Duchy Herbals Hyperi-lift Tincture

THR 01175/0123

UKPAR

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DUCHY HERBALS HYPERI-LIFT TINCTURE

THR 01175/0123

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted A. Nelson & Co. Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Duchy Herbals Hyperi-lift Tincture (Traditional Herbal Registration number: 01175/0123). This product is available without prescription and can be bought from pharmacies and other outlets.

Duchy Herbals Hyperi-lift Tincture is used to relieve the symptoms of slightly low mood and mild anxiety, based on traditional use only. This medicine is an oral liquid containing the active ingredient dried St John's Wort flowering tops tincture.

This registration is based exclusively upon evidence of traditional use of *Hypericum perforatum* L. 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 this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.

DUCHY HERBALS HYPERI-LIFT TINCTURE

THR 01175/0123

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Duchy Herbals Hyperi-lift Tincture (Traditional Herbal Registration number: 01175/0123) to A. Nelson & Co. Limited on 10 October 2008. This product is on the general sales list (GSL).

The application was submitted under Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme.

This product consists of oral liquid containing 1 ml of tincture from dried *Hypericum perforatum* L. flowering tops per 1 ml of liquid. Duchy Herbals Hyperi-lift Tincture is used to relieve the symptoms of slightly low mood and mild anxiety. This THR is based exclusively on evidence of traditional use of *Hypericum perforatum*. The recommended dose is 2.5 ml of tincture, in water, twice daily

The data supplied by the applicant demonstrate 30 years of traditional use of *Hypericum perforatum* in the European Community. A satisfactory review of the available safety data on *Hypericum perforatum* has also been provided.

PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE

General information

Scientific name of the plant: *Hypericum perforatum* L.
Common name: St John's Wort
Family: Hypericaceae (syn. Guttiferae)
Parts of the plant used: Dried flowering tops

Description of the plant/herbal substance

The herbal substance comes from the aerial parts of the plant St John's wort (*Hypericum perforatum* L.), which belongs to the Hypericaceae (syn. Guttiferae) family. The plant grows in middle Europe, Western Asia and North America on sunny dry or barren meadows.

Manufacture

The herbal substance used in this product is cultivated without pestitcies in either Macedonia or Germany. The plant material is collected in accordance with Good Agricultural and Collection Practice (GACP) guidelines, without the use of ethylene oxide.

Control of Herbal Substance

Herbal substance obtained from growers is quarantined prior to quality control and release. Release is dependent on receipt of a satisfactory Certificate of Analysis from the grower.

An appropriate specification based on the Ph Eur monograph for *Hypericum perforatum* is used. Tests carried out are stated to be in line with Ph Eur methods, therefore, additional validation is not required. The specification is supported by the batch data provided.

Container Closure System

A suitable container is used to store the herbal substance.

Stability

Stability data for the herbal substance are not available. The herbal substance is not stored prior to use in the manufacture of the the herbal preparation but is essentially ordered for immediate use in manufacture. Should delays in delivery of plant materials occur, plant material will be re-tested prior to use in manufacture of the herbal preparation.

HERBAL PREPARATION

General information

Latin ame: Hypericum perforatum herb tincture
Part of plant used: Dried flowering tops
Drug to extract ratio: 1:4
Extractant: Ethanol 45 % v/v

Manufacture
A satisfactory description and flow-chart of the manufacturing method has been provided.

An up to date GMP certificate has been provided for the manufacturing site.

Control of Materials
The materials used in the preparation of the herbal tincture are the herbal substance and the extraction solvent. The herbal substance is extracted with ethanol 45%. The ethanol complies with the Ph Eur and suitable certificates of analysis have been provided.

The water used is purified and complies with the Ph. Eur., a suitable specification is provided.

Controls of Critical Steps and Intermediates
No critical steps have been identified.

Process Validation and/or Evaluation
Manufacture of the tincture is a standard maceration process as described in Ph Eur. The Ph Eur describes tinctures prepared by maceration or percolation using ethanol of a suitable concentration, or by dissolving a soft or dry extract (prepared using the same strength of ethanol) in ethanol. Nelsons have considerable experience with manufacture of herbal and homoeopathic tinctures.

