

**Nature's Bounty
Hypericum Hard Capsules
St. John's Wort Extract**

Important Notes

Please read 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 a 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. Further 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.) 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 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 and 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 and 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:

Anaesthetics/pre-operative medicines - Fentanyl, propofol, sevoflurane, benzodiazepines e.g. midazolam

Some medicines for heart disease - Digoxin, ivabradine, amiodarone, eplerenone

Antibiotics - Erythromycin, clarithromycin, telithromycin

All medicines for preventing or treating clots - Warfarin, dabigatran, acenocoumarol

Antidepressants (all medicines for depression/anxiety) -

Amitriptyline, clomipramine, moclobemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, bupropion

Antiplatelets - Clopidogrel

All medicines for epilepsy - Carbamazepine, phenobarbital, phenytoin, primidone, sodium valproate

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, Earlsfort Terrace, IRL, Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie, email: medsafety@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.) (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.

This traditional herbal medicine also contains the following inactive ingredients: (excipients): 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.

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Traditional Herbal Registration Holder

Holland & Barrett Limited
Cedar Drive, Dublin Airport Logistics Park
St. Margarets, Co. Dublin
K67 E0C5
Ireland

Manufacturer

Wiewelhove GmbH,
Dörnebrink 19, 49479 Ibbenbüren, Germany

If you would like further information about this product, please contact:

Holland & Barrett Limited
Regulatory Services Department
Cedar Drive, Dublin Airport Logistics Park
St. Margarets, Co. Dublin
K67 E0C5
Ireland

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

Telephone: +353 (1) 517 6229

Email: customerservices@hollandandbarrett.com

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