



Package leaflet: Information for the user

Botanova®

Film-coated tablets

Active ingredients: St. John's Wort extract, Valerian extract, Passion flower extract.

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen, or do not improve after 6 weeks.
- If any of the side effects become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Botanova® is and what it is used for
2. Before you take Botanova®
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6. Contents of the pack and other information

1. What Botanova® is and what it is used for

Botanova® is a traditional herbal medicinal product used to relieve

- slightly low mood and mild anxiety
- sleep disturbances due to symptoms of mild anxiety based on traditional use only

2. Before you take Botanova®

Do not use Botanova®:

- if you know you are allergic (hypersensitive) to St. John's Wort, Passion flower or Valerian or to any of the other ingredients
- in children or adolescents under 18 years old
- if you are pregnant or breastfeeding
- if you have been diagnosed with depression or you think you may be depressed
- if you are about to undergo surgery
- if you are taking any of the medicines mentioned under taking Botanova® with other medicines below or for sleep or anxiety or that make you feel sleepy without prior consultation with your doctor
- if you know your skin is hypersensitive to light or if you are undergoing a phototherapy or any photodiagnostic procedures

Take special care with Botanova®:

If the condition worsens, or if symptoms persist for more than six weeks medical advice should be sought.

This product is intended for relief of slightly low mood and mild anxiety and of sleep disturbances due to symptoms of mild anxiety. Patients with signs and symptoms of depression should seek medical advice for appropriate treatment.

In very rare cases, particularly in light-skinned persons, sun burn type reactions on skin areas exposed to strong sunlight may occur due to photosensitisation by St. John's Wort. Persons using this product should avoid excessive sunbathing or the use of sunbeds or solariums.

This product should be discontinued at least 10 days prior to elective surgery due to the potential for interactions with medicines used during general and regional anaesthesia.

Taking Botanova® 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 following table.

Do not take Botanova® 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	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 Botanova® with these medicines unless a doctor or pharmacist 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)

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Taking Botanova® with food and drink: Botanova® can be taken with or without food and drink. The use of excessive alcohol should be avoided.

Pregnancy and Breastfeeding: Botanova® should not be used by pregnant or breastfeeding women since no appropriate studies have been performed.

Driving and using machines: Botanova® may make you feel sleepy or dizzy. If affected do not drive or operate machinery.

Important information about some of the ingredients: Each film-coated tablet contains lactose monohydrate (90.5 mg) and glucose (10.4 mg). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this product.

3. How to take Botanova®

Unless prescribed otherwise by your doctor or qualified healthcare practitioner, the recommended dose is as follows:

For the relief of slightly low mood and mild anxiety

adults and the elderly should take 2 film-coated tablets one to three times daily

For the relief of sleep disturbances due to symptoms of mild anxiety

adults and the elderly should take 2 film-coated tablets before going to sleep.

The maximum daily dose is 6 tablets.

The tablets should be swallowed whole with some liquid.

Do not take more medicine than the label tells you to.

Not to be taken by children or adolescents under 18 years of age.

If you take more Botanova® than you should: 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 Botanova®: Don't worry. Leave out that dose and take the next dose at the right time. Do not take a double dose to make up for the missed dose.

If your symptoms worsen or if they do not improve after six weeks speak to your doctor.

4. Possible side effects

Like all medicines, Botanova® can cause side effects, although not everybody gets them.

The following side effects have been reported: Nausea (feeling sick), vomiting, abdominal cramps, abdominal pain, diarrhoea, dyspepsia and constipation.

If these persist for more than a few days or become troublesome, stop taking this product.

Other side effects include anorexia, fatigue, restlessness, headaches, neuropathy, anxiety, dizziness, mania, nightmares or vivid dreams and allergic reactions. You should consult your doctor if you experience any of these effects. 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.

The frequency 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 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 Botanova®

Keep out of the sight and reach of children.

Do not use after the expiration date stated on the blister pack and carton.

The expiry date refers to the last day of the month.

Do not store above 30°C. Keep the blisters in the outer carton in order to protect from light.

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

6. Further Information

What Botanova® contains

- Each film-coated tablet contains: Active ingredients: 60 mg of extract (as dry extract) from St. John's Wort Herb (*Hypericum perforatum* L.) (4.6-6.5:1), extraction solvent: ethanol 38% (m/m); 28 mg of extract (as dry extract) from Valerian Root (*Valeriana officinalis* L.) (3.8-5.6:1), extraction solvent: ethanol 40% (m/m); 32 mg of extract (as dry extract) from Passion Flower Herb (*Passiflora incarnata* L.) (6.25-7.1:1), extraction solvent: ethanol 60% (m/m).
- The other ingredients are:

Excipients of the herbal preparation: Lactose monohydrate; glucose, liquid, spray-dried; maltodextrin; silica, colloidal anhydrous.

Excipients of the tablet: Lactose monohydrate; silica, colloidal anhydrous; talc; magnesium stearate; povidone K30; glycerol (85 per cent); croscarmellose sodium.

Excipients of the film coating: Basic butylated methacrylate copolymer; talc; indigo carmine laquer (E 132); macrogol 6000; magnesium stearate.

What Botanova® looks like and contents of the pack

Dark blue, biconvex, round film-coated tablets in blister pack containing 20 film-coated tablets per blister.

Packs of 60 and 100 film-coated tablets are available.

Not all pack sizes may be marketed.

Traditional Herbal Registration holder:

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