Characterisation
Suitable tests are performed to elucidate the characteristics of the herbal preparation.

Control of Herbal Preparation
Specification
A satisfactory specification, with appropriate tests and limits has been provided for the herbal preparation

Analytical Procedures/ Validation of Analytical Procedures
Analytical methods are either those of the Ph Eur or have been fully validated.

Batch Analyses
Batch analysis data are provided and these comply with the proposed specification.

Justification of Specification
The proposed specification has been justified satisfactorily.

Reference Standards or Materials
Reference materials used are all in accordance with Ph Eur standards.

Container Closure System
The herbal preparation is stored in a suitable container closure system. A description of the container closure system is provided. The stability data provided show no incompatibilities between the herbal preparation and the container.

Stability

No information has been provided. As the tincture is not stored prior to filling into the final container, this is satisfactory.

HERBAL PRODUCT

Description and Composition of the Drug Product

The product is an oral liquid consisting of the *Hypericum perforatum* flowering tops tincture without any excipients

The herbal preparation is an ethanolic extract containing 45% ethanol by volume. The high level of alcohol is considered to afford adequate antimicrobial preservation to the herbal preparation. There are no overages in this product.

Manufacture

Manufacture

Manufacture simply involves filling the bulk tincture into the final bottles.

Control of Excipients

Not applicable.

Control of Herbal Product

Specification

The finished product specifications at release and end of shelf life are detailed and the tests and limits applied were found to be satisfactory for a product of this nature.

Analytical Procedures

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

Batch Analyses

Satisfactory batch data have been provided to support the specifications.

Justification of Specification

The proposed release and shelf-life specifications have, in general been adequately justified with respect to the parameters controlled and the limits applied.

Reference Standards or Materials

Reference materials used are confirmed to be in accordance with Ph Eur standards.

Container Closure System

The finished product is presented in a 50 ml or 100 ml amber glass bottle with 1 ml graduated glass pipette (subdivided at 0.5 ml), butyl-rubber bulb and HDPE plastic cap. Plastic cap includes a tamper-evident collar that shears on first opening.

Stability

Stability studies have been conducted under ICH conditions (long term, accelerated). The results support the proposed shelf life of 18 months with the storage precaution ‘Do not store above 25°C’.

Product literature

The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product are pharmaceutically 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.

ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY

This product is satisfactory and a Traditional Herbal Registration can be granted.

NON-CLINICAL ASSESSMENT

NONCLINICAL ASPECTS

The Expert Safety Report submitted by the applicant lists relevant references to published work studying the toxicology of *Hypericum perforatum*.

NONCLINCIAL OVERVIEW

The applicant has submitted an adequate literature review with this application. An Expert Report on Safety was provided, which included reviews of some non-clinical data. The author of the Expert Safety Report has expertise in herbal medicines and the report is dated January 2007.

The overview submitted in support of this application is satisfactory.

Due to a shortage of published data on *Hypericum perforatum*, it is not possible to assess if the safety package for the phytochemical constituents of *Hypericum perforatum* 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.

Data in the literature for genotoxic and carcinogenic potential of the product is deficient as basic genotoxicity tests have not been conducted. The company have provided their assurance that they will address this lack of data before renewal of their licence.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPC for this product is satisfactory from a preclinical 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 demonstrating traditional use of *Hypericum perforatum* is acceptable. An adequate literature review of *Hypericum perforatum* has been carried out by the applicant and no new non-clinical data was submitted for assessment with this application. Granting of a THR is acceptable.

CLINICAL ASSESSMENT

LEGAL STATUS

Hypericum is currently on the General Sales List for external use only.

PROPOSED INDICATION

The applicant has proposed the following indication, which is acceptable:

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

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 an EU Member State.

The applicant has provided information that satisfies this requirement.

SAFETY REVIEW

Article 16 c 1 (D) requires the applicant to provide a bibliography of safety data together with a Safety Expert Report.

