HOLLAND & BARRETT ST. JOHN’S WORT CAPSULES
GNC LIVE WELL ST. JOHN’S WORT CAPSULES
LIFECYCLE ST. JOHN’S WORT CAPSULES
NATURE’S GARDEN ST. JOHN’S WORT CAPSULES

HOLLAND & BARRETT MAX STRENGTH ST. JOHN’S WORT CAPSULES
GNC LIVE WELL MAX STRENGTH ST. JOHN’S WORT CAPSULES
LIFECYCLE MAX STRENGTH ST. JOHN’S WORT CAPSULES
NATURE’S GARDEN MAX STRENGTH ST. JOHN’S WORT CAPSULES

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LAY SUMMARY  

The Medicines and Healthcare products Regulatory Agency (MHRA) granted NBTY Europe Limited Traditional Herbal Registration Certificates for the traditional herbal medicinal products Holland & Barrett St. John’s Wort Capsules, GNC Live Well St. John’s Wort Capsules, Lifecyle St. John’s Wort Capsules and Nature’s Garden St. John’s Wort Capsules (Traditional Herbal Registration number: THR 21710/0002) and Holland & Barrett Max Strength St. John’s Wort Capsules, GNC Live Well Max Strength St. John’s Wort Capsules, Lifecycle Max Strength St. John’s Wort Capsules and Nature’s Garden Max Strength St. John’s Wort Capsules (THR 21710/0003).

There are two products, but both products have many different names and will therefore be collectively referred to as St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules for the remainder of this report. St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules are available without prescription and can be bought from pharmacies and other outlets.

The active ingredient of this product is St. John’s Wort extract. St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules are used to relieve the symptoms of slightly low mood and mild anxiety, based on traditional use only.

These registrations are based exclusively upon evidence of traditional use of St. John’s Wort as a 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 these applications and it was, therefore, decided that these Traditional Herbal Registration Certificates could be granted.
HOLLAND & BARRETT ST. JOHN’S WORT CAPSULES
GNC LIVE WELL ST. JOHN’S WORT CAPSULES
LIFECYCLE ST. JOHN’S WORT CAPSULES
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SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted Traditional Herbal Registration Certificates for the traditional herbal medicinal products St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules on 9th November 2010. These products are on the general sales list (GSL) and are indicated to relieve the symptoms of slightly low mood and mild anxiety, based on traditional use only.

These applications were submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme.

Each St. John’s Wort Capsule contains 150mg of dry extract from St. John’s Wort (Hypericum perforatum L.) aerial parts (5-7:1) (equivalent to 750mg – 1050mg of St. John’s Wort) and each Max Strength St. John’s Wort Capsule contains 300mg of extract from St. John’s Wort aerial part (5-7:1) (Equivalent to 1500mg – 2100mg of St. John’s Wort).

The data supplied by the Applicant demonstrate 30 years of traditional use of Hypericum perforatum L. in the European Community. A satisfactory review of the available safety data on Hypericum perforatum L. has also been provided, together with an Expert Safety Report supporting the proposed products.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: ST. JOHN’S WORT
Name: *Hypericum perforatum* L.
Family: Hypericaceae
Common name: St. John’s Wort
Parts of the plant used: Cut dried flowering tops

*Hypericum perforatum* L. is a perennial plant of 1-3 feet in uncultivated ground (woods, hedges, roadsides and meadows). The leaves are pale green, sessile and oblong with pellucid dots or oil glands. The flowers are bright yellow. The calyx and corolla are marked with black dots and lines with 5 pear shaped petals. The plant blooms from June to August. The flowering tops are harvested during flowering time.

**Manufacture**
The plants are harvested manually from the wild in Chile in July and August. Following harvesting, the plants are dried in the sun.

The supplier of the *Hypericum perforatum* L. has provided confirmation that the herbal substance is collected under GACP controlled conditions. It is also stated that the plants are not treated with chemicals or irradiation following harvesting.

Satisfactory details for management plans in place for the sustainability of this herb have been provided.

The manufacturing process is clearly defined and the controls necessary are carried out to verify correct manufacture of the herbal substance.

**Control of Herbal Substance**
An appropriate specification based on the European Pharmacopoeia 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 Directive 2002/72/EC 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

General information
Herbal preparation: St John’s Wort quantified dry extract
Extraction solvent: Ethanol 60% (v/v)
Drug extract ratio (DER): 5-7:1
Excipients: Maltodextrin and silica colloidal anhydrous

Manufacture
A satisfactory description of the manufacturing process of the herbal substance and flow diagram has been provided. In-process controls have been described and are adequate.

Certificates of analysis for all materials used in the manufacture of the herbal preparation have been provided.

Validation data and the batch data results of the final preparation are provided supporting the proposed process.

Control of Herbal Preparation
A satisfactory specification with appropriate tests and limits has 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.

Container Closure System
The container closure system used to store the dry extract complies with Directive 2002/72/EC.

Stability
Batches were packed in the final container closure system and stored under ICH real time and accelerated conditions. The data support the storage conditions used.

HERBAL PRODUCT

Description and Composition of the Herbal Product
Both products are hard two-piece capsules with green brown powder fill; St. John’s Wort Capsules (THR 21710/002) are white coloured and Max Strength St. John’s Wort Capsules (THR 21710/003) are clear.

St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules contain 150mg and 300mg dry extract from St. John’s Wort (Hypericum perforatum L.) aerial part, respectively.

Manufacture
A copy of the manufacturing licence for the finished product manufacturing site is provided. The site complies with GMP standards. Satisfactory batch formulae have been provided for the manufacture of the products, along with a flow diagram summarising the manufacturing process and in-process controls.
In-process control tests are performed during manufacture. All are considered adequate.

**Control of Excipients**
Both products contain the excipients microcrystalline cellulose, magnesium stearate and silica colloidal hydrated. Excipients in the extract are maltodextrin and silica colloidal anhydrous. The capsule shells of both products contain hypromellose. St. John’s Wort Capsules (THR 21710/0002) contain the extra excipient titanium dioxide (E 171.).

All excipients are controlled in line with their respective European Pharmacopoeia monographs.

There are no excipients of human or animal origin used in the manufacture of the products. The supplier has provided confirmation that the magnesium stearate contained in these products is of vegetable origin. Certificates of Analysis have been provided for all excipients.

**Control of Herbal Product**
The finished product specifications for release and end of shelf life are detailed and the tests and limits used were found to be satisfactory for products of this nature.

Satisfactory details have been provided on all analytical procedures and these analytical procedures are valid.

Satisfactory batch data have been provided to support the specifications.

