

Orap[®] 4mg Tablets

(pimozide)

Patient Information Leaflet

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1) What Orap is and what it is used for
- 2) What you need to know before you take Orap
- 3) How to take Orap
- 4) Possible side effects
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1) What Orap is and what it is used for

The name of your medicine is Orap 4mg 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)

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) What you need to know before you take Orap

Do not take Orap:

- if you are allergic to pimozide or any of the other ingredients of this medicine (listed in section 6).
- You are allergic to similar medicines
- You have ever had an irregular heart beat (arrhythmia) or unusually slow heart beat (bradycardia)
- You have recently had a heart attack or have heart failure
- 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 or your reactions become slower

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.

Warnings and precautions

Talk to your doctor or pharmacist before using Orap

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

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

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.

Other medicines and Orap

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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
- antiviral protease inhibitors such as indinavir, ritonavir, saquinavir
- for the heart such as quinidine, disopyramide, procainamide, amiodarone, sotalol, bretylium
- for allergies such as terfenadine
- for some digestive problems such as cisapride
- for treating or preventing malaria such as mefloquine, quinine
- for depression such as nefazodone, amitriptyline, maprotiline, sertraline, paroxetine, citalopram, escitalopram
- for mental illness such as chlorpromazine, thioridazine, sertindole
- for weight control such as sibutramine

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

Tell your doctor before taking any of the following medicines.

- Anxiety or help you to sleep (tranquillisers)
- Severe pain (strong painkillers)
- Parkinson's disease
- Epilepsy or fits (convulsions)
- Sickness such as metoclopramide
- High blood pressure such as calcium channel blockers and diuretics

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

Orap with food, drink and alcohol

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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

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

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

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. 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

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

Use in children under 12 years old

Not recommended.

Use in 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

The tablet can be divided into equal doses.

If you stop taking 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
- Sweating

Always follow your doctor's instructions carefully.

If you take more Orap 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

- 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 to make up for a forgotten dose

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

4) Possible side effects

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

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.

- Rash, hives (also known as nettle rash or urticaria), severe irritation of your skin. These may be signs of a severe allergic reaction. This only happens in a small number of people
- A serious problem called 'neuroleptic malignant syndrome'. The signs may include:
 - Fast heart beat, changing blood pressure and sweating followed by fever
 - Faster breathing, muscle stiffness, reduced consciousness and coma
 - Raised levels of a protein in your blood (an enzyme called creatine phosphokinase)
- Your heart:
 - Beats abnormally (arrhythmia)
 - Flutters (fibrillates)
 - Beats unusually fast (tachycardia)

An arrhythmia can 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 spasm, shaking, trembling or tremors, feeling restless and stiff neck. More saliva than normal, twitching or unusual movements of the tongue, face, mouth, jaw or throat, difficulty speaking or rolling of the eyes. 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.

Tell your doctor 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) at night
- Feeling dizzy
- Feeling sleepy

Common side effects (affects up to 1 in 10 patients)

- Feeling agitated or restless
- Feeling low or depressed
- Difficulty sleeping
- Feeling tired or lacking in energy
- Loss of appetite
- Dry mouth
- Being sick
- Constipation
- Headache
- Blurred vision
- Very oily skin
- Need to pass water (urine) more often than usual
- In men, erection problems
- Weight gain

Uncommon side effects (affects up to 1 in 100 patients)

- In women, no monthly period
- Swollen face

Not known (cannot be estimated from the available data)

- Fits or seizures (convulsions)
- 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
- Body temperature changes

Test results:

- Sugar in the urine
- High blood sugar levels (if you already have diabetes)
- Abnormal heart traces (electrocardiogram, 'ECG') or brain traces (electroencephalogram 'EEG')

Medicines similar to 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 neuroleptics compared with those not receiving neuroleptics.

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

5) How to store Orap

- Keep all medicines out of the sight and reach of children.
- Do not store above 30°C.
- 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.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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

What Orap tablets contain:

Orap tablets contain 4mg of the active ingredient pimozide.

Orap tablets also contain calcium phosphate dibasic dihydrate, maize starch, microcrystalline cellulose, povidone K30, talc, hydrogenated vegetable oil, yellow iron oxide, indigotindisulphonate sodium and aluminium lake.

What Orap tablets look like and contents of the pack

Orap 4mg tablets are pale green, circular, biconvex tablets marked ORAP4 on one side and scored in half on the other.

Orap 4mg tablets are available as blister packs of 20 tablets.

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POM

Who makes and repackages your medicine?

Your medicine is manufactured by Lusomedicamenta Sociedade Tecnica Farmaceutica SA. Estrada Consiglieri Pedroso 69-B. Queluz De Baixo. PT-2730-055 Barcarena, Portugal or Eumedica N.V./S.A., Chemin de la Nauwelette 1, BE-7170 Manage, Belgium. Procured from within the EU by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS and repackaged by Primecrown Ltd, Northolt, UB5 5QS.

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