Patient Information Leaflet for ORAP® 1 mg and 4 mg

SCHEDULING STATUS: S5

ORAP® 1 mg tablets contain 1 mg of the active ingredient, pimozide.

ORAP® 4 mg tablets contain 4 mg of the active ingredient, pimozide.

Sugar free.

Read all of this leaflet carefully before ORAP is administered.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ORAP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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
5. How to store ORAP
6. Contents of the pack and other information.

1. What ORAP is and what it is used for

ORAP relieves thought, feeling and action disturbances in schizophrenic patients, like:

- unusual suspiciousness, believing something that is not true (delusions);
- hearing or seeing, or sensing in another way, something that is not there (hallucinations);
- difficulty in making contact with others.

2. What you need to know before you take ORAP

Do not take ORAP:

- if you are hypersensitive (allergic) to pimozide or any of the other ingredients of ORAP;
- if you suffer from depression which is not being treated;
- if you have Parkinson's disease;
- if you experience drowsiness and slowness due to illness or the use of medicine or alcohol;
- if you have now, or have had in the past, a heart problem involving irregular heartbeat (long QT interval);
- if you have a very slow heart rate.

You should not combine ORAP with:

- certain medicines called azoles that are given for fungal infections. Examples of azoles are ketoconazole, itraconazole, miconazole and fluconazole;
- certain antibiotics called macrolides, such as erythromycin, clarithromycin or troleandomycin;
- certain anti-AIDS medicines;
- certain antidepressants such as nefazodone, amitriptyline, maprotiline, sertraline, paroxetine, citalopram and escitalopram;
- certain other medicines used to treat mental illness such as chlorpromazine and sertindole;
- certain medicines that act on the heart such as quinidine, disopyramide, procainamide, amiodarone, sotalol and bepridil;
- certain antihistamines such as astemizole;
- cisapride, a medicine used for certain digestive problems;
- the antimalarial halofantrine;
- the antibacterial sparfloxacin.

Warnings and precautions

Take special care with ORAP

- If you have liver problems.

- If you are an elderly patient with dementia, which is a disease which causes mental decline with symptoms like memory loss, loss in attention and more difficulty with speaking, taking ORAP could be associated with additional risks.
- Your doctor will discuss with you
  - if you have epilepsy or any other problem that can cause fits (convulsions).
  - if you exercise hard, are going somewhere very hot or do not drink enough.

Other medicines and ORAP

Always tell your healthcare professional if you are taking any other medicine.

- You should not combine ORAP with certain medicines called azoles that are given for fungal infections. Examples of azoles are ketoconazole, itraconazole, miconazole and fluconazole. This also applies to certain antibiotics called macrolides, such as erythromycin, clarithromycin or troleandomycin. However, combining ORAP with their topical forms (e.g. creams, lotions, vaginal ovules) does not pose a problem.

Also, do not use ORAP with:

- See list of medicines under “You should not combine ORAP with:”

In addition, you should avoid grapefruit juice while on ORAP.

ORAP can change the effect of medicines for Parkinson’s disease.

ORAP with alcohol

ORAP increases the effect of alcohol. You should therefore avoid alcohol while on ORAP.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking ORAP.

If you are pregnant or plan to become pregnant see your doctor, who will decide if you can take ORAP.

Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and

difficulty in feeding may occur in newborns, if a mother uses ORAP in the last trimester of her pregnancy.
Small amounts of ORAP can end up in the breast milk. If you are on ORAP you should not breastfeed. If necessary, contact your doctor about this.

Driving and using machines

In the early part of the treatment, ORAP can cause drowsiness. This can make you less alert and reduce your driving ability. So, you should only use machines or drive if your doctor allows this.

3. How to take ORAP

Do not share medicines prescribed for you with any other person.

ORAP is taken once a day, preferably in the morning.
It is very important to take the right dose of ORAP. Your doctor will change the dose until the amount is found that suits you best. The amounts below give only a rough idea of how much you should take. Always take ORAP exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults

Generally, the treatment starts with 2 to 4 of the 1 mg tablets, or a half tablet or a whole tablet containing 4 mg.
Your doctor can increase the amount stepwise until the desired effect is obtained. The maximum amount per day that you should take is 5 of the 4 mg tablets (= 20 mg).

Older people

Older people are usually started on half the amounts mentioned under "Adults". Your doctor may change the amount depending on the effect obtained.

If you have the impression that the effect of ORAP is too strong or too weak, tell your doctor or

pharmacist.

If you take more ORAP than you should

In the event of overdosage with ORAP, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Possible signs of this are: unusually stiff muscles, inability to move or inability to sit still and irregular heartbeat.