**Reference Standards or Materials**
Certificates of analysis have been provided for all reference standards used.

**Container Closure System**
The finished products are packed in either:

i) Dark amber polyethylene terephthalate (PET) bottles with a low density polyethylene chiffon black hinge cap with a paper backed aluminium foil liner which acts as a tamper evident seal under the cap.

ii) Green polyethylene terephthalate (PET) bottles with a polypropylene chiffon green hinge cap with an inner seal liner designed to lift ‘n’ peel. The inner seal (polyester film, polymer adhesive layer, polyester tab, polyolefin foam, aluminium foil and sealable polyester film) acts as a tamper evident seal under the cap.

Pack sizes are 50 and 100 capsules.

Specifications and certificates are provided from the manufacturers and the applicant has confirmed that all components of the final container closure system comply with Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs.
Stability
Data is provided for production scale batches of both product strengths. Batches were packed in the final packaging and tested under ICH conditions of real, intermediate and accelerated time. Based on the data provided, a shelf life of 2 years with the storage precautions ‘Do not store above 25°C’ and ‘Store in the original container’ is acceptable.

PRODUCT LITERATURE
All product literature (SmPCs, PILs and labels) is satisfactory. The package leaflets were 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 leaflets are 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 they contain.

ADMINISTRATIVE
The Quality Overall Summary has been written by a suitably qualified expert and is satisfactory.

ASSESSOR’S OVERALL CONCLUSIONS ON QUALITY
These products are satisfactory and Traditional Herbal Registrations can be granted.
NON-CLINICAL ASSESSMENT

Non-clinical aspects
The Safety Expert Report submitted by the applicant lists relevant references to published work studying the toxicology of Hypericum perforatum L.

Non-clinical overview
The applicant has submitted an adequate literature review with these applications. An Expert Safety Report was also provided, which included reviews of some non-clinical data. It is written by suitably qualified professional who is a pharmacologist and medical herbalist.

The overview submitted in support of these applications is satisfactory.

Due to a shortage of published data on Hypericum perforatum L. it is not possible to assess if the safety package for the phytochemical constituents of Hypericum perforatum L. 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 may be acceptable and in compliance with guideline EMEA/HMPC/32116/05.

Genotoxicity testing has been carried out on a similar extract to that in the products under assessment and the results of this testing are accepted in the monograph adopted by the Committee on Herbal Medicinal Products (HMPC). Therefore, it is considered that no further testing of the extract is required.

Summary of product characteristics
The Summaries of Product Characteristics for these products are satisfactory.

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 demonstrating traditional use of Hypericum perforatum L. is acceptable. An adequate literature review for Hypericum perforatum L. has been carried out by the applicant and no new non-clinical data were submitted for assessment with this application. Granting of Traditional Herbal Registrations is acceptable.
CLINICAL ASSESSMENT

LEGAL STATUS
_Hypericum perforatum_ L. is currently on Schedule 1 of the General Sales List for internal use.

PROPOSED INDICATION
The applicant has proposed the following for both products:
‘A traditional herbal medicinal product for the relief of slightly low mood and mild anxiety, based on traditional use only’.

This indication is appropriate.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has submitted the following for St. John’s Wort Capsules:
‘For oral use only.
_Adults and the elderly_ – Take 1 capsule 3 times daily. Swallow the whole capsule with water.
Not for use in children or adolescents under 18 years (see section 4.4 ‘Special Warnings and Precautions for use’).
_Duration of use:_
If symptoms worsen or persist after 6 weeks of using the medicinal product, a doctor or a qualified healthcare practitioner should be consulted’.

The applicant has submitted the following for Max Strength St. John’s Wort Capsules:
‘For oral use only.
_Adults and the elderly_ – Take 1 capsule 2 times daily. Swallow the whole capsule with water.
Not for use in children or adolescents under 18 years (see section 4.4 ‘Special Warnings and Precautions for use’).
_Duration of use:_
If symptoms worsen or persist after 6 weeks of using the medicinal product, a doctor or a qualified healthcare practitioner should be consulted’.

Both posologies are acceptable.

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

EVIDENCE OF TRADITIONAL USE
Article 16 c 1 (c) requires the Applicant to provide bibliographic or expert evidence showing that the medicinal products in question, or a corresponding products, have been in medicinal use throughout a period of at least 30 years, including at least 15 years within the European Community.

The Applicant has provided a bibliographic review as evidence of the use of _Hypericum perforatum_ L. within the EU for a period exceeding 30 years.
The information provided is considered to satisfy the requirement to demonstrate 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 addressed for this aspect.

SAFETY REVIEW
Article 16 c 1 (d) requires the Applicant to provide a bibliographic review of the safety data together with a safety expert report.
A safety review has been provided as well as an expert report written by a suitably qualified professional who is a pharmacologist and medical herbalist.

The Safety Review and expert report are satisfactory.

SUMMARY OF PRODUCT CHARACTERISTICS
The SmPCs for these products are satisfactory.

PATIENT INFORMATION LEAFLET
The PILs for these products are satisfactory.

LABELLING
All labelling is satisfactory.

DISCUSSION
These are applications for registration under the Traditional Herbal Medicinal Products Directive. The data supplied by the Applicant are sufficient to demonstrate 30 years’ of traditional use within the European Community of corresponding products and satisfactory safety data have been provided supporting the proposed products.

RECOMMENDATIONS
Traditional Herbal Registrations may be granted.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with these applications 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 (THMP).

The Applicant has provided a bibliographic review which shows ample evidence for the use of *Hypericum perforatum* L. within the EU for a period exceeding 30 years.

A satisfactory review of the safety data has been provided.

The SmPCs, PILs and labelling are satisfactory.

RISK ASSESSMENT
The quality of the products is acceptable and no new non-clinical or clinical safety concerns have been identified.
STEPS TAKEN FOR ASSESSMENT

St. John’s Wort Capsules (THR 21710/0002)

1 The MHRA received the Traditional Herbal Registration application on 27th November 2009.
2 Following standard checks and communication with the applicant the MHRA considered the application valid on 7th January 2010.
3 Following assessment of the application the MHRA requested further information relating to the quality and clinical dossier on 19th March 2010, 29th April 2010, 5th July 2010, 14th July 2010, 15th September 2010 and 16th September 2010.
4 The applicant responded to the MHRA’s requests, providing further information on the dossier on 13th May 2010, 14th July 2010, 2nd August 2010, 10th August 2010 and 14th October 2010.
5 A Traditional Herbal Registration was granted on 9th November 2010.
St. John’s Wort Capsules (THR 21710/0003)

1 The MHRA received the Traditional Herbal Registration application on 15th December 2009.

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 7th January 2010.

