

LEAFLET SPEC**HB35292 MENOPAUSE MOOD RELIEF LEAFLET**

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PATIENT INFORMATION LEAFLET

HOLLAND & BARRETT

MENOPAUSE MOOD RELIEF TABLETS

St John's Wort extract 300mg and Black Cohosh root extract 6.4mg

Important notes

- ◆ Please read this leaflet carefully before you start taking these tablets; It contains some important information about Holland & Barrett Menopause Mood Relief tablets.
- ◆ 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
- 6 Further information

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

This product is a traditional herbal medicinal product used for the relief of symptoms of the menopause including hot flushes, night sweats, slightly low mood and mild anxiety, based on traditional use only. As there is evidence that Black cohosh may have hormone-like actions, this product should only be used by women of childbearing potential if contraception is used.

2 - Before you take this product

Do not take this product if:

- ◆ You are under 18 years of age
- ◆ You are pregnant or breastfeeding
- ◆ You are of childbearing potential and do not use adequate contraception
- ◆ You are allergic to any of the ingredients (listed in section 6)
- ◆ 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 have ever had or are suffering from liver or kidney disease (eg. hepatitis, jaundice or cirrhosis)
- ◆ You have or have ever had treatment for breast cancer or any other hormone-dependent tumour

Tell your doctor before using this product if you:

- ◆ Think you may be suffering from depression (see below)
- ◆ Have a persistent history of menstrual disorders
- ◆ Have been told by your doctor that you have an intolerance to some sugars. This product contains lactose monohydrate, sucrose and glucose - see section 6
- ◆ Are currently taking a medicine containing oestrogen

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

Suffering from depression?

Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, appetite or weight changes, sleep changes, 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.

Driving and using machines

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

Taking 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 yourself without a prescription. Therefore it is important that you do not take this product if you are using any of the medicines listed in the table opposite.

Do not take this product if you are taking any of the following medicines:

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**Taking other medicines (continued)**

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)

3 - How to take this product**Adults and the elderly:**

Take 1 tablet daily. Swallow the tablets whole with some water or other liquid. Do not chew the tablets. The tablets should be taken at the same time of day if possible (morning or evening).

Do not take more than the label / leaflet tells you to.

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.

You must speak to a qualified healthcare practitioner if your symptoms worsen, if they do not improve after six weeks, or if you notice any re-appearance or changes in menstrual bleeding.

4 - Possible side-effects

Like all medicines this product can have side-effects, although these are uncommon. These are listed below.

- ◆ Gastrointestinal disorders e.g indigestion, loss of appetite, nausea, diarrhoea, constipation
- ◆ Fatigue and restlessness
- ◆ Facial swelling, swelling of the feet, ankles or lower leg
- ◆ Weight gain
- ◆ Allergic skin reactions such as nettle rash, itching of the skin, hives

Stop taking this product immediately if you experience an allergic reaction. If these persist for more than a few days, or become troublesome, stop taking this product. These side-effects are often only temporary.

Other side-effects

These include headaches, nerve pain or tingling, anxiety, dizziness, mania. Also, sun-burn like reactions in skin exposed to strong sunlight or strong ultra-violet (UV) irradiation, e.g solarium, have been reported, particularly in fair-skinned individuals, when taking St John's Wort. Black Cohosh may rarely cause liver problems. If you become unwell (yellowing eyes/skin, nausea, vomiting, dark urine, abdominal pain, unusual tiredness) stop taking immediately and seek medical advice.

If you notice any other side-effect not mentioned above, or if any side-effect becomes serious, tell your doctor or pharmacist.

Reporting of side-effects

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not mentioned in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side-effects you can help provide more information on the safety of this medicine.

5 - How to store this product

- ◆ Do not use your tablets after the expiry date
- ◆ Return any out-of-date tablets to your pharmacist who will dispose of them for you. The expiry date is printed on the box and the blister pack
- ◆ Do not store above 25°C
- ◆ Keep the tablets out of the reach and sight of children
- ◆ Keep your tablets in the blister pack until it is time to take them

6 - Further information

Each coated tablet of this product contains 300mg of extract (as dry extract) from St John's Wort aerial parts (*Hypericum perforatum* L.) (3.5-6:1) (equivalent to 1050-1800mg of St John's wort). Extraction solvent: Ethanol 60% m/m; and 6.4mg of extract (as dry extract) from Black Cohosh rhizome and root (*Cimicifuga racemosa* (L.) Nutt.) (4.5-8.5:1) (equivalent to 28.80-54.40mg of Black Cohosh). Extraction solvent: Ethanol 60% v/v.

This product also contains the following ingredients:

Extract: Maltodextrin, silica colloidal anhydrous, lactose monohydrate cellulose powdered.
Tablet core: Silica, colloidal anhydrous, cellulose microcrystalline, croscarmellose sodium, sodium starch glycolate (type A), magnesium stearate.
Coating: Hypromellose, sucrose, talc, calcium carbonate E170, tragacanth, acacia, liquid glucose, titanium dioxide E171, iron oxide hydrate E172 (= yellow iron oxide), vanillin, beeswax white, carnauba wax, shellac.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. Each coated tablet contains 234mg of sucrose, 19mg of lactose monohydrate and 6mg glucose.

Each pack contains 30 coated tablets.

Registration holder for this product:

Schwabe Pharma (UK) Ltd,
Alexander House, Mere Park, Dedmere Road,
Marlow, Bucks, SL7 1FX

Manufactured for

Holland & Barrett International Limited by:
Viewelthove GmbH,
Dörnebrink 19, 49479 Ibbenbüren, Germany

Traditional Herbal Registration number: THR 23056/0013

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

Holland & Barrett International Limited,
Regulatory Services Department,
Samuel Ryder House, Barling Way,
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Is this leaflet hard to see or read? Contact us on:

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