

8001

Patient Information Leaflet

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

What is in this leaflet

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

This product is a traditional herbal medicinal product containing St John's Wort.

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

2. Before you take this product

Do not take this product if:

- Your skin is **exceptionally sensitive to sunlight** (*photosensitive*)
- You are having **light treatment** (*phototherapy*) for any condition
- You are suffering from **depression** (see below)
- You are **pregnant** or **breastfeeding**
- You are allergic to any of the ingredients (see section 6)
- You are under the age of 18 years

Suffering from depression?

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

While you are taking this product:

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

Driving and operating machinery

St John's Wort may make you feel dizzy or sleepy. If affected do not drive or use machines.

Taking this product with other medicines

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

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

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

All 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, 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.

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

- **fentanyl, propofol, sevoflurane, and midazolam** (anaesthetics/pre-operative medicines)
- **tramadol** (an analgesic)
- **erythromycin, clarithromycin and telithromycin** (antibiotics)

- **itraconazole and voriconazole** (antifungals)
- **artemether and lumefantrine** (antimalarials)
- **rasagiline** (an anti-Parkinson's medicine)
- **aripiprazole** (an antipsychotic medicine)
- **buspirone** (an anxiolytic)
- **aprepitant** (used to treat post-operative vomiting)
- **butobarbital and phenobarbital** (barbiturates)
- **methyl phenidate** (a central nervous system or CNS stimulant)
- **exemestane** (a hormone antagonist)
- **eplerenone** (a diuretic)
- **lansoprazole and omeprazole** (proton pump inhibitors)
- **theophylline** (a bronchodilator)
- **gliclazide** (an antidiabetic medicine)

If you are taking any other medicines whether prescribed for you or available without a prescription, you should consult a doctor or pharmacist before taking this product.

3. How to take this product

For oral use only

Adults and the elderly:

Take 1 tablet daily. Swallow the tablets whole with some water or other liquid. Do not chew the tablets.

Do not exceed the stated dose.

If you take too much of this product (overdose)

If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product

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

If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

After taking this product

If your symptoms worsen, if they do not improve after 6 weeks, if side effects become serious or if you experience side effects not mentioned in this leaflet, you must consult your doctor, pharmacist or qualified healthcare practitioner.

4. Possible side effects

Like all medicines, this product can have side effects.

The following side effects have been reported:

- gastrointestinal disorders such as indigestion, loss of appetite, nausea, diarrhoea 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.

Also sunburn-like reactions on skin exposed to strong sunlight or strong ultra-violet (UV) irradiation e.g. solarium have been reported, particularly in fair skinned individuals. Other side effects that have been reported include headaches, nerve pain or tingling, anxiety, dizziness and mania.

You must speak to a doctor or qualified healthcare practitioner if your symptoms worsen, if they do not improve after six weeks, or if any of the side effects become serious or if you notice any side effects not mentioned in the leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or qualified healthcare practitioner. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this product

Keep the tablets out of the sight and reach of children.

Keep your tablet in the packaging until it is time to take them.

Do not store above 25°C.

Do not use Lamberts® St. John's Wort tablets after the expiry date which is stated on the box and blister pack. The expiry date refers to the last day of that month. Return any out-of-date tablets to your pharmacist.

6. Further information

Active Ingredient

Each film-coated tablet contains 370mg of extract (as dry extract) from St. John's Wort aerial parts (*Hypericum perforatum* L.) (5-7:1) (equivalent to 1850mg-2590mg of St. John's Wort). Extraction Solvent: Ethanol 60% v/v.

This product also contains the following ingredients:

Excipients in the extract - Maltodextrin, Silica Colloidal Anhydrous.

Tablet Core - Maltodextrin, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Magnesium Stearate, Silica Colloidal Anhydrous.

Tablet Coating - Hypromellose, Glycerol.

The tablets are clear coated, brown speckled and oval shaped.

Each pack contains 30, 60 or 90 coated tablets.

Not all pack sizes may be marketed.

Traditional herbal registration holder for this product: Lamberts Healthcare Ltd., 1 Lamberts Road, Tunbridge Wells, Kent TN2 3EH.

Manufacturer of this product: Thompson & Capper Ltd, Hardwick Road, Astmoor, Runcorn, Cheshire WA7 1PH.

Traditional Herbal Registration Number: THR34425/0001

If you would like further information about this product or would like a large print, Braille or audio version of this leaflet please contact: Lamberts Healthcare Ltd., 1 Lamberts Road, Tunbridge Wells, Kent TN2 3EH. Tel: 01892 554312.

This leaflet was updated in July 2016.

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Certification Mark