



Coated Tablets
St. John's Wort Dry Extract

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 have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- You must contact your doctor if your symptoms worsen or do not improve after 4 weeks.
- If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

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1. What Pacifa Coated Tablets is and what it is used for

Pacifa is indicated for the short term treatment of mild depressive symptoms.

2. What you need to know before you take Pacifa Coated Tablets

Patients who are taking any medicines should tell their doctor or pharmacist before taking Pacifa Coated Tablets.

Do not take Pacifa Coated Tablets

- if you are allergic (hypersensitive) to St. John's Wort or any of the other ingredients of Pacifa Coated Tablets.
- if you are under 18 years of age.
- if you are pregnant or breast-feeding.
- if you are due to undergo surgery.
- if you have skin that is sensitive to sunlight or are undergoing light treatment .
- If you have undergone transplant surgery and are taking immunosuppressant medication.
- if you are being treated with any of the medicines mentioned in the "Taking other medicines section of this leaflet.

Warnings and precautions

Do not exceed the stated dose

This product is intended for the short term treatment of mild depressive symptoms.

If you have signs and symptoms of depression you should contact your doctor for further advice. Symptoms of depression include feelings of helplessness and hopelessness, loss of interest in daily activities, changes in appetite or weight, changes in sleeping patterns or habits, loss of energy and difficulty in concentrating,

Talk to your doctor urgently if you feel agitated, restless or have thoughts of harming yourself.

You may become more sensitive to sunlight while taking Pacifa Coated Tablets due to the active substance St. John's Wort. Therefore, you should avoid excessive sunbathing and the use of sunbeds or solariums. In very rare cases, particularly in light-skinned or HIV-infected persons, sunburn type reactions may occur on skin exposed to strong sunlight.

Children and adolescents

Pacifa Coated Tablets should not be used in children or adolescents under 18 years old. The dosing and safety of St. John's Wort (active substance in Pacifa Coated Tablets) have not been studied in children or adolescents below 18 years.

Women of childbearing potential and birth controls.

John's Wort can affect the levels of hormonal contraception and result in unintended pregnancy and bleeding between periods. Women using any form of hormonal contraception: Emergency contraception (morning after pill) , the birth control "Pill", hormonal implants/injections, hormonal creams or patches or the intrauterine device with hormones ("coil") should also use another form of birth control such as condoms. If you are unsure if your contraception contains hormones talk to your doctor or pharmacist

Surgery

Remember to tell your doctor you are taking this product if you are having an operation. You should stop taking Pacifa 10 days before surgery because St. John's Wort can interact with drugs used during general and regional anesthesia

Taking other medicines and Pacifa Coated Tablets

St John's Wort can affect the way some medicines work and reduce their effectiveness or could worsen side effects. Medicines that can be affected by St John's Wort include prescription medicines and those that are bought without a prescription.

- **Patients who are taking any medicines should tell their doctor or pharmacist before taking Pacifa Coated Tablets.**
- **If you are unsure how Pacifa may interact with any medicine you are taking, please talk to your doctor or pharmacist.**
- **It is important that you do not take Pacifa Coated Tablets if you are using any of the medicines in the following list :**
 - **All medicines for depression/anxiety:** Amitriptyline, clomipramine, moclobemide, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine. buspirone
 - **A medicine for regulating mood:** Lithium
 - **All hormonal Contraceptives:** The birth control 'Pill', hormonal implant, creams, patches, intra-uterine devices with hormones.
 - **Emergency contraception** the morning after Pill
 - **All hormonal replacement therapy (HRT) treatments** HRT tablets, patches gels, vaginal rings.
 - **All medicines for thinning the blood (anticoagulants)** Warfarin, acenocoumarol, clopidogrel, dabigatran, rivaroxaban.
 - **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, delaviridine
 - **Some medicines for cholesterol:** Simvastatin, atorvastatin.
 - **Some medicines for heart disease:** Digoxin, ivabradine, amiodarone.
 - **Some medicines for high blood pressure:** Amlodipine, nifedipine, felodipine, verapamil
 - **Some medicines for cancer:** Irinotecan, dasatinib, erlotinib, imatinib, sorafenib, sunitinib, etoposide, mitotane; exemestane (a hormone blocking medicine).
 - **Some medicines for migraine:** Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan.
 - **Some anaesthetics/preoperative medicines:** Fentanyl, propofol, sevoflurane and midazolam
 - **Some antibiotics:** Erythromycin, clarithromycin, and telithromycin
 - **Some antifungal medicine:** Itraconazole and voriconazole
 - **Some stomach medicines (proton pump inhibitors):** Lansoprazole and omeprazole
 - **Medicines to treat malaria:** Artemether and lumefantrine
 - **Barbiturates:** Butobarbital and phenobarbital
 - **Central nervous system stimulant:** Methylphenidate

