

PACKAGE LEAFLET: INFORMATION FOR THE USER

Orap[®] 4 mg tablets

Pimozide

Orap is a registered trademark

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, nurse or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist

In this leaflet

- 1 What Orap tablets are and what they are used for
- 2 Before you take Orap tablets
- 3 How to take Orap tablets
- 4 Possible side effects
- 5 How to store Orap tablets
- 6 Further information

1 What Orap tablets are and what they are used for

The name of your medicine is Orap 4 mg tablets. They are called 'Orap tablets' or just 'Orap' in this leaflet.

Orap tablets contain a medicine called pimozide. This belongs to a group of medicines called 'neuroleptics'.

Orap tablets are used for illnesses affecting the way you think, feel or behave. These illnesses may make you:

- Feel confused
- See, hear or feel things that are not there (hallucinations)
- Believe things that are not true (delusions)
- Feel unusually suspicious (paranoia)
- Feel elated or over excited (mania)

Important - it may take some time before you feel the full effect of the medicine but it is important that you carry on taking it for as long as your doctor has told you.

2 Before you take Orap tablets

Do not take Orap tablets if:

- You are allergic to anything in Orap tablets (listed in section 6 below)
- You are allergic to similar medicines
- You have an unusually slow heart beat (bradycardia)
- You suffer from a heart problem known as 'QT-prolongation'. This problem sometimes runs in families and can only be confirmed by an

electrocardiogram (ECG). An ECG measures the electrical activity of your heart

- You have lower than normal levels of minerals (electrolytes) in your blood. Your doctor will advise you
- You have Parkinson's disease
- You are suffering from depression
- You are less aware of things around you, your reactions become slower or you go into a coma

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Orap tablets.

Take special care with Orap tablets

Check with your doctor or pharmacist before using Orap tablets if you have:

- A heart problem or anyone in your close family has died suddenly of heart problems
- Liver or kidney problems
- Epilepsy or any other problem that can cause fits (convulsions)
- Problems with your thyroid gland
- A non-cancerous tumour of the adrenal gland (phaeochromocytoma)
- If you exercise hard, are going somewhere very hot or don't drink enough
- If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots

You may need to be more closely monitored, and the amount of Orap tablets you take may have to be altered.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Orap tablets.

Medical check ups

Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Orap tablets. The ECG measures the electrical activity of your heart.

Blood tests

Your doctor may want to check the levels of minerals (electrolytes) in your blood.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular, do not take this medicine and tell your doctor if you are taking any of the following medicines:

- for fungal infections such as ketoconazole, itraconazole, miconazole, fluconazole
- certain antibiotics such as erythromycin, clarithromycin, azithromycin, troleandomycin, sparfloxacin
- antiviral protease inhibitors such as indinavir, ritonavir, saquinavir
- for the heart such as quinidine, disopyramide, procainamide, amiodarone, sotalol, bepridil
- for allergies such as terfenadine, astemizole
- for some digestive problems such as cisapride

- for treating or preventing malaria such as halofantrine
- for depression such as nefazodone, amitriptyline, maprotiline, sertraline, paroxetine, citalopram, escitalopram
- for mental illness such as chlorpromazine, thioridazine, sertindole

Do not start taking Orap tablets and tell your doctor if you are taking any of the above.

Certain medicines may affect the way that Orap works

Tell your doctor if you are taking medicines for:

- Anxiety or to help you to sleep (tranquillisers)
- Severe pain (strong painkillers)
- Parkinson's disease
- Epilepsy or fits (convulsions)
- Lowering blood pressure, such as water tablets (diuretics)

Tell your doctor before taking any of the above. They may need to alter the dose of Orap tablets or your other medicine.

Taking Orap tablets with food and alcohol

You can take Orap tablets with or without food. Swallow the tablets with some water.

Do not drink grapefruit juice while taking Orap tablets.

Drinking alcohol while you are taking Orap tablets might make you feel drowsy and less alert. This means you should be careful how much alcohol you drink.

Pregnancy and breast-feeding

Talk to your doctor before taking Orap tablets if you are pregnant, think you may be pregnant or might become pregnant. The following symptoms may occur in newborn babies of mothers that have used Orap in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

You may still be able to take Orap tablets if your doctor thinks you need to.

Do not take this medicine if you are breast-feeding. This is because small amounts may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

This medicine may affect you being able to drive. Do not drive or use any tools or machines without discussing this with your doctor first.

3 How to take Orap tablets

Always take Orap tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much should you take

Your doctor will tell you how many Orap tablets to take and for how long. Your doctor will adjust the dose to suit you and may carry out a blood test to help

decide if the dose can be increased. It is very important you take the correct amount.

Your dose will depend on:

- Your age
- How serious your symptoms are
- How you have reacted to similar medicines in the past
- If you have a certain genetic make-up that means you break down certain medicines more slowly.

Adults and children over 12 years old

- Your starting dose will normally be between 2 mg and 4 mg. You will take this once a day, preferably in the morning.
- Your doctor may want to gradually increase this dose to find the dose which suits you best. The maximum amount that you should take in one day is 20 mg

If you are taking 6 mg of Orap or more a day, your doctor or pharmacist will give you a treatment card that will include how much Orap you are taking. Keep this card with you.