A safety review has been provided as well as an expert report written by a medical herbalist. His CV is included.

The clinical review of safety submitted in the dossier outlined adverse events from controlled and uncontrolled studies relevant to the safety of *Hypericum perforatum*.

Assessor's comment

A satisfactory and comprehensive review of the literature has been provided. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. The applicant has, therefore, provided assurance that appropriate genotoxicity testing will be performed prior to renewal of this registration.

PRODUCT LITERATURE

The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product are medically satisfactory.
The 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.

ASSESSMENT OF SUITABILITY FOR GSL STATUS FOR INTERNAL USE

In March 2007 the Herbal Medicines Advisory Committee advised that St John's wort is suitable for inclusion on the General Sales List (GSL) for internal use.

DISCUSSION

The data supplied by the Applicant are sufficient to demonstrate 30 years of traditional use, including at least 15 years within an EU Member State, for required for registration under the Traditional Herbal Medicines Product Directive.

A satisfactory review of the available safety data relating to *Hypericum perforatum* has been provided, together with an expert report supporting the registration of the product. All product literature is satisfactory.

RECOMMENDATIONS

A Traditional Herbal Registration may be granted.

OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

PRECLINICAL
No new preclinical 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 of the use of *Hypericum perforatum* for more than 30 years and within the EU for a period exceeding 15 years.

A satisfactory review of the safety data has been provided.

The SPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.

DUCHY HERBALS HYPERI-LIFT TINCTURE

THR 01175/0123

1	The MHRA received the Traditional Herbal Registration application on 27 January 2007
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 8 March 2007
3	Following assessment of the application the MHRA requested further information relating to the dossier on 30 March 2007
4	The applicant responded to the MHRA's requests, providing further information on the dossier on 18 May 2007
5	Following assessment of the response the MHRA requested further information relating to the dossier on 13 June 2007
6	The applicant responded to the MHRA's requests, providing further information on the quality dossier on 18 September 2008
7	A THR was granted on 10 October

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Duchy Herbals Hyperi-lift Tincture

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of oral liquid contains 1ml of tincture from dried St John's Wort (*Hypericum perforatum* L.) flowering tops (1:4). Extraction solvent: Ethanol 45% v/v.

1ml of tincture contains approximately 360mg ethanol (alcohol), equivalent to 9 ml of beer or 4 ml of wine.

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral liquid. Dark cherry-red to brownish-red.

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 short-term use only.

Adults and elderly:
2.5ml tincture, in water, twice daily.

Patients should consult a doctor if symptoms worsen or do not improve after six weeks.

Not suitable for children or adolescents under 18 years of age.

4.3 Contraindications

Hypersensitivity to the active ingredient.

Children or adolescents under 18 years of age.

Pregnancy and lactation (see Section 4.6)

Patients with known dermal photosensitivity or patients undergoing phototherapy or any photodiagnostic procedures.

This medicine 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 and CYP3A4 as well as transport protein P-glycoprotein. This results in pharmacokinetic interactions with a large number of medicines 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.

Contains alcohol – up to 900mg ethanol per dose (equivalent to 23 ml beer or 9 ml wine). Harmful for those suffering from alcoholism. To be taken into account in high-risk groups such as patients with liver-disease or epilepsy.

If the condition worsens, or if symptoms persist for more than six weeks medical advice should be sought.

The dosing and safety of St John's Wort have not been studied in children or adolescents below 18 years and safety is not established.

This product is intended for relief of symptoms of slightly low mood and mild anxiety. Patients with signs and symptoms of depression should seek medical advice for appropriate treatment.

In very rare cases, particularly in light-skinned persons, sunburn-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

Contains alcohol, and should therefore be avoided in patients taking other medications known to interact with alcohol (e.g. metronidazole).

Substances in St John's Wort (*Hypericum perforatum*) have been shown to induce the cytochrome P450 isoenzymes CYP1A2, 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. Clinically significant interactions have been reported with for example: warfarin, cyclosporin, HIV protease inhibitors, theophylline, digoxin, oral contraceptives, and anticonvulsants.