- **A medicine to control diabetes:** Gliclazide
 - **A medicine used to control Asthma :** Theophylline
 - **A painkiller medicine:** Tramadol
 - **A medicine for Parkinson's disease:** Rasagiline
 - **An antiemetic** (anti-sickness medicine): Aprepitant
 - **A diuretic:** Eplerenone
 - **A thyroid hormone:** Thyroxine
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Taking Pacifa Coated Tablets with Food and Drink

The tablets can be taken with or without food.

Pregnancy, breast-feeding and fertility

Safety during pregnancy and breast-feeding has not been established therefore you should not take Pacifa if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Driving and using machines

Pacifa Coated Tablets may cause drowsiness, if affected do not drive or operate machinery.

Pacifa Coated Tablets contains sucrose and glucose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Pacifa Coated Tablets

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

The recommended dose for Adults is:

1 coated tablet once or twice a day, swallowed with some liquid.

As with other antidepressants in general, it may take up to 14 days before you feel any antidepressive effect. If your condition worsens, or if your symptoms persist for more than 4 weeks you should consult your doctor.

If you take more Pacifa Coated Tablets than you should have. You should consult your doctor. Depending on the amount taken there may be a need for additional protection from sunlight and other UV-light sources for 1-2 weeks.

If you forget to take Pacifa Coated Tablets.

Do not take a double dose to make up for a forgotten tablet, wait and take your next tablet at the correct time.

If you stop taking Pacifa Coated Tablets.

This medicine has been prescribed for you. You should not stop taking Pacifa Coated Tablets before discussing this with your doctor or pharmacist.

If you have any further questions ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency is very rare but fair-skinned individuals may react with intensified sunburn-like symptoms under intense sunlight.

The frequency is not known.

- gastrointestinal disorders (symptoms like indigestion, loss of appetite, nausea, diarrhoea and constipation)
- allergic skin reactions (symptoms like rash, nettle type rash, itching)
- fatigue
- restlessness

Side effect frequencies:

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

Reporting of side effects

You can also report side effects directly via: HPRA Pharmacovigilance, Earlsfort Terrace

IRL – Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie

E-mail: medsafety@hpra.ie

By reporting any side effects you can help provide more information on the safety of this medicine.

5. How to store Pacifa Coated Tablets

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last day of the month.

Do not store above 25°C.

Do not use this medicine if you notice signs of deterioration such as cracked tablets or discolouration of tablets. 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 protect the environment.

6. Contents of the pack and other information

What Pacifa Coated Tablets contains:

The active substance is St. John's Wort dry extract.

Each tablet contains 425 mg of extract (as dry extract) from *Hypericum perforatum* L., herba (St. John's Wort) (3.5-6: 1), corresponding to: 0.5-1.4 mg of total hypericins; 25.5-89.1 mg of flavonoids, expressed as rutin; maximum 23.6 mg of hyperforin.

Extraction solvent: ethanol 60% m/m.

The other ingredient(s) are: Tablet core:

Maltodextrin, colloidal anhydrous silica, microcrystalline cellulose, croscarmellose sodium, sodium starch glycollate (type A) and magnesium stearate.

Tablet coating:

Hypromellose, sucrose, talc, calcium carbonate E 170, tragacanth, acacia, liquid glucose, titanium dioxide E 171, iron oxide hydrate E 172 (yellow iron oxide), vanillin, white beeswax, carnauba wax & shellac.

What Pacifa Coated Tablets looks like and contents of the pack

Each tablet is yellow, coated and shaped like lenses, free from ruptures.

The coated tablets are sealed in binary blisters made of PVC / PVDC and aluminium with 10 tablets each. Packs of 30, 60, 90 or 100 coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Fannin Limited
Fannin House,
South County Business Park, Leopardstown,
Dublin 18

Manufacturer responsible for batch release

Wiewelhove GmbH, Dörnebrink 19,
49479 Ibbenbüren, Germany
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