

Patient Information Leaflet

# MenoMood<sup>®</sup> Menopause Mood Relief Tablets

St John's wort extract 300 mg and Black cohosh root extract 6.4 mg

**Please read this leaflet carefully before you start taking these tablets.**

It contains some important information about MenoMood 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

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

**MenoMood Menopause Mood Relief** 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. This usage is 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 breast-feeding**
- 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)
- have or have ever had **liver or kidney problems** (e.g. hepatitis, jaundice or cirrhosis)
- 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**

In rare cases 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 MenoMood 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

<b>All hormonal contraceptives</b>	The birth control 'Pill', emergency contraception (also known as the morning after pill), hormonal implants, creams, patches, intra-uterine devices with hormones.
<b>All medicines for depression/anxiety</b>	Amitriptyline, clomipramine, moclobemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine.
<b>All hormonal replacement therapy (HRT) treatments</b>	HRT tablets, patches, gels, vaginal rings
<b>All medicines for thinning the blood (anticoagulants)</b>	Warfarin, acenocoumarol
<b>All medicines for epilepsy</b>	Carbamazepine, phenobarbitone, phenytoin, primidone, sodium valproate
<b>All immunosuppressant medicines</b>	Ciclosporin, tacrolimus
<b>All medicines for HIV infections</b>	Amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir, efavirenz, nevirapine, delavirdine
<b>Some medicines for cholesterol</b>	Simvastatin, atorvastatin
<b>Some medicines for cancer</b>	Irinotecan, dasatinib, erlotinib, imatinib, sorafenib, sunitinib, etoposide, mitotane
<b>Some medicines for heart disease</b>	Digoxin, ivabradine, amiodarone
<b>Some medicines for migraines</b>	Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
<b>Some medicines for high blood pressure</b>	Amlodipine, nifedipine, felodipine, verapamil
<b>A medicine for regulating mood</b>	Lithium
<b>A thyroid hormone</b>	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 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.**

**4: Possible side-effects**

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

<ul style="list-style-type: none"> <li>• <b>gastrointestinal disorders</b> e.g indigestion, loss of appetite, nausea, diarrhoea, constipation</li> <li>• <b>fatigue and restlessness</b></li> <li>• <b>facial swelling, swelling of the feet, ankles or lower leg</b></li> <li>• <b>weight gain</b></li> </ul>	<p>If these persist for more than a few days, or become troublesome, stop taking this product.</p> <p>These side-effects are often only temporary.</p>
<ul style="list-style-type: none"> <li>• <b>allergic skin reactions</b> such as nettle rash, itching of the skin, hives</li> </ul>	<p>Stop taking this product immediately if you experience an allergic reaction.</p>

**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.

**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](http://www.mhra.gov.uk/yellowcard). By reporting side-effects you can help provide more information on the safety of this medicine.

**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.**

**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.

**Store the tablets in a cool dry place.** Do not store the tablets in a place where the temperature goes 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 300 mg of extract (as dry extract) from St John's wort aerial parts (*Hypericum perforatum* L.) (3.5-6:1) (equivalent to 1050-1800 mg of St John's wort). Extraction solvent ethanol 60% m/m; and 6.4 mg of extract (as dry extract) from Black Cohosh rhizome and root (*Cimicifuga racemosa* (L.) Nutt.) (4.5-8.5:1) (equivalent to 28.80-54.40 mg 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 234 mg of sucrose, 19 mg of lactose monohydrate and 6 mg glucose.

Each pack contains 28, 30, 56 or 60 coated tablets.

Not all pack sizes may be marketed.

**Registration holder for this product**

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

**Manufacturer of this product**

Wiewelhoe GmbH, Gildestrasse 39, 49477 Ibbenbüren, Germany

Traditional Herbal Registration number: THR 23056/0013

If you would like further information about this product, please contact: Schwabe Pharma (UK) Ltd, Alexander House, Mere Park, Dedmere Road, Marlow, Bucks, SL7 1FX

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This leaflet was revised in 02/2015.

For a large print, Braille or audio version of this leaflet, call 01628 401980



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