Patients who are taking anticoagulants should talk to their doctor or pharmacist before taking Pacifa Coated Tablets.

Some medicines that can be affected by St. John's Wort include prescription medicines and those that are bought without a prescription.

- If you are taking any other medicines for thinning the blood (anticoagulants): Some medicines that can be affected by St. John’s Wort include prescription medicines and those that are bought without a prescription.

You should stop taking these medicines at least 2 weeks before starting Pacifa Coated Tablets to allow their effects to wear off, and you should not start taking these medicines again until you have spoken to your doctor or pharmacist.

- If you have any questions or symptoms of depression you should contact your doctor for further advice. Symptoms of depression include low mood, 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.

- 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.

- If you are due to undergo surgery.

- Emergency contraception: Morning after pill.

- Women using any form of hormonal contraception.

- Some medicines for high blood pressure.

- Some antibiotics.

- Some anaesthetics/preoperative medicines.

- Some medicines for regulating mood.

- Some analgesics.

- Some painkillers.

- Some medicines that can interact with your other medicines.

- Some antidepressants.

- Some anti-inflammatory agents.

- Some oestrogen-containing hormonal contraceptives.

- Some medicines that can interact with your other medicines.

- Some medicines for skin infections.

- Some medicines for heart disease.

- Some medicines for cancer.

- Some injectable medicines.

- Some medicines that can interact with your other medicines.

- Some medicines for seizures.

- Some medicines for skin problems.

- Some medicines for diabetes.

- Some medicines for HIV.

- Some medicines for depression.

- Some medicines for anxiety.

- Some medicines for sleep disorders.

- Some medicines for incontinence.

- Some medicines for hormone-related disorders.

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Taking Pacific 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 Pacific if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Driving and using machines

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

Pacific Coated Tablets contains sucrone 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 Pacific 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 during use, or if your symptoms persist for more than 4 weeks you should consult your doctor.

If you have thoughts of self harm or suicide contact your doctor urgently.

If you take more Pacific Coated Tablets than you should have.

You should consult your doctor. Depending on the amount taken there may be a need for additional precautions from sunlight and other UV-light sources for 1-2 weeks.

If you forget to take Pacific Coated Tablets.

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

If you stop taking Pacific Coated Tablets.

This medicine has been prescribed for you. You should not stop taking Pacific 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)
- skin reactions (symptoms like rash, nettle type rash, itching)
- fatigue

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

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

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: HPRA Pharmacovigilance, Earlfort Terrace

16 – Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762177 Website: www.hpra.ie

E-mail: medication@hpra.ie

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

3. How to store Pacific 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 Pacific Coated Tablets contain:

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

Each tablet contains 425 mg of extract (as dry extract) from Hypericum perforatum L., herb (St. John’s Wort) 3.5:1.1, corresponding to 0.5-1.4 mg of total hypericins, 25.5-88.1 mg of flavonoids, expressed as rutin, maximum 23.5 mg of hyperforin.

Extraction solvent: ethanol 60% m/m.

The other ingredients (s) are:

Tablet core:

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

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

What Pacific Coated Tablets looks like and contents of the pack

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

The coated tablets are sealed in binary blisters made of PVC / PVDC and aluminium with 10 tablets each.

Pack of 50, 60, 90 or 100 coated tablets.

Not all packs sizes may be marketed.