PATIENT INFORMATION LEAFLET

HOLLAND & BARRETT Max Strength St. John's Wort Capsules St. John's Wort Extract 284mg

Important Notes

- Please read this leaflet carefully before you use this product because it contains important information
- Keep this leaflet; you may need to read it again
- Seek professional advice if you need more information
- Please tell a Doctor or a qualified Healthcare Practitioner if your symptoms worsen or do not improve after 6 weeks of taking this product
- Please tell a Doctor, Pharmacist or a qualified Healthcare Practitioner if you suffer from side effects not listed in this leaflet or if any of the side effects become serious

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I - What this product is and what it is used for

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

2 - Before you take this product

Do not take this product if you are:

- Under 18 years of age
- About to undergo surgery
- Allergic to any of the ingredients (see section 6 of this leaflet)
- Pregnant or breastfeeding
- Having UV light treatment (phototherapy) for any condition
- Exceptionally sensitive to sunlight on your skin (photosensitive)
- Suffering from depression

Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, changes in appetite or weight, changes in sleeping patterns or habits, loss of energy and difficulty in concentrating.

If your Doctor has told you that you are suffering from depression do not use this product.

If you think you may be suffering from depression, tell your Doctor before taking this product.

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 yourself without a prescription.

Do not take St. John's Wort if you are using 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/anxiety -Amitriptyline, clomipramine, moclobemide, citalopram, 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 migraine - Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan

Some medicines for high blood pressure -Amlodipine, nifedipine, verapamil, felodipine

A medicine for regulating mood - Lithium

A thyroid hormone - Thyroxine

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

- Anaesthetics/pre-operative medicines: Fentanyl, propofol, sevoflurane, midazolam
- Analgesics: Tramadol
- Antibiotics: Erythromycin, clarithromycin, telithromycin
- Antifungals: Itraconazole, voriconazole
- Antimalarials: Artemether, lumefantrine
- Anti-Parkinson's: Rasagiline
- Antipsychotics: Aripiprazole
- Anxiolytics: Buspirone

Treatment of post-operative vomiting: Aprepitant

- Barbiturates: Butobarbital, phenobarbital
- CNS Stimulants: Methyl phenidate
- Hormone antagonists: Exemestane
- Diuretics: Eplerenone
- Proton pump inhibitors: Lansoprazole, omeprazole
- Bronchodilator: Theophylline

Antidiabetic medicine: Gliclazide

While you are taking this product:

- Avoid excessive sunbathing or use of sunbeds/solariums
- Stop using it at least 10 days prior to undergoing any surgery

Driving and operating machinery

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

3 - How to take this product

For oral use only.

For adults and elderly: Take I capsule 2 times daily. Swallow the whole capsule with water. Do not exceed the stated dose.

If you take too much of the product (overdose): speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

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.

Duration of use: If symptoms worsen or do not improve after 6 weeks, or if any of the side effects become serious or if any side effects not mentioned in the leaflet occur, speak to a Doctor, Pharmacist or a 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.
- Sunburn-like reactions on skin exposed to strong sunlight or strong ultra-violet (UV) irradiation e.g. solarium, particularly in fair skinned individuals.

Other side effects that have been reported include headaches, nerve pain or tingling, anxiety, dizziness and mania.

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.

5 - How to store this product

- Keep the capsules in the bottle until it is time to take them
- Do not take the capsules after the expiry date (see outer label). The expiry date refers to the last day of the month
- Do not store above 25°C. Store in the original packaging
- Keep the bottle tightly closed
- Keep the capsules out of sight and reach of children

6 - Further information

About this product: This product is a traditional herbal medicinal product containing St. John's Wort extract. Each hard capsule contains 284mg of extract (as dry extract) from St. John's Wort aerial parts (*Hypericum perforatum* L.) (equivalent to 1422mg-1991mg of St. John's Wort). Extraction solvent: Ethanol 60% v/v. This product also contains the following inactive (excipient) ingredients: Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated. Excipients in the extract: Maltodextrin, Silica colloidal anhydrous. Capsule shell: Hypromellose. Each bottle contains 50 or 100 clear, hard, two piece capsules with green/Drown powder.

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Traditional Herbal Registration Holder

NBTY Europe Limited Samuel Ryder House, Barling Way, Nuneaton, Warwickshire, CV10 7RH, United Kingdom

Manufacturer

NBTY Europe Limited Vitality House, Sixth Avenue, Centrum 100, Burton-on-Trent, Staffordshire, DE14 2WP, United Kingdom

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

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Is this leaflet hard to see or read? Contact us on: Telephone: +44 (0) 2476 215 400 Fax: +44 (0) 2476 215 452 Email: customerservices@NBTYeurope.com

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

Alternatively you can get a paper Yellow Card form from your GP's surgery or pharmacy,

or call freephone 0808 100 3352 This leaflet was prepared on: 23/08/2011

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