

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

**Food Supplement Company Herbal Mood Relief Tablets (logo)
St John's Wort extract 334 mg**

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

- Always take this medicine exactly as described in this leaflet, or as your doctor, or pharmacist or qualified healthcare practitioner has told 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 or qualified healthcare practitioner if your symptoms worsen or do not improve after six weeks.
- If you get any side effects, talk to your doctor, pharmacist or qualified healthcare practitioner. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

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1. What Food Supplement Company Herbal Mood Relief Tablets are and what they are used for

What Food Supplement Company Herbal Mood Relief Tablets are

This product is a traditional herbal medicinal product containing St John's Wort extract. Each film-coated tablet contains 334mg of extract (as dry extract) from St John's Wort aerial parts (*Hypericum perforatum* L.) (5-7:1) (equivalent to 1670mg – 2338mg of St John's Wort). Extraction solvent: Ethanol 60% v/v.

What Food Supplement Company Herbal Mood Relief Tablets are used for
Food Supplement Company Herbal Mood Relief Tablets are a traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety. This is based on traditional use only.

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, thoughts of self-harm or suicide. 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 before taking this product.**

2. Before you take Food Supplement Company Herbal Mood Relief Tablets
Do not take this product if:

- Your skin is **exceptionally sensitive to sunlight** (photosensitive)

- You are having **light treatment** (phototherapy) for any condition
- You are suffering from **depression** (see above)
- You are **pregnant or breastfeeding**
- You are allergic to any of the ingredients (see Section 6)
- You are taking any of the medicines listed below
- You are due to have an operation in the next 10 days
- You are under the age of 18 years

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

St John's Wort may make you feel dizzy or sleepy. If affected do not drive or use 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 without a prescription.

Therefore it is important that you do not take St John's Wort if you are using any of the medicines in the following list.

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 Food Supplement Company Herbal Mood Relief Tablets

Adults and the elderly

Take 1 or 2 tablets a day. 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 your condition worsens or if symptoms persist for more than 6 weeks after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. 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. The following side effects have been reported:

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

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Food Supplement Company Herbal Mood Relief Tablets

Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.

Do not store above 25 °C. Store in the original packaging.

Keep the tablets out of the sight and reach of children.

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

6. Further Information

Active ingredient: Each film-coated tablet contains 334mg of extract (as dry extract) from St John's Wort aerial parts (*Hypericum perforatum* L.) (5-7:1) (equivalent to 1670mg – 2338mg of St John's Wort). Extraction solvent: Ethanol 60% v/v.

This product also contains the following ingredients:

Tablet core: Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate, Stearic Acid.

Tablet coating: Hypromellose, Iron Oxide Yellow (E172), Titanium Dioxide (E171), Purified Talc.

What these tablets look like

Food Supplement Company Herbal Mood Relief Tablets are pale yellow oval biconvex film coated tablets. This product is available in 30, 60, 90 pack sizes.

Not all pack sizes may be marketed.

Traditional Herbal Registration Number: THR 02231/0002

Registration holder for this product:

The Herbal Research Company Limited, 27 Old Gloucester Street, London WC1N 3XX

Manufacturers:

Surepharm Services Ltd, Burton on Trent, Derby, DE15 0YZ, UK

Wasdell Packaging Ltd., Swindon, SN5 8YW, UK

If you would like further information about this product please contact: **FSC Food Supplement Company, Lancaster Road, Carnaby, Bridlington, East Yorkshire, YO15 3QY**

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For a large print, Braille or audio version of this leaflet call 033 022 08548.

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