sight of children.
- Keep your tablets in the blister pack until it is time to take them.

6. Further Information
Each film-coated tablet contains 334 mg of extract (as dry extract) from St John's Wort aerial parts (Hypericum perforatum L.) (5-7:1) (equivalent to 167mg - 2338mg of St John's Wort). Extraction solvent: Ethanol 60% v/v.
This product also contains the following ingredients:
- Tablet core: Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate, Starch Acid
- Tablet coating: Hypromellose, Iron Oxide Yellow (E172), Titanium Dioxide (E171), Purified Talc.

What these tablets look like
bettermood are pale yellow oval biocoat film coated tablets. This product is available in 30, 60, 90 pack sizes.
Not all pack sizes may be marketed.

Traditional Herbal Registration Number: THR 02231/0002

Registration holder for this product:
The Herbal Research Company Limited, 27 Old Gloucester Street, London WC1N 3XX
Manufacturer of this product:
Honeywood Ltd, Edmonds Close, Denington Industrial Estate, Wellingborough, Northants, NN8 2QY
If you would like further information about this product please contact: Principle Healthcare Ltd., Millenium Road, Skipton, North Yorkshire BD23 1TZ. Email: enquiries@principlehealthcare.com. Tel: +44 (0) 1756 792600.
You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper yellow card form from your GP's surgery or pharmacy, or call free phone 0808 100 3352 (available 10am - 2pm Monday to Friday).
For a large print, Braille or audio version of this leaflet call 01756 792600.
This leaflet was last revised in May 2012.
PATIENT INFORMATION LEAFLET

Food Supplement Company Herbal Mood Relief tablets
St John’s Wort extract 334 mg

Please read this information carefully before you start taking these tablets. It contains some important information about this product. Keep this leaflet with the tablets. You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet?
1. What Food Supplement Company Herbal Mood Relief is and what it is used for
2. Before you take Food Supplement Company Herbal Mood Relief
3. How to take Food Supplement Company Herbal Mood Relief
4. Possible Side Effects
5. How to store Food Supplement Company Herbal Mood Relief
6. Further Information

1. What Food Supplement Company Herbal Mood Relief is and what it is used for

What Food Supplement Company Herbal Mood Relief is
This product is a traditional herbal medicinal product containing St John’s Wort extract. Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5-7:1) (equivalent to 1670mg - 2338mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v.

What Food Supplement Company Herbal Mood Relief is used for
Food Supplement Company Herbal Mood Relief is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety. This is based on traditional use only.

Suffering from depression?
Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, appetite or weight changes, sleep changes, loss of energy and difficulty concentrating, thoughts of self harm or suicide. If your doctor has told you that you are suffering from depression do not use this product. If you think that you may be suffering from depression you should tell your doctor before taking this product.

2. Before you take Food Supplement Company Herbal Mood Relief

Do not take this product if:

- Your skin is exceptionally sensitive to sunlight (photosensitive)
- You are having light treatment (phototherapy) for any condition
- You are suffering from depression (see above)
- You are pregnant or breastfeeding

While you are taking this product:

- avoid excessive sunbathing or the use of sunbeds/solariums
- stop using it at least 10 days prior to undergoing any surgery

Driving and operating machinery
In rare cases St John’s Wort may make you feel dizzy or sleepy. If affected do not drive or use machines.

Taking other medicines
St John’s Wort can affect the way some medicines work and reduce their effectiveness. Medicines that can be affected by St John’s Wort include prescription medicines, and those that you may have bought without a prescription. Therefore it is important that you do not take St John’s Wort if you are using any of the medicines in the following list.

All hormonal contraceptives: The birth control ‘Pill’, emergency contraception, hormonal implants, creams, patches, intrauterine devices with hormones.
All medicines for depression/anxiety: Amitriptyline, clomipramine, moclobemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine
All hormonal replacement therapy (HRT) treatments: HRT tablets, patches, gels, vaginal rings
All medicines for thinning the blood (anticoagulants): Warfarin, acenocoumarol
All medicines for epilepsy: Carbamazepine, phenobarbitone, phenytoin, primidone, sodium valproate
All immunosuppressant medicines: Ciclosporin, tacrolimus
All medicines for HIV infections: Ampraravir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir, efavirenz, nevirapine, delavirdine
Some medicines for cholesterol: Simvastatin, atorvastatin
Some medicines for cancer: Imotecan, dasatinib, erlotinib, imatinib, sorafenib, sunitinib, cetopoxide, mitotane
Some medicines for heart disease: Digoxin, ivabradine, amirolodone
Some medicines for migraines: Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
Some medicines for high blood pressure: Amlodipine, nifedipine, felodipine, verapamil
A medicine for regulating mood: Lithium
A thyroid hormone: Thyroxine