3 Following assessment of the application the MHRA requested further information relating to the quality and clinical dossier on 19th March 2010, 29th April 2010, 5th July 2010, 14th July 2010, 15th September 2010 and 23rd September 2010

4 The applicant responded to the MHRA’s requests, providing further information on the dossier on 13th May 2010, 14th July 2010, 2nd August 2010, 10th August 2010 and 14th October 2010.

5 A Traditional Herbal Registration was granted on 9th November 2010. The application was completed on 16th November 2010.
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
- Holland & Barrett St. John’s Wort Capsules
- GNC Live Well St. John’s Wort Capsules
- Lifecycle St. John’s Wort Capsules
- Nature’s Garden St. John’s Wort Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains 150mg of extract (as dry extract) from St. John’s Wort aerial parts
\textit{(Hypericum perforatum L.)} (5-7:1) (Equivalent to 750mg – 1050mg of St. John’s Wort)
Extraction solvent: ethanol 60% v/v.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Capsule, hard
White, hard, two piece capsules with green brown powder fill.

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
For oral use only.
\textit{Adults and the elderly} – Take 1 capsule 3 times daily. Swallow the whole capsule with water.
Not for use in children or adolescents under 18 years (see section 4.4 ‘Special Warnings and Precautions for use’).
\textit{Duration of use:}
If symptoms worsen or persist after 6 weeks of using the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

4.3 Contraindications
- Hypersensitivity to St. John’s Wort or any of the excipients in this product
- This product should not be used in patients with known dermal photosensitivity or those undergoing phototherapy or any photodiagnostic procedures.
- This product should not be taken concomitantly with any of the medicines specified in section 4.5. This is because St. John’s wort (\textit{Hypericum perforatum}) has been shown to induce the cytochrom P450 isoenzymes CYP1A2, CYP2C19, CYP2C9 and CYP3A4 as well as the transport protein
- P-gycoprotein. This results in pharmacokinetic interaction with a large number of medicines including a possible decrease in the effectiveness of those medicines.
- Pharmacodynamic interactions have also been identified with antidepressants, particularly the SSRI antidepressants and the triptan group of medicines

4.4 Special warnings and precautions for use
If the condition worsens or if symptoms persist for more than 6 weeks a doctor or a qualified healthcare practitioner should be consulted.

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 individuals, sunburn type reactions may occur on skin areas exposed to strong sunlight due to photosensitisation by St. John’s wort. Patients taking this product should avoid excessive sunbathing or the use of sunbeds or solariums.

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

Do not exceed the stated dose.

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, CYP2C19, CYP2C9 and CYP3A4 as well as the transport protein P-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 concentrations is possible.

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

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

This product should not be taken concomitantly with the medicines included in the 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></td>
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<tr>
<td>Fentanyl, propofol, sevoflurane, midazolam</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Based on the elimination half-life of hypericin and hyperforin this product should be discontinued at least 10 days prior to elective surgery</td>
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<tr>
<td>Analgesics</td>
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<tr>
<td>Tramadol</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
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<tr>
<td>Antianginals</td>
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<tr>
<td>Ivabradine</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
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<tr>
<td>Anti-arrhythmics</td>
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<tr>
<td>Amiodarone</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
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<tr>
<td>Antibacterials</td>
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<tr>
<td>Erythromycin, Clarithromycin, telithromycin</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
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<tr>
<td>Anticoagulants (blood thinning medicines)</td>
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<tr>
<td>Warfarin, acenocoumarol</td>
<td>Reduced anticoagulant effect</td>
<td>Do not take with this product</td>
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and need for increased dose

<table>
<thead>
<tr>
<th>Antidepressants</th>
<th>Interaction</th>
<th>Recommendations concerning co-administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tricyclics eg</td>
<td>Increased serotonergic effects with increased incidence of adverse reactions</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td>Amitiptyline</td>
<td></td>
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<tr>
<td>Clomipramine</td>
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<td>MAOIs eg</td>
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<td>Moclobemide</td>
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<td>SSRIs eg</td>
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<td>Citalopram</td>
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<td>escitalopram</td>
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<td>Fluoxetin</td>
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<td>Fluvoxamine</td>
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<tr>
<td>Paroxetin, sertraline</td>
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<tr>
<td>Others eg</td>
<td></td>
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<tr>
<td>Duloxetin</td>
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<tr>
<td>Venlafaxine</td>
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<thead>
<tr>
<th>Co-administered drug</th>
<th>Interaction</th>
<th>Recommendations concerning co-administration</th>
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<tbody>
<tr>
<td>Antiepileptics</td>
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<tr>
<td>All drugs in this class including:</td>
<td>Reduced blood levels with increased risk of frequency and severity of seizures.</td>
<td>Do not take with this product</td>
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<tr>
<td>Carbamazepine</td>
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<tr>
<td>Phenobarbitone</td>
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<td>Phenytoin</td>
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<td>Primidone</td>
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<td>Sodium valproate</td>
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<tr>
<td>Antifungals</td>
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<tr>
<td>Itraconazole, voriconazole</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
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<tr>
<td>Antimalariars</td>
<td></td>
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<tr>
<td>Artemether lumefantrine</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
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<tr>
<td>Anti-parkinsons</td>
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<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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<tr>
<td>Antipsychotics</td>
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<tr>
<td>aripiprazole</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
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<tr>
<td>Antivirals</td>
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<tr>
<td>Co-administered drug</td>
<td>Interaction</td>
<td>Recommendations concerning co-administration</td>
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<tr>
<td>Calcium channel blockers</td>
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<tr>
<td>Amlodipine, nifedipine</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
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<tr>
<td>Verapamil, felodipine</td>
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<tr>
<th>Cardiac glycosides</th>
<th>Interaction</th>
<th>Recommendations concerning co-administration</th>
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<tbody>
<tr>
<td>Digoxin</td>
<td>Reduced blood levels and loss of control of heart rhythms or heart failure</td>
<td>Do not take with this product</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CNS Stimulants</th>
<th>Interaction</th>
<th>Recommendations concerning co-administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl phenidate</td>
<td>Reduced blood levels and loss of control of heart rhythms or heart failure</td>
<td>Do not take with this product</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cytotoxics</th>
<th>Interaction</th>
<th>Recommendations concerning co-administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irinotecan, dasatinib, erlotinib, imatinib, Sorafenib, sunitinib, Etoposide, mitotane</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>Hormonal contraceptives</th>
<th>Interaction</th>
<th>Recommendations concerning co-administration</th>
</tr>
</thead>
<tbody>
<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>---------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------</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>
</tbody>
</table>