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.

Co-administerd drug	Interaction	Recommendations concerning co-administration
Anaesthetics / Pre-operative Medicines		
Fentanyl, Propofol, Sevoflurane, Midazolam	Reduced blood levels with risk of therapeutic failure.	Based on the elimination half-lives of hypericin and hyperforin this product should be discontinued at least 10 days prior to elective surgery.
Analgesics		
Tramadol	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
Antianginals		
Ivabradine	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
rhythmics		
Amiodarone	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
cterials		
Erythromycin, Clarithromycin, Telithromycin	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
agulants		
Warfarin, Acenocoumarol	Reduced anticoagulant effect and need for increased dose	Do not take with this product.

Antidepressants		
Tricyclics e.g. Amitriptyline, Clomipramine **MAOIs** e.g. Moclobemide **SSRIs** e.g. Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Paroxetine, Sertraline **Others** e.g. Duloxetine, Venlafaxine	Increased serotonergic effects with increased incidence of adverse reactions.	Do not take with this product.
Antiepileptics		
All drugs in this class including: Carbamazepine, Phenobarbitone Phenytoin, Primidone, Sodium Valproate	Reduced blood levels with increased risk of frequency and severity of seizures.	Do not take with this product.
Antifungals		
Itraconazole, Voriconazole	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
Antimalarials		
Artemether, Lumefantrine	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
Antiparkinsons		
Rasagiline	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
Antipsychotics		
Aripiprazole	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
Antivirals		
HIV protease inhibitors: Amprenavir, Atazanavir, Darunavir, Fosamprenavir, Indinavir, Lopinavir, Nelfinavir, Ritonavir, Saquinavir, Tipranavir	Reduced blood levels with possible loss of HIV suppression.	Do not take with this product.
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.
Calcium Agonists		
Felodipine	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
Calcium Channel Blockers		
Amlodipine,Nifedipine, Verapamil	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 rhythm or heart failure.	Do not take with this product.
CNS Stimulants		
Methylphenidate	Reduced blood levels with risk of therapeutic 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		
Oral Contraceptives Emergency Hormonal Contraception Hormonal implants and injections Transdermal patches, creams etc. Intra-uterine devices with hormones	Reduced blood levels with risk of unintended pregnancy and breakthrough bleeding.	Do not take with this product.
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.

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		
Cyclosporin, Tacrolimus	Reduced blood levels with risk of transplant rejection.	Do not take with this product.
Lipid Regulating Medicines		
Simvastatin, Atorvastatin	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
Lithium	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
Oral Hypoglycaemics		
Gliclizide	Reduced blood levels.	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		
Thyroxine	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.

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 during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed. This product contains alcohol (see Section 2).

4.8 Undesirable effects

A drug-monitoring study of 3,250 patients receiving St John's Wort included an overall rate of adverse reactions of 2.4%. All patients were treated with St John's Wort extract (300 mg three times daily). Adverse events were spontaneously reported by 79 (2.4%) patients during 4 weeks of treatment. Gastrointestinal symptoms were the most frequently reported adverse

events (n=18, 0.6%) followed by allergic reactions (n=17, 0.5%) and fatigue (n=13, 0.4%). Gastrointestinal adverse events reported include dyspepsia, anorexia, nausea, diarrhoea and constipation. Other ADRs reported in the literature include headaches, neuropathy, anxiety, dizziness, mania and allergic reactions.

When St John's Wort is used, sunburn-like reactions in the parts of skin exposed to strong UV irradiation (sun, solarium) can rarely occur, particularly in fair-skinned individuals, due to the increased sensitivity of the skin to sunlight (photosensitisation).

4.9 Overdose

There are no data on human overdose with St John's Wort. Where a large overdose has occurred, phototoxic reactions may occur. The skin of the patient should be protected for one week from UV irradiation. 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.