St John’s Wort may also affect the following medicines. Therefore do not take this product with these medicines unless a doctor has said it is safe to do so:
- fentanyl, propofol, sevoflurane, and midazolam (anaesthetics/pre-operative medicines)
- tramadol (an analgesic)
- erythromycin, clarithromycin and telithromycin (antibiotics)

MHRA PAR; HRI GOOD MOOD TABLETS, ASDA ST JOHN’S WORT TABLETS, POWER HEALTH ST JOHN’S WORT TABLETS, BETTERMOOD TABLETS, FOOD SUPPLEMENT COMPANY HERBAL MOOD RELIEF TABLETS AND SUPERDRUG ST JOHN’S WORT TABLETS, THR 02331/0002
• itraconazole and vericonazole (antifungals)
• artemether and lumefantrine (antimalarials)
• raloxifene (an anti-Parkinson’s disease medication)
• aripiprazole (an antipsychotic medicine)
• buspirone (an anxiolytic)
• aprepitant (used to treat post-operative vomiting)
• barbiturates and phenobarbital (barbiturates)
• methylphenidate (a central nervous system or CNS stimulant)
• exemestane (a hormone antagonist)
• eplerenone (a diuretic)
• lansoprazole and omeprazole (proton pump inhibitors)
• theophylline (a bronchodilator)
• glimepiride (an antidiabetic medicine)

3. How to take Food Supplement Company Herbal Mood Relief

Adults and the elderly
Take 1 or 2 tablets a day. Swallow the tablets whole with some water or other liquid. Do not chew the tablets.

Do not exceed the stated dose.

If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.

If your condition worsens or if symptoms persist for more than 6 weeks after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects

Like all medicines, this product can have side effects. The following side effects have been reported:
- gastrointestinal disorders such as indigestion, loss of appetite, nausea, diarrhoea, constipation: fatigue and restlessness.
- allergic skin reactions such as rash, hives or itching of the skin. If you experience allergic skin reactions, stop taking the product and consult your doctor.
- also sunburn-like reactions on skin exposed to strong sunlight or strong ultraviolet (UV) irradiation e.g. solarium have been reported, particularly in fair skinned individuals. Other side effects that have been reported include headaches, nerve pain or tingling, anxiety, dizziness and mania.
If any of the above side effects become serious or if other side effects not mentioned above occur, a doctor or pharmacist should be consulted.

5. How to Store Food Supplement Company Herbal Mood Relief

✓ Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste.
✓ Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.
✓ The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.
✓ Do not store above 25°C. Store in the original packaging.
✓ Keep your tablets out of the reach and sight of children.
✓ Keep your tablets in the blister pack until it is time to take them.

6. Further Information

Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5:1:1) (equivalent to 1670 mg - 2338 mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v.

This product also contains the following ingredients:
Tablet core: Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate, Stearic Acid
Tablet coating: Hypropromellose, Iron Oxide Yellow (E172), Titanium Dioxide (E171), Purified Talc.

What these tablets look like
Food Supplement Company Herbal Mood Relief tablets are pale yellow oval biconvex film coated tablets. This product is available in 38, 60, 90 pack sizes. Not all pack sizes may be marketed.

Traditional Herbal Registration Number: THR 02231/0002

Registration holder for this product:
The Herbal Research Company Limited, 27 Old Gloucester Street, London WC1N 3XX

Manufacturer of this product: Honeywood Ltd, Edmonds Close, Derington Industrial Estate, Welldingborough, Northants, NN8 2QY

If you would like further information about this product please contact:
FSC Food Supplement Company, Lancaster Road, Carnaby, Bridlington, East Yorkshire Y015 3QY.
Email: info@beehealth.com Tel: +44(0)1262 607890 and Fax: +44(0)1262 424012

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.yellowcard.gov.uk.
Alternatively you can get a paper/yellow card form from your GP’s surgery or pharmacy, or call free phone 0808 100 3352 (available 10am - 2pm Monday to Friday).