**Hormone Replacement Therapy**

| Oral |
| Trandermal patches, Gels Vaginal rings |
| Reduced blood levels with risk of therapeutic failure |
| Do not take with this product |

**Hormone antagonists**

| Exemestane |
| Reduced blood levels with risk of therapeutic failure |
| Do not take with this product |

**Diuretics**

| Eplerenone |
| Reduced blood levels with risk of therapeutic failure |
| Do not take with this product |

**Co-administered drug**

| Interaction |
| Recommendations concerning co-administration |

**5HT agonists**

| Almotriptan, eletriptan, Frovatriptan, naratriptan, Rizatriptan, sumatriptan, And zolmitriptan |
| Increased serotonergic effects with increased incidence of adverse reactions |
| Do not take with this product |

**Immunosuppressants**

| Cyclosporine tacrolimus |
| Reduced blood levels with risk of therapeutic failure |
| Do not take with this product |

**Lipid regulating drugs**

| Simvastatin atorvastatin |
| Reduced blood levels with risk of transplant rejection. |
| Do not take with this product |

**Lithium**

| Reduced blood levels with risk of therapeutic failure |
| Do not take with this product |

**Proton pump inhibitors**

| Lansoprazole, omeprazole |
| Reduced blood levels with risk of therapeutic failure |
| Do not take with this product |
Theophylline

Reduced blood levels and loss of control of asthma or chronic airflow limitation

Do not take with this product

Thyroid hormones

Reduced blood levels with risk of therapeutic failure

Do not take with this product

Oral hypoglycaemic drugs

Reduced blood levels with risk of therapeutic failure

Do not take with this product

4.6 Pregnancy and lactation

Safety during pregnancy and lactation has not been established. Due to the lack of data, use during 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 (e.g. dyspepsia, anorexia, nausea, diarrhoea, constipation), allergic skin reactions (e.g. rash, urticaria, pruritus) fatigue and restlessness may occur. The frequency is not known

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

If other adverse reactions not mentioned above occur, a doctor, pharmacist or a qualified health care practitioner should be consulted

4.9 Overdose

There is 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.

Where 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

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC amended.

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 have been detected in further in vitro and in vivo test systems.

Tests on reproductive toxicity revealed equivocal results.

Test on the carcinogenic potential have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose

Magnesium stearate

Silica colloidal hydrated
Excipients in the extract:
Maltodextrin
Silica colloidal anhydrous

Capsule Shell:
Hyromellose
Titanium dioxide (E 171.)

6.2 Incompatibilities
Not applicable

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
Container:
1. Dark amber Polyethylene terephthalate (PET) bottles with a chiffon black hinge cap (low density Polyethylene) with a paper backed aluminium foil liner which acts as a tamper evident seal under the cap.
2. Green Polyethylene terephthalate (PET) bottles with a chiffon green hinge cap (Polypropylene), with an inner seal liner designed to lift ‘n’ peel. The inner seal acts as a tamper evident seal under the cap. The Inner seal liner is made up of polyester film, polymer adhesive layer, polyester tab, polyolefin foam, aluminium foil and sealable polyester film

Pack size: 50 capsules and 100 capsules

6.6 Special precautions for disposal
No special requirements

7 MARKETING AUTHORIZATION HOLDER
NBTY Europe Limited
Samuel Ryder House,
Barling Way,
Nuneaton,
Warwickshire,
CV10 7RH
United Kingdom

8 MARKETING AUTHORIZATION NUMBER(S)
THR 21710/0002

9 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION
09/11/2010

10 DATE OF REVISION OF THE TEXT
09/11/2010
1 NAME OF THE MEDICINAL PRODUCT
- Holland & Barrett Max Strength St. John’s Wort Capsules
- GNC Live Well Max Strength St. John’s Wort Capsules
- Lifecycle Max Strength St. John’s Wort Capsules
- Nature’s Garden Max Strength St. John’s Wort Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains 300mg of extract (as dry extract) from St. John’s Wort aerial parts (*Hypericum perforatum* L.) (5-7:1) (Equivalent to 1500mg – 2100mg of St. John’s Wort)
Extraction solvent: ethanol 60% v/v.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Capsule, hard
Clear, hard, two piece capsules with green brown powder fill.

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
For oral use only.
Adults and the elderly – Take 1 capsule 2 times daily. Swallow the whole capsule with water.
Not for use in children or adolescents under 18 years (see section 4.4 ‘Special Warnings and Precautions for use’).

Duration of use:
If symptoms worsen or persist after 6 weeks of using the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

4.3 Contraindications
Hypersensitivity to St. John’s Wort or any of the excipients in this product
This product should not be used in patients with known dermal photosensitivity or those undergoing phototherapy or any photodiagnostic procedures.
This product should not be taken concomitantly with any of the medicines specified in section 4.5.
This is because St. John’s wort (*Hypericum perforatum*) has been shown to induce the cytochrom P450 isoenzymes CYP1A2, CYP2C19, CYP2C9 and CYP3A4 as well as the transport protein P-gycoprotein. This results in pharmacokinetic interaction with a large number of medicines including a possible decrease in the effectiveness of those medicines.
Pharmacodynamic interactions have also been identified with antidepressants, particularly the SSRI antidepressants and the triptan group of medicines.

4.4 Special warnings and precautions for use
If the condition worsens or if symptoms persist for more than 6 weeks a doctor or qualified healthcare practitioner should be consulted.

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 individuals, sunburn type reactions may occur on skin areas exposed to strong sunlight due to photosensitisation by St. John’s wort. Patients taking this product should avoid excessive sunbathing or the use of sunbeds or solariums.

The 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.
The use of this product is not recommended in children and adolescents below the age of 18 years because data are not sufficient and medical advice should be sought.
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, CYP2C19, CYP2C9 and CYP3A4 as well as the transport protein P-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 concentrations is possible.

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

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

This product should not be taken concomitantly with the medicines included in the Table below.