Overdose of this product may result in alcohol intoxication: the amount in a full bottle (18g in 50ml, 36g in 100ml: equivalent to one or two large glasses of wine, respectively) may result in intoxication and should be treated accordingly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Herbal medicinal product for the treatment of depressive disorders. ATC code: N06AP01

5.2 Pharmacokinetic properties

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

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (from tincture)

6.2 Incompatibilities

None known.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

50ml or 100ml amber glass bottle, with 1 ml graduated glass pipette (subdivided at 0.5 ml), butyl-rubber bulb and HDPE plastic cap. Plastic cap includes a tamper-evident collar that shears on first opening.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

A. Nelson & Co. Limited.
5 Endeavour Way
Wimbledon
London
SW19 8UH

8 MARKETING AUTHORISATION NUMBER(S)

THR 01175/0123

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/10/2008

10 DATE OF REVISION OF THE TEXT

10/10/2008

PATIENT INFORMATION LEAFLET

DUCHY HERBALS

Hyperi-Lift Tincture

Hypericum perforatum
(St John's Wort) flowering tops

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

For oral administration

Please read this leaflet carefully before taking this product. It contains important information, including what this product does, what you need to know before you take it, how you should take it and how you should keep it.

PLEASE KEEP THIS LEAFLET, YOU MAY NEED TO READ IT AGAIN.

Ask your doctor, pharmacist or healthcare practitioner if you feel you need further information and advice about taking this product.

PRODUCT DESCRIPTION:

Hyperi-Lift Tincture is a dark cherry red liquid.
Each 1ml of oral liquid contains 1ml of tincture from dried St John's Wort (***Hypericum perforatum*** L.) flowering tops (1:4).
Extraction solvent: Ethanol 45% v/v.
There are no other ingredients in this product.
This product is available in packs of 50ml and 100ml.

The Traditional Herbal Registration Holder and Manufacturer of this product is:

A Nelson & Co. Ltd,
5 Endeavour Way,
Wimbledon,
London,
SW19 8UH

THR 1175/0123
Leaflet prepared September 2008

Further information on Hypericum:

Hypericum is a herbaceous perennial plant, commonly known as St John's Wort. It has a long standing tradition of use as a herbal remedy, dating back to the middle ages, and use by herbal practitioners is documented from the late 19th century onwards.

Hypericum grows throughout Britain and Europe, and can be easily recognised by its bright and cheery five-petalled yellow flowers.

What is 'Low Mood'?

Everybody occasionally has a 'bad day' and can have feelings of melancholy or mild anxiety. Hypericum has been used to traditionally lift this low mood. However, if symptoms persist or worsen, then advice should be sought from your doctor, pharmacist or healthcare practitioner.

POSSIBLE SIDE EFFECTS:

Like all medicines, Hyperi-Lift Tincture may cause side effects although not everybody gets them.

Side effects from Hypericum are uncommon (affecting fewer than 1 in 10 people), but can include:

- digestive (stomach) upsets, nausea (sickness), loss of appetite, diarrhoea, constipation. These side effects are often only temporary
- fatigue (tiredness)
- allergic skin reactions, hives or itching

If you notice a rash or skin reaction after using this product, stop taking it and consult your doctor or pharmacist.

Rarer side effects to Hypericum can include:
Headaches, nerve pain (neuropathy), anxiety, dizziness and mania.

Sunburn-like reactions in skin exposed to strong ultra-violet (UV) irradiation (eg from sunbeds or solariums) have been reported, particularly in fair-skinned individuals.

If your symptoms worsen, if they do not get better after 6 weeks, or side effects not mentioned in this leaflet occur, contact your doctor or pharmacist for further advice.

STORING THIS PRODUCT:

Keep all medicines out of the reach and sight of children.

Once opened, store in a cool dry place.

Do not store above 25°C.

Do not use after the expiry date shown on the carton and bottle.

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.

WHAT THIS PRODUCT IS AND WHAT IT IS USED FOR:

Hyperi-Lift Tincture is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety. This usage is based on traditional use only.

This product contains ***Hypericum perforatum*** tincture, which is the active ingredient. Each 1ml of oral liquid contains 1ml of tincture from dried St John's Wort (***Hypericum perforatum*** L.) flowering tops (1:4).