For a large print, Braille or audio version of this leaflet call 01262 607890.
This leaflet was last revised in September 2010.
Patient Information Leaflet

Superdrug®
St John’s Wort Tablets
St John’s Wort extract 334 mg

Please read this information carefully before you start taking these tablets. It contains some important information about this product. Keep this leaflet with the tablets. You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet?
1. What SUPERDRUG St John’s Wort is and what it is used for
2. Before you take SUPERDRUG St John’s Wort
3. How to take SUPERDRUG St John’s Wort
4. Possible Side Effects
5. How to store SUPERDRUG St John’s Wort
6. Further Information

1. What SUPERDRUG St John’s Wort is and what it is used for

What SUPERDRUG St John’s Wort is
This product is a traditional herbal medicinal product containing St John’s Wort extract. Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5:7:1) equivalent to 1670mg - 2238mg of St John’s Wort. Extraction solvent: Ethanol 60% v/v.

What SUPERDRUG St John’s Wort is used for
SUPERDRUG St John’s Wort is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety. This is based on traditional use only.

Suffering from depression?
Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, appetite or weight changes, sleep changes, loss of energy and difficulty concentrating, thoughts of self harm or suicide. If your doctor has told you that you are suffering from depression do not use this product. If you think that you may be suffering from depression you should tell your doctor before taking this product.

2. Before you take SUPERDRUG St John’s Wort

Do not take this product if:
- Your skin is exceptionally sensitive to sunlight (photosensitive)
- You are having light treatment (phototherapy) for any condition
- You are suffering from depression (see above)
- You are pregnant or breastfeeding

While you are taking this product:
- avoid excessive sunbathing or the use of sunbeds/solariums
- stop using it at least 10 days prior to undergoing any surgery

Driving and operating machinery
In rare cases St John’s Wort may make you feel dizzy or sleepy. If affected do not drive or use machines.

Taking other medicines
St John’s Wort can affect the way some medicines work and reduce their effectiveness. Medicines that can be affected by St John’s Wort include prescription medicines, and those that you may have bought without a prescription.

Therefore it is important that you do not take St John’s Wort if you are using any of the medicines in the following list even if your doctor approves.

- All hormonal contraceptives: The birth control "pill", emergency contraception (also known as the morning after pill), hormonal implants, creams, patches, intra-uterine devices with hormones.
- All medicines for depression/anxiety: Amitriptyline, clomipramine, moclobemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine.
- All medicines for depression/anxiety: Carbamazepine, phenobarbitone, phenytoin, primidone, sodium valproate.
- All immunosuppressant medicines: Ciclosporin, tacrolimus
- All medicines for HIV infection: Amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir, elavirenz, nevirapine, delavirdine
- Some medicines for cholesterol: Simvastatin, atorvastatin
- Some medicines for cancer: Irinotecan, dasatinib, erlotinib, imatinib, sorafenib, sunitinib, etoposide, mitotane
- Some medicines for heart disease: Digoxin, ivabradine, amiodarone
- Some medicines for migraine: Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
- Some medicines for high blood pressure: Amlodipine, infliximab, felodipine, verapamil
- A medicine for regulating mood: Lithium
- A thyroid hormone: Thyroxine
- St John’s Wort may also affect the following medicines. Therefore do not take this product with these medicines unless a doctor has said it is safe to do so:
  - fentanyl, propofol, sevoflurane, and midazolam (anaesthetics/pre-operative medicines)
  - tramadol (an analgesic)
  - erythromycin, clarithromycin and telithromycin (antibiotics)
3. How to take SUPERDRUG St John’s Wort

Adults and the elderly
Take 1 or 2 tablets a day. Swallow the tablets whole with some water or other liquid. Do not chew the tablets. Do not exceed the stated dose.

If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.

If your condition worsens or if symptoms persist for more than 6 weeks after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects

Like all medicines, this product can have side effects. The following side effects have been reported:

- gastrointestinal disorders such as indigestion, loss of appetite, nausea, diarrhoea, constipation: fatigue and restlessness.
- allergic skin reactions such as rash, hives or itching of the skin. If you experience allergic skin reactions, stop taking the product and consult your doctor.
- also sunburn-like reactions on skin exposed to strong sunlight or strong ultraviolet (UV) irradiation e.g. solarium have been reported, particularly in fair skinned individuals. Other side effects that have been reported include headaches, nerve pain or tingling, anxiety, dizziness and mania.