<table>
<thead>
<tr>
<th>Co-administered drug</th>
<th>Interaction</th>
<th>Recommendations concerning co-administration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anaesthetics/pre-operative medicines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fentanyl, propofol, sevoflurane, midazolam</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Based on the elimination half–life of hypericin and hyperforin this product should be discontinued at least 10 days prior to elective surgery</td>
</tr>
<tr>
<td><strong>Analgesics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tramadol</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Anti-arrhythmics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ivabradine</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Anti-bacterials</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erythromycin</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td>Telithromycin</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Anticoagulants (blood thinning medicines)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warfarin, acenocoumarol</td>
<td>Reduced anticoagulant effect and need for increased dose</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Antidepressants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-administered drug</td>
<td>Interaction</td>
<td>Recommendations concerning co-administration</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td><strong>Tricyclics eg</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amitriptyline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clomipramine</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MAOIs eg</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moclobemide</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SSRIs eg</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citalopram</td>
<td></td>
<td></td>
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<tr>
<td>escitalopram</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoxetine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluvoxamine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paroxetine, sertraline</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Others eg</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duloxetine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venlafaxine</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increased serotonergic effects with increased incidence of adverse reactions</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Co-administered drug</strong></td>
<td>Interaction</td>
<td>Recommendations concerning co-administration</td>
</tr>
<tr>
<td><strong>Antiepileptics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All drugs in this class including:</td>
<td>Reduced blood levels with increased risk of frequency and severity of seizures.</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phenobarbitone</td>
<td></td>
<td></td>
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<tr>
<td>Phenytoin</td>
<td></td>
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<tr>
<td>Primidone</td>
<td></td>
<td></td>
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<tr>
<td>Sodium valproate</td>
<td></td>
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</tr>
<tr>
<td><strong>Antifungals</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itraconazole, voriconazole</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Antimalarias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artemether</td>
<td></td>
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</tr>
<tr>
<td>Lumefantrine</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Anti-parkinsons</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rasagline</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Antipsychotics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Antivirals</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HIV protease inhibitors:</strong></td>
<td>Reduced blood levels with possible loss of HIV suppression</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td>Amprenavir, atazanavir, Darunavir, fosamprenavir, Indinavir, lopinavir, Nelfinavir, ritonavir, Saquinavir, tipranavir,</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*MHRA PAR; St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules*
### HIV non-nucleoside reverse transcriptase inhibitors: efavirenz, nevirapine, delavirdine
- Reduced blood levels with possible loss of HIV suppression
- Do not take with this product

### Anxiolytics
- **Buspirone**
  - Increased serotonergic effects with increased incidence of adverse reactions
  - Do not take with this product

### Aprepitant
- Reduced blood levels with risk of therapeutic failure
- Do not take with this product

### Barbiturates
- Butobarbital, phenobarbital
  - Reduced blood levels with risk of therapeutic failure
  - Do not take with this product

### Co-administered drug
- **Calcium channel blockers**
  - Amlodipine, nifedipine, Verapamil, felodipine
    - Reduced blood levels with risk of therapeutic failure
    - Do not take with this product

### Cardiac glycosides
- **Digoxin**
  - Reduced blood levels and loss of control of heart rhythms or heart failure
  - Do not take with this product

### CNS Stimulants
- **Methylphenidate**
  - Reduced blood levels and loss of control of heart rhythms or heart failure
  - Do not take with this product

### Cytotoxics
- Irinotecan, dasatinib, erlotinib, imatinib, Sorafenib, sunitinib, Etoposide, mitotane
  - Reduced blood levels with risk of therapeutic failure
  - Do not take with this product

### Hormonal contraceptives
<table>
<thead>
<tr>
<th>Include</th>
<th>Effect</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<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>
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<td></td>
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<tr>
<td>Hormonal implants injections</td>
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<tr>
<td>Transdermal patches creams etc.</td>
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</tr>
<tr>
<td>Intra-uterine devices with hormones</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hormone Replacement Therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td>Tranadermal patches, Gels Vaginal rings</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hormone antagonists</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exemestane</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Diuretics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>eplerenone</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
</tbody>
</table>

**Co-administered drug**

**Interaction**

**Recommendations concerning co-administration**

### 5HT agonists

<table>
<thead>
<tr>
<th>Name</th>
<th>Interaction</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almotriptan, eletriptan, Frovatriptan, naratriptan, Rizatriptan, sumatriptan, And zolmitriptan</td>
<td>Increased serotonergic effects with increased incidence of adverse reactions</td>
<td>Do not take with this product</td>
</tr>
</tbody>
</table>

### Immunosuppressants

<table>
<thead>
<tr>
<th>Name</th>
<th>Interaction</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclosporine tacrolimus</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
</tbody>
</table>

### Lipid regulating drugs

<table>
<thead>
<tr>
<th>Name</th>
<th>Interaction</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simvastatin atorvastatin</td>
<td>Reduced blood levels with risk of transplant rejection.</td>
<td>Do not take with this product</td>
</tr>
</tbody>
</table>

### Lithium

<table>
<thead>
<tr>
<th>Name</th>
<th>Interaction</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
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</table>

### Proton pump inhibitors

<table>
<thead>
<tr>
<th>Name</th>
<th>Interaction</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lansoprazole, omeprazole</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Theophylline</strong></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>------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td><strong>Thyroid hormones</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>thyroxine</td>
<td>Reduced blood levels with risk of therapeutic failure</td>
<td>Do not take with this product</td>
</tr>
<tr>
<td><strong>Oral hypoglycaemic drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>gliclazide</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 during pregnancy and lactation has not been established. Due to the lack of data, use during 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 (e.g. dyspepsia, anorexia, nausea, diarrhoea, constipation), allergic skin reactions (e.g. rash, urticaria, pruritus) fatigue and restlessness may occur. The frequency is not known.
Fair-skinned individuals may react with intensified sunburn-like symptoms under intense sunlight or strong ultra-violet (UV) irradiation.
If other adverse reactions not mentioned above occur, a doctor, pharmacist or a qualified health care practitioner should be consulted.

### 4.9 Overdose
There is 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.
Where 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
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

#### 5.2 Pharmacokinetic properties
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

#### 5.3 Preclinical safety data
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC amended.
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 have been detected in further in vitro and in vivo test systems.
Tests on reproductive toxicity revealed equivocal results.
Test on the carcinogenic potential have not been performed.

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients
- Microcrystalline cellulose
- Magnesium stearate
- Silica colloidal hydrated
Excipients in the extract:  
Maltodextrin  
Silica colloidal anhydrous  
Capsule Shell:  
Hypermellose

6.2 Incompatibilities  
Not applicable

6.3 Shelf life  
2 years

6.4 Special precautions for storage  
Do not store the capsules above 25°C.  
Store in the original packaging.

6.5 Nature and contents of container  
Container:  
1. Dark amber Polyethylene terephthalate (PET) bottles with a chiffon black hinge cap (low density Polyethylene) with a paper backed aluminium foil liner which acts as a tamper evident seal under the cap.  
2. Green Polyethylene terephthalate (PET) bottles with a chiffon green hinge cap (Polypropylene), with an inner seal liner designed to lift ‘n’ peel. The inner seal acts as a tamper evident seal under the cap. The Inner seal liner is made up of polyester film, polymer adhesive layer, polyester tab, polyolefin foam, aluminium foil and sealable polyester film

Pack size: 50 capsules and 100 capsules

6.6 Special precautions for disposal  
No special requirements

7 MARKETING AUTHORISATION HOLDER  
NBTY Europe Limited  
Samuel Ryder House,  
Barling Way,  
Nuneaton,  
Warwickshire,  
CV10 7RH  
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)  
THR 21710/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION  
09/11/2010

10 DATE OF REVISION OF THE TEXT  
09/11/2010
PATIENT INFORMATION LEAFLET

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 yourself without a prescription.