Extraction solvent: Ethanol 45% v/v.

BEFORE TAKING THIS PRODUCT:

Do not take if sensitive to any of the ingredients or to plants from the Hypericum (St John's Wort) family (Clusiaceae or Guttiferae).

Do not take this product if:

- you are under 18 years of age
- you are pregnant or breast feeding
- your skin is very sensitive to light (photosensitive)
- you are having light treatment (phototherapy) for any condition
- you are suffering from depression (see below)

Symptoms of depression

Symptoms of depression can include feelings of helplessness and hopelessness, loss of interest in daily activities, appetite or weight changes, sleep changes, loss of energy and difficulty concentrating. If your doctor has told you that you are suffering from depression, do not take this product. If you think you may be suffering from depression, talk to your doctor.

When you are taking this product:

- avoid excessive sunbathing or use of sunbeds
- stop taking it at least 10 days before undergoing any surgery or operations
- you should avoid alcohol

Driving and operating machinery

In rare cases, Hypericum can make people feel dizzy or sleepy.
If this happens, do not drive or use machinery.

This product contains 45% v/v ethanol (alcohol). i.e up to 800mg per dose; equivalent to 20ml of beer or 8ml of wine per dose.
Harmful for people suffering from alcoholism.

TAKING THIS PRODUCT WITH OTHER MEDICINES:

Hypericum can affect how other medicines work. If you are taking another medicine prescribed by your doctor, or a medicine that you have bought for yourself without a prescription, talk to your doctor before taking this product.

DO NOT TAKE THIS PRODUCT IF YOU ARE TAKING 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	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	Cylosporin, tacrolimus
All medicines for HIV infections	Amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, 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 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

Hypericum may also affect the following medicines. Do not take this product if you are taking the following medicines, unless your doctor or pharmacist has told you that you can:

- fentanyl, propofol, sevoflurane, midazolam (anaesthetics/ pre-operative medicines)
- tramadol (an analgesic)
- erythromycin, clarithromycin, and telithromycin (antibiotics)
- itraconazole and voriconazole (antifungals)
- artemether and lumefantrine (antimalarials)
- rasagiline (an anti-Parkinson's medicine)
- aripiprazole (an antipsychotic medicine)
- buspirone (an anxiolytic)
- aprepitant (a post-operative medicine)
- butobarbital and phenobarbitol (barbiturates)
- methyl phenidate (a central nervous system (cns) stimulant)
- exemestane (a hormone antagonist)
- lansoprazole and omeprazole (proton pump inhibitors)
- theophylline (a bronchodilator)

This product contains alcohol and should not be used together with medicines known to interact with alcohol, for example metronidazole.

HOW TO TAKE THIS PRODUCT:

Check that the bottle seal is intact before first use.
This pack contains a glass dropper inside the bottle. You can use this dropper to measure out medicine into a glass of water.

Adults and the elderly:

Take 2.5ml in a glass of water twice daily.

Not suitable for children or adolescents under the age of 18 years.

Do not exceed stated dose.

If you take too much of this product (overdose)

Overdose of this product may result in alcohol intoxication and should be treated accordingly. See section "Before taking this product".