If you forget to take ORAP

Do not take a double dose to make up for forgotten individual doses.

If you stop taking ORAP

It may take some time before you feel the full effect of the medicine. Only if your doctor allows you, should you stop taking ORAP. If you stop too soon, without your doctor's agreement, your problem may return. So, stay in contact with your doctor from the moment you stop.

4. Possible side effects

ORAP can have side effects.

Not all side effect reported for ORAP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ORAP, please consult your health care provider.

Side effects could include:

- Movement problems – usually mild – may occur, like not being able to sit still, trembling, and slight muscle stiffness. If this happens, contact your doctor, who may decide to lower your dose or give you another medicine. These effects will then probably go away.
- During long-term treatment twitching of the tongue, face, mouth, or jaws may occur. Should this happen, contact your doctor.

- During long-term treatment, some people may experience breast enlargement, unexpected milk production, or menstruation disorders.
- Drowsiness, sleeplessness, and digestive problems, like constipation or dry mouth can occur but are rare and generally harmless.
- Hypersensitivity to ORAP may occur. It can be recognised, for instance, by skin rash, itching, shortness of breath or swollen face. If any of these signs occur, see your doctor.
- The following effects can occur but are very rare: irregular heartbeat or prolonged changes in body temperature. Should this happen, contact your doctor.
- High blood sugar in patients with diabetes.
- Loss of appetite.
- Depression; difficulty in going to sleep or remaining asleep; restlessness or agitation.
- Dizziness; sleepiness; headache; tremor; coordination abnormalities or involuntary muscle movements (also known as extrapyramidal symptoms [EPS] or parkinsonism), including slow, stiff or jerking movements of the limbs, neck, face, eyes or mouth and tongue that can result in an unusual, involuntary posture or facial expressions; slurred speech; sluggishness; seizures; severe EPS associated with high fever.
- Blurred vision.
- Serious irregular heartbeat affecting how your heart pumps.
- Dry mouth; excessive saliva production; vomiting; constipation.
- Excessive sweating; oily skin; itching of the skin; hives; rash.
- Frequent urination; excessive night-time urination; sugar in the urine.
- Enlargement of breasts, even in males; discharge of fluid from the nipples; loss of menstrual periods; loss of sexual drive; impotence or erectile dysfunction (“ED”).
- Low body temperature.
- Abnormalities in the heart tracing (electrocardiogram, “ECG” or “EKG”).
- Extreme exhaustion.
- Electrolyte imbalance of body fluids.
- Increase in weight.

The following are examples of side effects grouped according to seriousness:

If you experience palpitations, dizziness, fainting, high fever, stiff muscles, fast breathing, abnormal sweating or decreased mental alertness, contact your doctor immediately. Your body may not be reacting properly to the medicine.

These are all very serious side effects. If you have them, you may have had a serious reaction to ORAP. You may need urgent medical attention or hospitalisation.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of ORAP.

5. How to store ORAP

Store all medicines out of the reach of children.

Store at or below 30 °C.

Protect from light.

This medicine can only be kept for a limited period. Do not use ORAP after the date (month and year) printed after “EXP”, even if it has been stored properly.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What ORAP contains

The active substance is pimozide.

The other ingredients are:

ORAP 1 mg tablets: calcium hydrogen phosphate dihydrate, maize starch, microcrystalline cellulose, polyvidone, talc, hydrogenated cottonseed oil, yellow ferric oxide and orange yellow S aluminium lake.

ORAP 4 mg tablets: calcium hydrogen phosphate dihydrate, maize starch, microcrystalline

cellulose, polyvidone, talc, hydrogenated cottonseed oil, yellow ferric oxide and indigotindisulfonate aluminium lake.

What ORAP looks like and contents of the pack

Cartons containing blister packs of 20 or 25 tablets each.

1 mg: Orange, circular, biconvex tablet with the inscription "ORAP 1" on one side.

4 mg: Green, circular, biconvex tablet with the inscription "ORAP 4" on one side and single-scored on the other side.

Holder of Certificate of Registration

LeBasi Pharmaceuticals (Pty) Ltd

San Domenico Building, Unit 6, Ground Floor

10 Church Street

Durbanville

7551

Tel: 087 551 3245

This leaflet was last revised in

Registration: 11 June 1979

Last revision: 19 May 2026

Registration numbers

ORAP 1 mg: B/2.6.5/1017

ORAP 4 mg: K/2.6.5/137

Namibia: NS3

Orap 1 mg: 90/2.6.5/00633

Orap 4 mg: 90/2.6.5/00634

Manufacturer

Lusomedicamenta Sociedade Tecnica Farmaceutica S.A.

69-B Queluz de Baixo, 2730-055

Barcarena, Portugal