Do not take St. John's Wort if you are using any of the following medicines:

- All hormonal contraceptives - The birth control 'Pill', emergency contraception, hormonal implants, creams, patches, intra-uterine devices with hormones
- All medicines for depression/anxiety - Amitriptyline, clomipramine, moclobemide, citalopram, 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 - Amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nefavir, ritonavir, saquinavir, tipranavir, efavirenz, nevirapine, delavirdine
- Some medicines for cholesterol - Simvastatin, atorvastatin
- Some medicines for cancer - Imatinib, dasatinib, erlotinib, imatinib, sorafenib, sunitinib, etoposide, mitotane
- Some medicines for heart disease - Digoxin, ivabradine, amiodarone
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- A medicine for regulating mood - Lithium
- A thyroid hormone - Thyroxine

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

- Anaesthetics/pre-operative medicines: Fentanyl, propofol, sevoflurane, midazolam
- Analgesics: Tramadol
- Antibiotics: Erythromycin, clarithromycin, telithromycin
- Antifungals: Itraconazole, voriconazole
- Antimalarials: Artemether, lumefantrine
- Anti-Parkinsons: Rasagline
- Antipsychotics: Aripiprazole
- Anxiolytics: Buspirone

Important Notes

- Please read this leaflet carefully before you use this product because it contains important information.
- Keep this leaflet; you may need to read it again.
- Seek professional advice if you need more information.
- Please tell a Doctor or a qualified Healthcare Practitioner if your symptoms worsen or do not improve after 6 weeks of taking this product.
- Please tell a Doctor or Pharmacist if you suffer from side effects not listed in this leaflet or if any of the side effects become serious.

In this leaflet

1. What this product is and what it is used for.
2. Before you take this product.
3. How to take this product.
4. Possible side effects.
5. How to store this product.
6. Further information.

1 - What this product is and what it is used for.

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

2 - Before you take this product.

Do not take this product if you are:

- Under 18 years of age.
- About to undergo surgery.
- Allergic to any of the ingredients (see section 6 of this leaflet).
- Pregnant or breastfeeding.
- Having UV light treatment (phototherapy) for any condition.
- Exceptionally sensitive to sunlight on your skin (photosensitive).
- Suffering from depression.

Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, changes in appetite or weight, changes in sleeping patterns or habits, loss of energy and difficulty in concentrating.

If your Doctor has told you that you are suffering from depression do not use this product.

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For oral use only.

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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 and constipation.
- Fatigue and restlessness.
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- Sunburn-like reactions on skin exposed to strong sunlight or strong ultra-violet (UV) irradiation e.g. solarium, particularly in fair skinned individuals.

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- Keep the bottle tightly closed
- Keep the capsules out of sight and reach of children

6 - Further information

About this product: This product is a traditional herbal medicinal product containing St John’s Wort extract. Each capsule contains 150mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5:1) (equivalent to 750mg-1050mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v. This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate, Silica colloidial hydrated. Excipients in the extract: Maltodextrin, Silica colloidial anhydrous.

Capsule shell: Hypromellose, Titanium dioxide (E 171). Each bottle contains 50 or 100 white, hard, two piece capsules with green/brown powder.

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Manufacturer of this product: Vita Health Products Inc
150 Beghin Avenue, Winnipeg, Manitoba, R2J 3W2, Canada

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MHRA PAR; St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules

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THR21710/0002-3
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Treatment of post-operative vomiting: Aprepitant
- Barbiturates: Butoobarbital, phenobarbital
- CNS Stimulants: Methyl phenidate
- Hormone antagonists: Exemestane
- Diuretics: Eperenone
- Proton pump inhibitors: Lansoprazole, omeprazole
- Bronchodilators: Theophylline
- Antidiabetic medecine: Glicazide

While you are taking this product:
- Avoid excessive sunbathing or 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 operate machinery.

3 - How to take this product
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BS09-000 137857-000

CERTIFICATION MARK

MHRA PAR; St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules

THR21710/0002-3 34
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PATIENT INFORMATION LEAFLET

GNC Live Well
Max Strength St. John's Wort Capsules
St. John’s Wort Extract 300mg

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6 Further information

1 - What this product is and what it is used for
This product contains St. John’s Wort extract. It is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety, based on traditional use only.

2 - Before you take this product
Do not take this product if you are:
◆ Under 18 years of age.
◆ About to undergo surgery.
◆ Allergic to any of the ingredients (see section 6 of this leaflet).
◆ Pregnant or breastfeeding.
◆ Having UV light treatment (phototherapy) for any condition.
◆ Exceptionally sensitive to sunlight on your skin (photosensitive).
◆ Suffering from depression.

Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, changes in appetite or weight, changes in sleeping patterns or habits, loss of energy and difficulty in concentrating.

If your Doctor has told you that you are suffering from depression do not use this product.

If you think you may be suffering from depression, tell your Doctor before taking this product.

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 yourself without a prescription.

Do not take St John’s Wort if you are using any of the following medicines:

- All hormonal contraceptives - The birth control 'pill', emergency contraception, hormonal implants, creams, patches, intra-uterine devices with hormones.
- All medicines for depression/anxiety - Amitriptyline, clomipramine, moclobemide, citalopram, 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, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nevirapine, ritonavir, saquinavir, tipranavir, elvirena, 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, verapamil, felodipine.
- A medicine for regulating mood - Lithium.
- A thyroid hormone - Thyroxine.

St John’s Wort may also affect the following medicines. Do not take this product with these medicines unless a Doctor has said it is safe to do so:
◆ Anaesthetics/pre-operative medicines - Fentanyl, propofol, sevoflurane, midazolam.
◆ Analgesics - Tramadol.
◆ Antibiotics - Erythromycin, clarithromycin, telithromycin.
◆ Antifungals - Itraconazole, voriconazole.
◆ Antimalarials - Artemether, lumefantrine.
◆ Anti-Parkinsons - Rasagiline.
◆ Antipsychotics - Aripiprazole.
◆ Anxiolytics - Buspirone.
3 - How to take this product

For oral use only.