Your doctor may reduce the dose of Orap tablets when your symptoms begin to improve

Children under 12 years old

Not recommended.

Elderly people

- Elderly people are normally started on a lower dose
- The amount of Orap tablets you take will then be adjusted until the doctor finds the dose that suits you best

When to stop using Orap tablets

Take the medicine for as long as your doctor has told you. It may be some time before you feel the full effect of the medicine.

Unless your doctor tells you otherwise, you should stop taking Orap tablets gradually. Stopping treatment suddenly may cause effects such as:

- Feeling sick (nausea) or being sick (vomiting)
- Difficulty sleeping

Always follow your doctor's instructions carefully.

If you take more Orap tablets than you should

If you take more Orap tablets than you were told to or if someone else has taken any Orap tablets, talk to a doctor or go to the nearest hospital casualty department straight away.

If you forget to take Orap tablets

- If you forget to take a dose, take your next dose as usual. Then keep taking your medicine as your doctor has told you
- Do not take a double dose

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Orap tablets can cause side effects, although not everybody gets them. If you get side effects, there are several things you can do depending on the nature and severity of the side effect:

Stop using Orap tablets and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- A severe allergic reaction. This only happens in a small number of people: An allergic reaction may be recognised as a rash, hives (urticaria), severe irritation, reddening or blistering of your skin, itching, swollen face or lips or throat, or shortness of breath
- A serious problem called 'neuroleptic malignant syndrome'. The signs may include:
 - Fast heart beat, feeling faint, and sweating
 - The above signs can be followed by fever, severe muscle stiffness and loss of consciousness
- Your heart is beating abnormally (for example, too fast or irregularly). This could be an arrhythmia (abnormal heart rhythm) and could cause your heart to stop beating (cardiac arrest). Unexplained deaths have occurred rarely in patients taking this type of medicine.
- Jerky movements and problems such as slowness, muscle stiffness or spasms, trembling and feeling restless, more saliva than normal, twitching or unusual movements of the tongue, face, mouth, neck, jaw or throat, rolling of the eyes, difficulty speaking. If you get any of these effects, you may be given an additional medicine
- Low sodium levels in the blood which can cause tiredness and confusion, muscle twitching, fits or coma. This only happens in a very small number of people
- Fits or seizures (convulsions)

If you notice or suspect any of the above, stop using Orap tablets and tell your doctor straight away.

Tell your doctor, nurse or pharmacist straight away if you notice or suspect any of the following side effects:

Very common side effects (affects more than 1 in 10 patients)

- Sweating more than usual
- Urinating (passing water) a lot at night
- Feeling dizzy
- Feeling sleepy

Common side effects (affects more than 1 in 100 patients)

- Feeling agitated or restless
- Feeling low or depressed
- Difficulty in sleeping
- Feeling tired or lacking in energy
- Loss of appetite
- Dry mouth
- Being sick (vomiting)
- Constipation

- Headache
- Blurred vision
- Excessively oily skin
- Frequent need to pass water (urine)
- Difficulty in getting and/or sustaining an erection (impotence)
- Weight gain

Uncommon side effects (affects fewer than 1 in 100 patients)

- In women, no monthly period

Other side effects:

- Abnormalities in heart traces (electrocardiogram, 'ECG' or 'EKG') or brain traces (electroencephalogram 'EEG')
- Sugar in the urine (detected on testing the urine)
- High blood sugar (if you already have diabetes)
- Hormone changes which may lead to:
 - Some women unexpectedly producing breast milk
 - Some men experiencing swelling of their breast
 - Some people losing interest in sex
- Low body temperature
- Stiff neck

Medicines like Orap may cause blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately

Medicines similar to Orap used by mothers in the last trimester (last three months of pregnancy) have been associated with the following symptoms in newborn babies: shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

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, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie

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

5 How to store Orap tablets

Keep out of the reach and sight of children.

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

Do not use Orap tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. These measures will help protect the environment. Return any leftover Orap tablets to your pharmacist.

6 Further information

The active substance in Orap tablets is pimozide. The tablets contain 4 mg of pimozide.

The other ingredients are calcium hydrogen phosphate dihydrate, maize starch, microcrystalline cellulose, povidone (E1201), talc, cottonseed oil-hydrogenated, ferric oxide (E172) and indigotinedisulphonate (E132) aluminium lake.

What Orap tablets look like and contents of the pack

Orap 4 mg tablets are pale green, circular tablets. They are marked “Janssen” on one side and “X” on the other.

The tablets are available in a pack containing 100 tablets.

The product authorisation is held by:

JANSSEN-CILAG LTD, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK

Orap tablets are made by:

Lusomedicamenta-Sociedade Tecnica Farmaceutica SA, Estrada Consiglieri Pedroso 69-B, Queluz de Baixo, 2730-055 Barcarena, Portugal

OR

McGregor Cory Ltd, Middleton Road, Banbury, Oxfordshire, UK OX16 4RS, UK

For information in large print, tape, CD or Braille, telephone 1800 709 122.

This leaflet was last revised in March 2015.