

## **Package leaflet: Information for the user**

### **Holland & Barrett Hypericum Hard Capsules St John's Wort Dry Extract**

#### **Important Notes**

**Please read all of this leaflet carefully before you use this traditional herbal medicine because it contains important information for you**

- Always take this traditional herbal medicine exactly as described in this leaflet or as your doctor or pharmacist has told you
- Keep this leaflet. You may need to read it again
- Ask a healthcare professional e.g. a doctor or pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you feel worse or if you do not feel better after 4 weeks of taking this traditional herbal medicine.

#### **What is in this leaflet**

1. What this traditional herbal medicine is and what it is used for
2. What you need to know before you take this traditional herbal medicine
3. How to take this traditional herbal medicine
4. Possible side effects
5. How to store this traditional herbal medicine
6. Contents of the pack and other information

#### **1. What this traditional herbal medicine is and what it is used for**

This traditional herbal medicine contains St. John's Wort (*Hypericum perforatum* L.) Dry Extract. It is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood in adults, exclusively based upon long-standing use.

#### **2. What you need to know before you take this traditional herbal medicine**

Do not take this traditional herbal medicine if:

- You are allergic to St. John's Wort or any of the ingredients in this traditional herbal medicinal product (listed in Section 6 of this leaflet).
- You are taking any of the medicines listed in the table below
- You are taking any medicines for depression or migraine
- You are taking medicines to suppress your immune system after transplant surgery
- You are pregnant or breastfeeding
- You have skin that is sensitive to sunlight or are having light treatment
- You are about to undergo surgery

#### **Warnings and Precautions**

Talk to your doctor before taking this traditional herbal medicine if:

- You are taking any prescribed medicines
- You think you may be suffering from depression
- You have a history of bipolar disorder/manic depression or any other psychiatric illness

If you think you may be suffering from depression, tell your doctor before taking this product. Symptoms of depression include low mood, feelings of helplessness and hopelessness, loss of interest in daily activities, changes in appetite or weight, changes in sleeping patterns, loss of energy, difficulty in concentrating and thoughts of self-harm or suicide. Patients should consult their doctor urgently if they feel agitated, restless or have thoughts of harming themselves or of suicide.

#### **Changing between products**

Not all St. John's Wort products are prepared in the same way and this may affect the ingredients of the product. It may have an impact on how it works, how it affects other medicines that you take or what side effects may occur. This should be taken into account when changing between different St. John's Wort products or brands. If you are considering changing from one product or brand to another, please consult your doctor or pharmacist for advice before doing so.

### **Surgery**

Remember to tell your doctor if you are taking St. John's Wort if you are having an operation. You should stop taking St. John's Wort 10 days before surgery because St. John's Wort can interact with many drugs used during surgery.

### **Skin reactions**

Your skin may become more sensitive to sunlight while taking St. John's Wort, particularly if you are fair-skinned. You should avoid excessive sunbathing and the use of sunbeds/solariums while taking St. John's Wort.

### **Women of childbearing potential**

St. John's Wort can affect the levels of hormonal contraceptives and result in unintended pregnancy and bleeding between periods. Women using any form of hormonal contraception (e.g. the birth control 'pill', hormonal implants, injections, patches or intrauterine devices or 'coils' that contain hormones) should also use another form of non-hormonal birth control. If you are unsure if your contraception contains hormones, talk to your doctor or pharmacist.

### **Pregnancy, breastfeeding and fertility**

Do not take this traditional herbal medicine if you are pregnant, breastfeeding, think you may be pregnant or are planning to have a baby, as it is not known if it is safe to do so.

### **Children and adolescents**

St. John's Wort should not be used in children and adolescents under 18 years of age as it is not known if it is safe to do so. Children and adolescents who have feelings of low mood or depression should see a doctor for assessment and advice.

### **Other medicines and St. John's Wort**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

St. John's Wort can affect the way some medicines work and reduce their effect or worsen side effects. Medicines that can be affected by St. John's Wort include prescription medicines and those that you may have bought yourself without a prescription. Patients who are taking any medicines should tell their doctor or pharmacist before taking St. John's Wort. If you are unsure how St. John's Wort may interact with any medicine you are taking, please talk to a doctor or pharmacist.