For adults and elderly: Take 1 capsule 2 times daily. Swallow the whole capsule with water. Do not exceed the stated dose.

If you take too much of the product (overdose): speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product: Do not take a double dose to make up for the missed dose(s). Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 6 weeks, or if any of the side effects become serious or if any side effects not mentioned in the leaflet occur; speak to a Doctor, Pharmacist or a 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 and 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.
- Sunburn-like reactions on skin exposed to strong sunlight or strong ultra-violet (UV) irradiation e.g. solarium, 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 this product

- Keep the capsules in the bottle until it is time to take them.
- Do not take the capsules after the expiry date (see outer label). The expiry date refers to the last day of the month.
- Do not store above 25°C. Store in the original packaging.
- Keep the bottle tightly closed.
- Keep the capsules out of sight and reach of children.

6 - Further information

About this product: This product is a traditional herbal medicinal product containing St. John’s Wort extract. Each capsule contains 300mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5-7%) equivalent to 1500mg-2100mg of St John’s Wort. Extraction solvent Ethanol 60% v/v. This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated. Excipients in the extract: Maltodextrin, Silica colloidal anhydrous. Capsule shell: Hypromellose. Each bottle contains 50 or 100 clear, hard, two piece capsules with green/brown powder.

Traditional Registration Holder:
THR 21710/0003

NBTY Europe Ltd
Samuel Ryder House, Barling Way, Nuneaton, Warwickshire, CV10 7RH, United Kingdom

Manufacturer of this product: Vita Health Products Inc
150 Beighin Avenue, Winnipeg, Manitoba, R2J 3W2, Canada

For: NBTY Europe Ltd
Samuel Ryder House, Barling Way, Nuneaton, Warwickshire, CV10 7RH, United Kingdom

If you would like further information about this product, please contact:
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Alternatively you can get a paper Yellow Card form from your GP’s surgery or pharmacy, or call freephone 0808 100 3352

Certification Mark

MHRA PAR; St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules

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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 yourself without a prescription.

Do not take St John's Wort if you are using any of the following medicines:

- **All hormonal contraceptives** - The birth control pill, emergency contraception, hormonal implants, creams, patches, intra-uterine devices with hormones
- **All medicines for depression/anxiety** - Amitriptyline, clomipramine, moclobemide, citalopram, 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, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nevirapin, ritonavir, 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 migraine** - Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
- **Some medicines for high blood pressure** - Amlodipine, nifedipine, verapamil, felodipine
- **A medicine for regulating mood** - Lithium
- **A thyroid hormone** - Thyroxine

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

- Anaesthetics/pre-operative medicines: Fentanyl, propofol, sevoflurane, midazolam
- Analgesics: Tramadol
- Antibiotics: Erythromycin, clarithromycin, telithromycin
- Antifungals: Itraconazole, voriconazole
- Antimalarials: Arteether, lumefantrine
- Anti-Parkinson: Rasagiline
- Antipsychotics: Aripiprazole
- Anxiolytics: Buspirone
- Treatment of post-operative vomiting: Aprepitant
- Barbiturates: Butobarbital, phenobarbital
- CNS Stimulants: Methylphenidate
- Hormone antagonists: Exemestane
- Diuretics: Eplerenone
- Proton pump inhibitors: Lansoprazole, omeprazole
- Bronchodilator: Theophylline
- Antidiabetic medicine: Gliclazide

While you are taking this product:
- Avoid excessive sunbathing or 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 operate machinery.

3 - How to take this product
For oral use only.
For adults and elderly: Take 1 capsule 2 times daily. Swallow the whole capsule with water: Do not exceed the stated dose.

If you take too much of the product (overdose): speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product: Do not take a double dose to make up for the missed dose(s). Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 6 weeks, or if any of the side effects become serious or if any side effects not mentioned in the leaflet occur; speak to a Doctor, Pharmacist or a 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 and 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.
- Sunburn-like reactions on skin exposed to strong sunlight or strong ultra-violet (UV) irradiation e.g. solarium, 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 this product
- Keep the capsules in the bottle until it is time to take them.
- Do not take the capsules after the expiry date (see outer label). The expiry date refers to the last day of the month.
- Do not store above 25°C. Store in the original packaging.
- Keep the bottle tightly closed.
- Keep the capsules out of sight and reach of children.

6 - Further information
About this product: This product is a traditional herbal medicinal product containing St John’s Wort extract. Each capsule contains 300mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5-7:1) (equivalent to 1500mg:2100mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v. This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate, Silica colloidial hydrated. Excipients in the extract: Maltodextrin, Silica colloidial anhydrous. Capsule shell: Hypromellose. Each bottle contains 50 or 100 clear hard, two piece capsules with green/brown powder.

Traditional Registration Holder:
THR 21710/0003

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Manufacturer of this product: Vita Health Products Inc
150 Beghin Avenue, Winnipeg, Manitoba, R2J 3W2, Canada

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Alternatively you can get a paper Yellow Card form from your GP’s surgery or pharmacy, or call freephone 0808 100 3352

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THR21710/0002-3
PATIENT INFORMATION LEAFLET

Max Strength St. John’s Wort Capsules
St. John’s Wort Extract 300mg

Important Notes

- Please read this leaflet carefully before you use this product because it contains important information.
- Keep this leaflet; you may need to read it again.
- Seek professional advice if you need more information.
- Please tell a Doctor or a qualified Healthcare Practitioner if your symptoms worsen or do not improve after 6 weeks of taking this product.
- Please tell a Doctor, Pharmacist or a qualified Healthcare Practitioner if you suffer from side effects not listed in this leaflet or if any of the side effects become serious.

In this leaflet

1. What this product is and what it is used for
2. Before you take this product
3. How to take this product
4. Possible side effects
5. How to store this product
6. Further information

1 - What this product is and what it is used for

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

2 - Before you take this product

Do not take this product if you are:

- Under 18 years of age
- About to undergo surgery
- Allergic to any of the ingredients (see section 6 of this leaflet)
- Pregnant or breastfeeding
- Having UV light treatment (phototherapy) for any condition
- Exceptionally sensitive to sunlight on your skin (photosensitive)
- Suffering from depression

Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, changes in appetite or weight, changes in sleeping patterns or habits, loss of energy and difficulty in concentrating.

If your Doctor has told you that you are suffering from depression do not use this product.

If you think you may be suffering from depression, tell your Doctor before taking this product.

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 yourself without a prescription.

