

SUMMARY OF PRODUCT CHARACTERISTICS

DUCHY HERBALS HYPERI-LIFT TINCTURE

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-administered drug | Interaction | Recommendations concerning co-administration |
|---|--|--|
| <i>Anaesthetics / Pre-operative Medicines</i> | | |
| Fentanyl, Propofol, Sevoflurane, Midazolam | Reduced blood levels with risk of therapeutic failure. | Based on the elimination half-lives of hypericin and yperforin this product should be discontinued at least 10 days prior to elective surgery. |
| <i>Analgesics</i> | | |
| Tramadol | Reduced blood levels with risk of therapeutic failure | Do not take with this product. |
| <i>Antianginals</i> | | |
| Ivabradine | Reduced blood levels with risk of therapeutic failure | Do not take with this product. |
| <i>Anti-arrhythmics</i> | | |
| Amiodarone | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Antibacterials</i> | | |
| Erythromycin, Clarithromycin, Telithromycin | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Anticoagulants</i> | | |
| Warfarin, Acenocoumarol | Reduced anticoagulant effect and need for increased dose | Do not take with this product. |
| <i>Antidepressants</i> | | |

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| 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. |
| <i>Antiepileptics</i> | | |
| 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. |
| <i>Antifungals</i> | | |
| Itraconazole, Voriconazole | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Antimalarials</i> | | |
| Artemether, Lumefantrine | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Antiparkinsons</i> | | |
| Rasagiline | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Antipsychotics</i> | | |
| Aripiprazole | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Antivirals</i> | | |
| 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 | Reduced blood levels with possible loss of HIV | Do not take with this product. |

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| inhibitors: Efavirenz, Nevirapine, Delavirdine | suppression | |
| <i>Anxiolytics</i> | | |
| 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. |
| <i>Barbiturates</i> | | |
| Butobarbital, Phenobarbital | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Calcium Agonists</i> | | |
| Felodipine | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Calcium Channel Blockers</i> | | |
| Amlodipine, Nifedipine, Verapamil | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Cardiac Glycosides</i> | | |
| Digoxin | Reduced blood levels and loss of control of heart rhythm or heart failure. | Do not take with this product |
| <i>CNS Stimulants</i> | | |
| Methylphenidate | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Cytotoxics</i> | | |
| Irinotecan, Dasatinib, Erlotinib, Imatinib, Sorafenib, Sunitinib, Etoposide, Mitotane | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Hormonal Contraceptives</i> | | |
| 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. |

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| <i>Hormone Replacement Therapy</i> | | |
| Oral Transdermal patches, gels Vaginal rings | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Hormone Antagonists</i> | | |
| Exemestane | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Diuretics</i> | | |
| Eplerenone | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>5HT Agonists</i> | | |
| Almotriptan, Eletriptan, Frovatriptan, Naratriptan, Rizatriptan, Sumatriptan and Zolmitriptan | Increased serotonergic effects with increased incidence of adverse reactions. | Do not take with this product. |
| <i>Immunosuppressants</i> | | |
| Cyclosporin, Tacrolimus | Reduced blood levels with risk of transplant rejection. | Do not take with this product. |
| <i>Lipid Regulating Medicines</i> | | |
| Simvastatin, Atorvastatin | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Lithium</i> | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Oral Hypoglycaemics</i> | | |
| Gliclazide | Reduced blood levels | Do not take with this product. |
| <i>Proton Pump Inhibitors</i> | | |
| Lansoprazole, Omeprazole | Reduced blood levels with risk of therapeutic failure. | Do not take with this product. |
| <i>Theophylline</i> | Reduced blood levels and loss of control of asthma or chronic airflow limitation. | Do not take with this product. |
| <i>Thyroid Hormones</i> | | |
| 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

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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