

Patient Information Leaflet

KarmaMood[®] Maximum Strength St John's Wort Tablets St John's Wort extract 425mg

Please read this leaflet carefully before you start taking these tablets. It contains some important information about KarmaMood Maximum Strength St John's Wort.

Keep this leaflet with the tablets.

You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

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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. Each coated tablet of this product contains 425mg of extract (as dry extract) from St John's Wort aerial parts (*Hypericum perforatum* L.) (3.5-6:1) (equivalent to 1490-2550mg of St John's Wort). Extraction solvent: Ethanol 60% v/v.

KarmaMood Maximum Strength St John's Wort is a traditional herbal medicinal product used for the relief of slightly low mood and mild anxiety. This usage is based on traditional use only.

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 **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)

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.**

Tell your doctor before using this product if you have an intolerance to some sugars (see section 6).

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**

Driving and operating machinery

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

Taking this product with 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 St John's Wort 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 |

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. **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.

You must speak to a qualified healthcare practitioner if your symptoms worsen, if they do not improve after six weeks, if any side-effect becomes serious or if side-effects not mentioned in this leaflet occur.

4: Possible side-effects

Like all medicines, this product can have side-effects, although the frequency is not known. These side-effects are listed below.

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> ● digestive upsets such as indigestion, loss of appetite, nausea, diarrhoea, constipation ● fatigue and restlessness ● allergic skin reactions such as rash, hives or itching | Stop taking this product immediately if you experience an allergic reaction. |
| Other side-effects | |
| These include headaches, nerve pain or tingling (neuropathy), anxiety, dizziness and mania. Also sunburn-like reactions in skin exposed to strong ultra-violet (UV) irradiation (e.g. sun, solarium) have been reported, particularly in fair-skinned individuals. | |
| If you notice any other side-effect not mentioned above or 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 listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard . 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.

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 425mg of extract (as dry extract) from St John's Wort aerial parts (*Hypericum perforatum* L.) (3.5-6:1) (equivalent to 1490-2550mg of St John's Wort). Extraction solvent: Ethanol 60% v/v.

This product also contains the following ingredients:

Tablet core: Maltodextrin, silica colloidal anhydrous, microcrystalline cellulose, croscarmellose sodium, sodium starch glycolate (Type A), magnesium stearate.

Coating: Hypromellose, sucrose, talc, calcium carbonate E170, tragacanth, acacia, liquid glucose (dry substance), 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 tablet contains 6mg of glucose and 234mg of sucrose.

Each pack contains 30, 60 or 90 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

Wiewelhove GmbH,
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Traditional Herbal Registration number: THR 23056/0007

If you would like further information about this product, please contact:
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This leaflet was revised in 05/2014.

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



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