

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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. What Micropride is and what it is used for
2. What you need to know before you take Micropride
3. How to take Micropride
4. Possible Side Effects
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6. Contents of the pack and other information

1. What Micropride is and what it is used for

Levosulpiride belongs to a group of medicines called psycholeptic and antipsychotics. It is used for:

- Short-term treatment of dyspeptic syndrome (anorexia, bloating, a feeling of epigastric tenderness, postprandial headache, heartburn, belching, diarrhoea, constipation) from delayed gastric emptying related to organic factors (diabetic gastroparesis, cancer, etc.) and / or functional factors (visceral somatisation in anxious subjects - depressants) in patients who failed to respond to other therapy.
- Symptomatic short-term treatment of nausea and vomiting (induced by anticancer drugs) after failure of first-line therapy.
- Symptomatic short-term treatment of dizziness, tinnitus, hearing loss and nausea associated with Meniere's syndrome.

2. What you need to know before you take Micropride

Do not take Levosulpiride if:

If you are allergic to Levosulpiride or any of the other ingredients of this medicine (listed in section 6).

- If you have epilepsy.

- If you have mood disorder that can make you feel excited (manic states or in the manic phase of manic-depressive psychosis).
- If you have high blood pressure which is suspected to be due to pheochromocytoma.
- If you have breast cancer.

Warnings and precautions

Talk to your doctor or pharmacist before taking Levosulpiride:

- If you have presence of gastrointestinal bleeding, mechanical obstructions or perforations.
- If you suffer from dementia (loss of memory or other mental abilities), or if you have ever had a stroke or “mini” stroke.
- If you suffer from cardiovascular diseases (diseases of the heart and circulation) or if you have a family history of an abnormal heart rhythm tracing (ECG) that shows a problem called QT prolongation.
- If you suffer from blood clots or someone else in your family has a history of blood clots, as antipsychotics have been associated with formation of blood clots.
- If you are in treatment with other neuroleptics because of the risk of developing a complex symptoms disorder (such as fever, severe muscle stiffness, severe movement difficulties (akinesia), excessive sweating, rapid heartbeat, impaired pressure or loss of consciousness) potentially fatal, called Neuroleptic Malignant Syndrome, that has been reported with use of this medicines (in general in the course of treatment with antipsychotic drugs). In this case, stop taking Levosulpiride and contact your doctor immediately.

Other medicines and Levosulpiride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly if you are taking:

- Medicines that prolong the QT interval (an abnormal heart rhythm).
- Medicines that cause electrolyte disturbances (an abnormality in the concentration of electrolytes in the body).
- Other medicines that act on the Nervous Central System.

Levosulpiride with alcohol

You should avoid simultaneous intake of alcohol.

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.

Do not use Levosulpiride in pregnancy, possible pregnancy and during the breastfeeding period.

The following symptoms have been observed in neonates of mothers who used antipsychotics, including levosulpiride, during the last 3 months of pregnancy: tremor, rigidity and / or muscle weakness, somnolence, agitation, breathing problems and difficulties in food intake. If your child shows any of these symptoms, contact your doctor.

Driving and using machines

Levosulpiride may have an influence on the ability to drive and use machines.

Patients under treatment may experience numbness, dizziness or involuntary movements (dyskinesia); therefore, they should be advised to avoid driving or operating machines.

3. How to take Micropride

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

Adult: 25 mg tid.

Elderly: Dose reductions may be necessary

Oral administration

Use in children and adolescents

This medicine should not be used in children and adolescents because no data are available.

Elderly

If you are elderly your doctor will prescribe the most appropriate dose for you.

If you take more Levosulpiride than you should

If you take more Levosulpiride than prescribed, tell your doctor immediately or contact your nearest hospital. Bring this sheet with you.

Tremors, difficulty and slowness in movement (extrapyramidal disorders) or sleep disorders may occur with the highest doses. Your doctor will decide whether to revise the dose or to stop the therapy.

If you forget to take Levosulpiride

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

If you stop taking Levosulpiride

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.

The following effects have been reported:

Very common (may affect more than 1 in 10 people)

- Sleepiness, torpor.

Common (may affect up to 1 in 10 people)

- Dizziness, vertigo.

Rare (may affect up to 1 in 1,000 people)

- Alteration of the heart rhythm: QT prolongation, ventricular arrhythmias such as torsades de pointes, ventricular tachycardia, ventricular fibrillation, cardiac arrest.

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

- Weight gain.
- Parkinsonism (tremor, bradykinesia, rigidity, and postural instability), dyskinesia (involuntary muscle movements), tremor, dystonia (twisting and repetitive movements or abnormal fixed postures), psychomotor agitation (unintentional and purposeless motions and restlessness), disorders of the autonomic nervous system (control system that acts unconsciously and regulates bodily functions).
- Sudden death.

Not known (frequency cannot be estimated from the available data)

- Neuroleptic Malignant Syndrome (life-threatening reaction, symptoms include hyperpyrexia, muscle rigidity, serious difficult in movements (akinesia), irregular pulse or blood pressure, sweating, tachycardia, arrhythmias, loss of consciousness).

Amenorrhea (absence of a menstrual period), gynaecomastia (increase in the size of male breast), Galactorrhea (spontaneous flow of milk from the breast), changes in libido. Thromboembolism (formation of a blood clot inside a blood vessel, including cases of pulmonary embolism and deep venous thrombosis)

- Neonatal withdrawal syndrome (withdrawal syndrome of infants after birth caused by in utero exposure to drugs of dependence), extrapyramidal symptoms (drug-induced movement disorders).
- Hyperprolactinemia (presence of abnormally high levels of prolactin in the blood).

5. How to store Micropride

Store below 30°C. Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister strip after **Exp.**

The expiry date refers to the last day of that month. Store in the original package.

This medicinal product does not require any special storage conditions.

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 Micropride contains

Active ingredient: Levosulpiride

The other ingredients are: Maize Starch, Microcrystalline Cellulose, Croscarmellose Sodium, Povidone K-30, Colloidal Silicon Dioxide, Magnesium Stearate

What Micropride looks like and contents of the pack

White, circular, flat, beveled uncoated tablets

Blister pack of 10 tablets

Manufacturer

MICRO LABS LIMITED

92, SIPCOT,

HOSUR-635 126, INDIA

Marketing Authorization Holder

MICRO LABS LIMITED

31, Race Course Road

Bangalore-560001

INDIA

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