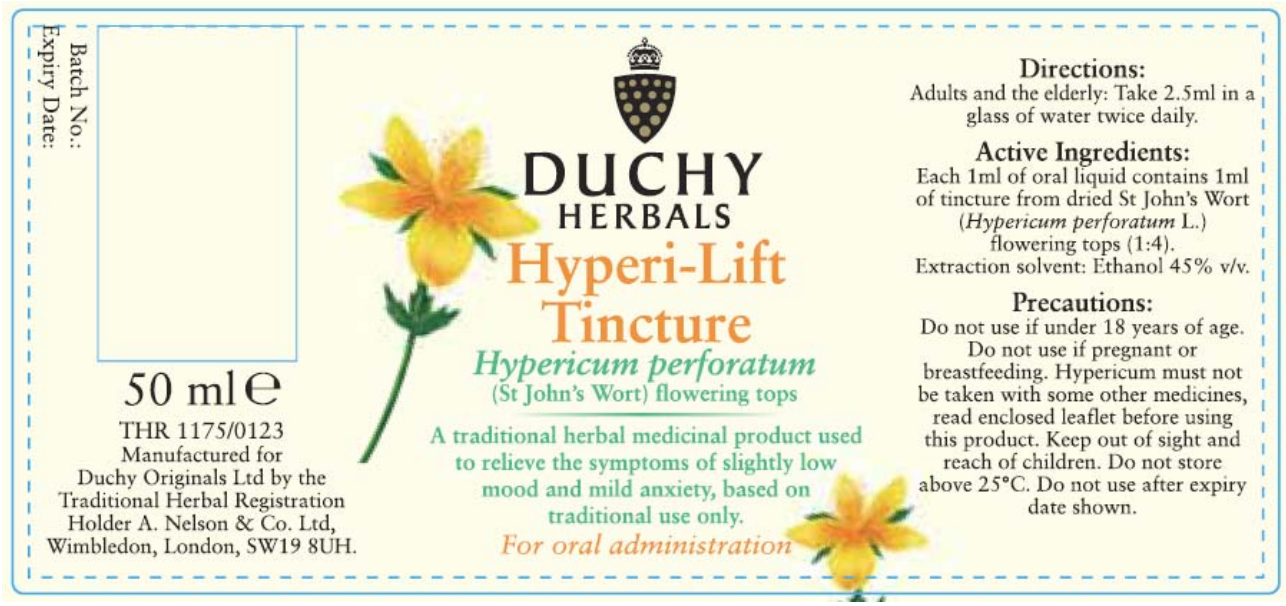
Speak to your doctor or pharmacist and take this leaflet with you.

If you forget to take this product

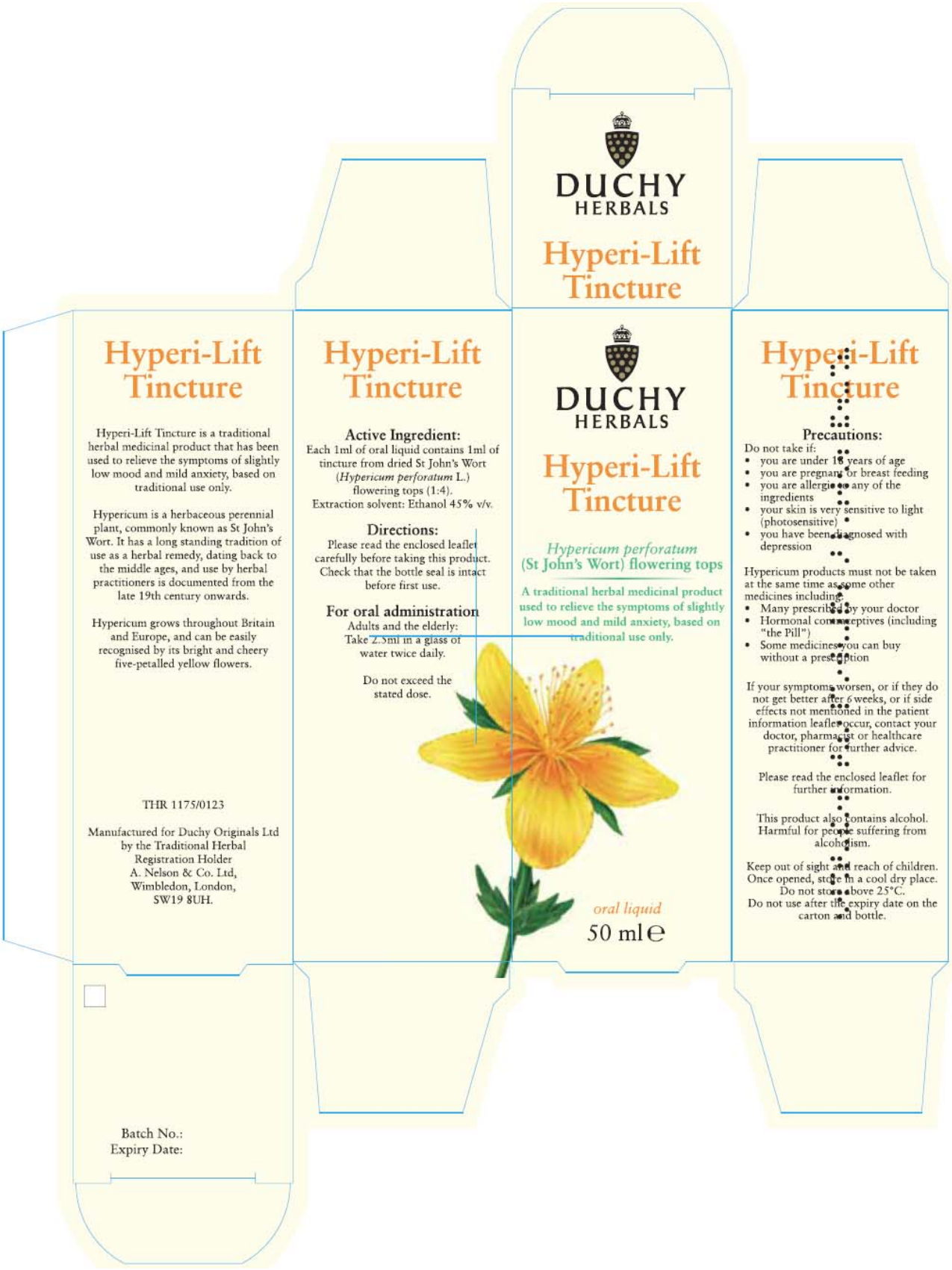
Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