Do not take St. John’s Wort if you are using any of the following medicines:

- All hormonal contraceptives - The birth control 'pill', emergency contraception, hormonal implants, creams, patches, intra-uterine devices with hormones
- All medicines for depression/anxiety - Amitryptiline, clomipramine, moclobemide, citalopram, flupoxetine, 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 - Amprenavir, atazanavir, darunavir, fosamprenavir, indinivir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir, efavirenz, nevirapine, delavirdine
- Some medicines for cholesterol - Simvastatin, atorvastatin
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- Some medicines for heart disease - Digoxin, ivabradine, amiodarone
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- Some medicines for high blood pressure - Amlodipine, nifedipine, verapamil, felodipine
- A medicine for regulating mood - Lithium
- A thyroid hormone - Thyroxine

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

- Anaesthetics/pre-operative medicines: Fentanyl, propofol, sevoflurane, midazolam
- Analgesics: tramadol
- Antibiotics: Erythromycin, clarithromycin, telithromycin
- Antifungals: Itraconazole, voriconazole
- Antimalarials: Artemether, lumefantrine
- Anti-Parkinsons: Rasagiline
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- Keep the capsules out of sight and reach of children.

6 - Further information

About this product: This product is a traditional herbal medicinal product containing St John’s Wort extract. Each capsule contains 300mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5-7:1) (equivalent to 1500mg-2100mg of St John’s Wort). Extraction solvent: Ethanol 60% w/v. This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate, Silica, colloidal hydrated. Excipients in the extract: Maltodextrin, Silica, colloidal anhydrous. Capsule shell: Hypromellose. Each bottle contains 50 or 100 clear hard, two piece capsules with green/brown powder.

Traditional Registration Holder:
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- **Analgesics** - Tramadol
- **Antibiotics** - Erythromycin, clarithromycin, telithromycin
- **Antifungals** - Itraconazole, voriconazole
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- **Antipsychotics** - Aripiprazole
- **Anxiolytics** - Buspirone
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For adults and elderly: Take 1 capsule 2 times daily. Swallow the whole capsule with water.
Do not exceed the stated dose.

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If you forget to take this product: Do not take a double dose to make up for the missed dose(s). Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 6 weeks, or if any of the side effects become serious or if any side effects not mentioned in the leaflet occur, speak to a Doctor, Pharmacist or a 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 and 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.
- Sunburn-like reactions on skin exposed to strong sunlight or strong ultra-violet (UV) irradiation e.g. solarium, particularly in fair skinned individuals.

Other side effects that have been reported include headaches, nerve pain or tingling, anxiety, dizziness and mania.

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6 - Further Information

About this product: This product is a traditional herbal medicinal product containing St John’s Wort extract. Each capsule contains 300mg of extract (as dry extract) from St John’s Wort aerial parts (Hypericum perforatum L.) (5-7:1) (equivalent to 1500mg - 2100mg of St John’s Wort). Extraction solvent: Ethanol 60% v/v. This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated. Excipients in the extract: Maltodextrin, Silica colloidal anhydrous. Capsule shell: Hypromellose. Each bottle contains 50 or 100 clear, hard, two piece capsules with green/brown powder.

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B508-000 00A 138090-000
LABELLING

Please note that the labelling shown below are for St. John’s Wort Capsules and Max Strength St. John’s Wort 50 capsules only. Other pack sizes are available.
Warnings:
DO NOT EXCEED THE STATED DOSE
Do not take this product if you are:
- Under 18 years of age
- About to undergo surgery
- Suffering from depression or think you may be depressed
- Allergic to any of the ingredients
- Pregnant or breastfeeding

St. John’s Wort must be taken at the same time as some other medicines.

- Many prescribed by your doctor (see enclosed leaflet)
- Hormonal contraceptives including the ‘pill’
- Some you can get without prescription

Please read the enclosed leaflet carefully before using this product.

Increased sensitivity of the skin to sunlight may occur in rare cases, especially fair-skinned individuals.

Active Ingredients:
Each capsule contains 150mg of extract (as dry extract) from St. John’s Wort aerial part (Hypericum perforatum L.) (5-7:1) equivalent to 750mg-1050mg of St. John’s Wort. Extraction solvent: Ethanol 60% v/v.

Dosage:
For oral use only.
For adults and elderly: Take 1 capsule 3 times daily.
Swallow the whole capsule with water.

Duration of use:
If symptoms worsen or do not improve after 6 weeks, or if any of the side effects become serious or if any side effects not mentioned in the leaflet occur, speak to a Doctor or a qualified Healthcare Practitioner.

Storage:
Do not store above 25°C. Store in the original packaging. Keep the bottle tightly closed. Keep out of sight and reach of children.

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

50 Capsules

MHRA PAR; St. John’s Wort Capsules and Max Strength St. John’s Wort Capsules

THR21710/0002-3
Active Ingredients: Each capsule contains 150mg of extract (as dry extract) from St. John’s Wort aerial part (Hypericum perforatum L.) (5:7:1) (equivalent to 750mg-1500mg of St. John’s Wort). Extraction solvent: Ethanol 60% w/w.

Dosage: For oral use only. 
- For adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water.
- For children: Keep out of sight and reach of children.

Duration of use: If symptoms worsen or do not improve after 6 weeks, or if any of the side effects become serious or if any side effects not mentioned in the leaflet occur, speak to a Doctor or a qualified Healthcare Practitioner.

Warnings: Do not exceed the stated dose.
- Do not take this product if you are:
  - Under 18 years of age
  - About to undergo surgery
  - Suffering from depression or think you may be depressed
  - Allergic to any of the ingredients
  - Pregnant or breastfeeding
  - St John’s Wort must not be taken at the same time as some other medicines including:
    - Many prescribed by your doctor (see enclosed leaflet)
    - Hormonal contraceptives including the ‘pill’
    - Some can get without prescription

Increased sensitivity of the skin to sunlight may occur in rare cases, especially fair-skinned individuals.

Active Ingredients: Each capsule contains 300mg of extract (as dry extract) from St. John’s Wort aerial part (Hypericum perforatum L.) (5:7:1) (equivalent to 1500mg-2100mg of St. John’s Wort). Extraction solvent: Ethanol 60% v/v.

Dosage: For oral use only. For adults and elderly: Take 1 capsule 2 times daily. Swallow the whole capsule with water.

Duration of use: If symptoms worsen or do not improve after 6 weeks, or if any of the side effects become serious or if any side effects not mentioned in the leaflet occur, speak to a Doctor or a qualified Healthcare Practitioner.

Warnings:
- DO NOT EXCEED THE STATED DOSE
- Do not take this product if you are:
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- St. John’s Wort must not be taken at the same time as some other medicines including:
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- Increased sensitivity of the skin to sunlight may occur in rare cases, especially fair-skinned individuals.