### **Do not take St. John's Wort if you are using any of the medicines listed in the following table:**

<p><b>Anaesthetics/pre-operative medicines</b> - Fentanyl, propofol, sevoflurane, benzodiazepines e.g. midazolam</p> <p><b>Some medicines for heart disease</b> - Digoxin, ivabradine, amiodarone, eplerenone</p> <p><b>Antibiotics</b> - Erythromycin, clarithromycin, telithromycin</p> <p><b>All medicines for preventing or treating clots</b> - Warfarin, dabigatran, acenocoumarol</p> <p><b>Antidepressants (all medicines for depression/anxiety)</b> - Amitriptyline, Clomipramine, moclobemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, bupropion</p> <p><b>Antiplatelets</b> - Clopidogrel</p> <p><b>All medicines for epilepsy</b> - Carbamazepine, phenobarbital, phenytoin, primidone, sodium valproate</p>
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**Antifungals** - Itraconazole, voriconazole  
**Antimalarials** - Artemether, lumefantrine  
**Anti-Parkinson's** - Rasagiline Antipsychotics - Aripiprazole  
**All medicines for HIV infections** - Amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir, efavirenz, nevirapine, delavirdine  
**Medicines for anxiety** - Buspirone, benzodiazepines e.g. midazolam  
**Treatment for post-operative vomiting** - Aprepitant  
**Bronchodilator (a medicine for breathing difficulties)** - Theophylline  
**Calcium channel blockers (some medicines for high blood pressure)** - Amlodipine, nifedipine, verapamil, felodipine  
**A medicine used for ADHD** - Methyl phenidate  
**Some medicines for cancer** - Irinotecan, dasatinib, erlotinib, imatinib, sorafenib, sunitinib, etoposide, mitotane, docetaxel, exemestane  
**Hormonal contraceptives** - Oral contraceptives ('the pill'), emergency contraception, hormonal implants and injections, patches, intra-uterine devices with hormones ('the coil')  
**Hormone Replacement Therapy (HRT)** - Tablets, capsules, patches, gels, vaginal rings  
**Some medicines for migraine** - Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan  
**Immunosuppressant medicines** - Cyclosporin, tacrolimus  
**Some medicines for high cholesterol** - Simvastatin, atorvastatin  
**A medicine for regulating mood** - Lithium  
**An antidiabetic medicine** - Gliclazide  
**Opiates/Pain medicines** - Tramadol, methadone, oxycodone  
**Proton pump inhibitors (antacids)** - Lansoprazole, omeprazole  
**Thyroid hormone** - Thyroxine

### **Driving and operating machinery**

In rare cases St. John's Wort may make you feel dizzy or sleepy. If you are affected, do not drive or operate machinery.

### **3. How to take this traditional herbal medicine**

Always take this traditional herbal medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For oral short-term use only.

**Adults and older people:** Take 1 capsule daily. Swallow the whole capsule with water.

**Do not exceed the stated dose.**

This product is not suitable for children and adolescents under 18 years of age. Children and adolescents who have feelings of low mood or depression should see a doctor for assessment and advice.

**Duration of use:** The effects of this traditional herbal medicine may not be felt immediately. If your symptoms worsen or do not improve after 4 weeks, you should consult your doctor. If you have thoughts of harming yourself or of suicide, consult your doctor urgently.

**If you take too much of the product (overdose):** You should consult your doctor and take this leaflet and bottle with you. Depending of the amount taken, there may be a need for additional protection from sunlight and other UV light sources for 1-2 weeks.

**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.

If you have further questions on the use of this medicine, ask your doctor or pharmacist.

#### 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, poor appetite, feeling sick, diarrhoea and constipation
- Tiredness 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) light e.g. sunbeds. This is more likely to occur in fair-skinned people

Other side effects that have been reported include headaches, nerve pain or tingling, anxiety, dizziness, over-activity, racing thoughts and decreased need for sleep. 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.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can report side effects directly via HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. How to store this traditional herbal medicine

- Keep this traditional herbal medicine out of sight and reach of children
- Keep this traditional herbal medicine in the bottle until it is time to take it
- Do not use this traditional herbal medicine after the expiry date which is stated on the carton and bottle label after 'EXP'. The expiry date refers to the last day of that month
- Do not store above 25°C
- Keep the bottle tightly closed in order to protect from light and moisture

#### 6. Contents of the pack and other information

##### What this traditional herbal medicine contains

Each hard capsule contains 284mg of extract (as dry extract) from St. John's Wort aerial parts (*Hypericum perforatum* L.) (DER 5-7:1), corresponding to: 0.3mg-0.9mg of total hypericins; not less than 18mg of flavonoids, expressed as rutin; maximum 1mg of hyperforin.

Extraction solvent: Ethanol 60% v/v.

##### What this traditional herbal medicine looks like and contents of the pack

Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.

**Inactive ingredients in the extract:** Maltodextrin, Silica colloidal anhydrous.

**Capsule shell:** Hypromellose.

Each bottle contains 50 or 100 clear, hard, two piece capsules with green/brown fill.

**TR 23157/003/001**

**Traditional Registration Holder**

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Is this leaflet hard to see or read? Contact us on:  
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