LABELLING

Label:



Carton:


DUCHY HERBALS
Hyperi-Lift Tincture
Hyperi-Lift Tincture
Hyperi-Lift Tincture is a traditional herbal medicinal product that has been used to relieve the symptoms of slightly low mood and mild anxiety, based on traditional use only.
Hypericum is a herbaceous perennial plant, commonly known as St John's Wort. It has a long standing tradition of use as a herbal remedy, dating back to the middle ages, and use by herbal practitioners is documented from the late 19th century onwards.
Hypericum grows throughout Britain and Europe, and can be easily recognised by its bright and cheery five-petalled yellow flowers.
THR 1175/0123
Manufactured for Duchy Originals Ltd by the Traditional Herbal Registration Holder A. Nelson & Co. Ltd, Wimbledon, London, SW19 8UH.
Batch No.:
Expiry Date:
Hyperi-Lift Tincture
Active Ingredient:
Each 1ml of oral liquid contains 1ml of tincture from dried St John's Wort (Hypericum perforatum L.) flowering tops (1:4).
Extraction solvent: Ethanol 45% v/v.
Directions:
Please read the enclosed leaflet carefully before taking this product. Check that the bottle seal is intact before first use.
For oral administration
Adults and the elderly:
Take 2.5ml in a glass of water twice daily.
Do not exceed the stated dose.
DUCHY HERBALS
Hyperi-Lift Tincture
Hypericum perforatum
(St John's Wort) flowering tops
A traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety, based on traditional use only.
oral liquid
50 ml e
Hyperi-Lift Tincture
Precautions:
Do not take if:
you are under 18 years of age
you are pregnant or breast feeding
you are allergic to any of the ingredients
your skin is very sensitive to light (photosensitive)
you have been diagnosed with depression
Hypericum products must not be taken at the same time as some other medicines including:
Many prescribed by your doctor
Hormonal contraceptives (including "the Pill")
Some medicines you can buy without a prescription
If your symptoms worsen, or if they do not get better after 6 weeks, or if side effects not mentioned in the patient information leaflet occur, contact your doctor, pharmacist or healthcare practitioner for further advice.
Please read the enclosed leaflet for further information.
This product also contains alcohol. Harmful for people suffering from alcoholism.
Keep out of sight and reach of children.
Once opened, store in a cool dry place.
Do not store above 25°C.
Do not use after the expiry date on the carton and bottle.