

Certification
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Patient Information Leaflet

Kira®

LowMood relief

film-coated tablets
St. John's Wort extract 450 mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- 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 do not feel better or if you feel worse after 6 weeks.

What is in this leaflet

1. What Kira® LowMood relief is and what it is used for
2. What you need to know before you take Kira® LowMood relief
3. How to take Kira® LowMood relief
4. Possible side effects
5. How to store Kira® LowMood relief
6. Contents of the pack and other information

1. What Kira® LowMood relief is and what it is used for

This product is a traditional herbal medicinal product containing St. John's Wort extract. Each film-coated tablet contains 450mg extract (as dry extract) from St. John's Wort aerial parts (*Hypericum perforatum* L.)

(3-6:1) (equivalent to 1350–2700 mg of St. John's Wort). Extraction solvent: Methanol 80% v/v.

Kira® LowMood relief is a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety. This usage is based on traditional use only.

You must talk to a doctor if you do not feel better or if you feel worse after 6 weeks.

2. What you need to know before you take Kira LowMood relief

Do not take Kira® LowMood relief if:

- You are allergic to peanut and soya
- You are allergic to St. John's Wort or any of the other ingredients (listed in section 6)
- You are under 18 years of age
- You are pregnant or breast-feeding
- Your skin is exceptionally sensitive to sunlight (photosensitive)
- You are having light treatment (phototherapy) for any condition
- You are suffering from depression (see below)

Warnings and precautions

Are you 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 take this product. If you think you are suffering from depression you should tell your doctor.**

This product contains lactose and soy polysaccharides. Tell your doctor before taking this product if you have an intolerance to some sugars (see section 6). Patients who are allergic to peanut or soya must not use this medicinal product.

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 using machines

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

Other medicines and Kira LowMood relief

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 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 following table.

DO NOT TAKE THIS PRODUCT IF YOU ARE TAKING ANY OF THE FOLLOWING MEDICINES

All hormonal contraceptives	The birth control "Pill", emergency contraception (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

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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 (anti-Parkinson's medicine)
- Aripiprazole (antipsychotic medicine)
- Buspirone (anxiolytic)
- Aprepitant (to treat vomiting)
- Butobarbital and Phenobarbital (barbiturates)
- Methyl phenidate (central nervous system or CNS stimulant)
- Exemestane (hormone antagonist)
- Eplerenone (diuretic)
- Lansoprazole and omeprazole (proton pump inhibitors)
- Theophylline (bronchodilator)
- Gliclazide (antidiabetic medicine)

3. How to take Kira® LowMood relief

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and the elderly

Take 1 tablet daily. Swallow the tablet whole with some water or other liquid. Do not chew the tablets. Do not exceed the stated dose.

If you take more Kira® LowMood relief than you should

If you take more than the recommended dose, speak to a doctor, pharmacist or healthcare practitioner and take this leaflet with you.

If you forget to take Kira® LowMood relief

Do not take a double dose to make up for a forgotten tablet.

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 medicine can cause side effects, although not everybody gets them.

The following side effects have been reported:

- gastrointestinal disorders such as indigestion, loss of appetite, nausea, diarrhoea, constipation
- fatigue
- 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.

Also sunburn-like reactions on skin exposed to strong sunlight or strong ultraviolet (UV) irradiation e.g. solarium have been reported, particularly in fair skinned individuals.

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

The frequency of these effects occurring is not known.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: 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 Kira® LowMood relief

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is

stated on the carton and blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Store the tablets in a cool dry place.

Do not store above 25° C.

Store in original package.

Keep your tablets in the blister pack until it is time to take them.

6. Contents of the pack and other information

What Kira® LowMood relief contains

- The active substance is 450 mg of extract (as dry extract) from St. John's Wort aerial parts (*Hypericum perforatum* L.) (3–6:1) (equivalent to 1350–2700 mg of St. John's Wort). Extraction solvent: Methanol 80 % v/v.

- The other ingredients are:

Extract excipients: Lactose monohydrate, silica colloidal anhydrous

Tablet core: Cellulose microcrystalline, silica colloidal anhydrous, soy polysaccharides, long-chain partial glycerides

Film-coating: Hypromellose, cellulose microcrystalline, stearic acid, titanium dioxide (E171), iron oxide hydrate E 172 (yellow iron oxide), vanillin.

Each film-coated tablet contains 19.15 mg of lactose and 42 mg of soy polysaccharides.

What Kira® LowMood relief looks like and contents of the pack

Each pack contains 30 or 60 film-coated tablets. The film-coated tablets are yellow with smooth, undamaged surface.

Traditional Herbal Registration Holder

Cassella-med GmbH & Co.KG
Gereonsmuehlengasse 1
50670 Cologne
Germany

Manufacturer

Klosterfrau Berlin GmbH
Motzener Strasse 41
12277 Berlin
Germany

Traditional herbal registration number:
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If you would like further information about this product, please contact:
Ceuta Healthcare Ltd.,
41 Richmond Hill,
BOURNEMOUTH BH2 6HS,
United Kingdom.

Telephone: 01202 780558

Fax: 01202 780559

Email.: info@ceutahealthcare.com

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For a large print, Braille or audio version of this leaflet, call Ceuta Healthcare Ltd.

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