If any of the above side effects become serious or if other side effects not mentioned above occur, a doctor or pharmacist should be consulted.

5. How to store SUPERDRUG St John’s Wort

- Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.
- The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original packaging.
- Keep the tablets out of the reach and sight of children.
- Keep your tablets in the blister pack until it is time to take them.

6. Further Information

Each film-coated tablet contains 334 mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5:7:1) (equivalent to 1670mg - 2338mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v.

This product also contains the following ingredients:

Tablet core: Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate, Stearic Acid
Tablet coating: Hypromellose, Iron Oxide Yellow (E172), Titanium Dioxide (E171), Purified Talc.

What these tablets look like
SUPERDRUG St John’s Wort are pale yellow oval biconvex film coated tablets. This product is available in 30, 60, 90 pack sizes. Not all pack sizes may be marketed.

Traditional Herbal Registration Number: THR 02331/0002

Registration holder for this product:

The Herbal Research Company Limited, 27 Old Gloucester Street, London WC1N 3XX

Manufacturer of this product:
Honeywood Ltd, Edmonds Close, Denington Industrial Estate, Wellingborough, Northants, NN8 2QY

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper yellow card form from your GP’s surgery or pharmacy, or call free phone 0808 100 3352 (available 10am - 2pm Monday to Friday).

For a large print, Braille or audio version of this leaflet call 01932 854825.

This leaflet was last revised in March 2012.
LABELLING

HRI Good Mood Tablets

Blister:
HRI GOOD MOOD TABLETS

HRI Good Mood is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety based on traditional use only.

Active Ingredients: Each film-coated tablet contains 334 mg extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (1%·), equivalent to 1074 mg of St John’s Wort. 

Dose: Adults: up to 1 or 2 tablets daily. The tablets must be swallowed whole with a little water.

Warnings: Do not exceed the stated dose. Do not use if:
- you are under 18
- you are pregnant or breast-feeding
- you have an allergy to any of the ingredients
- you are suffering from depression or think you may be
- you have had a stroke

St John’s Wort should not be taken at the same time as certain medications, including:
- hormone replacement therapy
- hormone contraceptives
- some antidepressants
- some medications for improving the PIM (prescription in the UK)
- some you can buy without prescription

You must read the enclosed leaflet before taking this product. If your condition worsens or if symptoms persist for more than 6 weeks after taking the product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult your doctor or qualified healthcare practitioner.

Keep out of the reach of children. Do not store above 25°C. Store in the original packaging. Expiry dates are based.
Asda St John’s Wort Tablets

Blister:
Power Health St John’s Wort Tablets

Blister:

MHRA PAR; HRI GOOD MOOD TABLETS, ASDA ST JOHN’S WORT TABLETS, POWER HEALTH ST JOHN’S WORT TABLETS, BETTERMOOD TABLETS, FOOD SUPPLEMENT COMPANY HERBAL MOOD RELIEF TABLETS AND SUPERDRUG ST JOHN’S WORT TABLETS, THR 02331/0002
**Carton:**

[Image of a product carton with text and graphics]
Food Supplement Company Herbal Mood Relief Tablets

Blister:
Superdrug St John’s Wort Tablets

Blister:
Module 6

Steps taken after THR grant

The following table lists updates made to the Traditional Herbal Registration for this product that have been approved by the MHRA since the product was first granted a THR.

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/05/2011</td>
<td>Type IB variation</td>
<td>To add FSC Food Supplement Company Limited (Carnaby Industrial Estate, Lancaster Road, Carnaby, Bridlington, YO15 3QY, UK) as an own-label supplier with the new medicinal product name Food Supplement Company Herbal Mood Relief Tablets.</td>
<td>Approved 13/10/2011</td>
</tr>
<tr>
<td>24/06/2011</td>
<td>Type IB variation</td>
<td>To add Asda as an own label supplier with the new medicinal product name Asda St John’s Wort Tablets.</td>
<td>Approved 11/07/2011</td>
</tr>
<tr>
<td>23/04/2012</td>
<td>Type IB variation</td>
<td>To add Superdrug Stores PLC, Admail 838, Croydon, CR9 4WZ as an own label supplier with the new medicinal product name Superdrug St John's Wort Tablets.</td>
<td>Approved 17/05/2012</td>
</tr>
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