PATIENT INFORMATION LEAFLET LEVOSULPIRIDE SUSTAINED RELEASE TABLETS 75 mg (MICROPRIDE SR 75)



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 SR 75 is and what it is used for
- 2. What you need to know before you take Micropride SR 75
- 3. How to take Micropride SR 75
- 4. Possible Side Effects
- 5. How to store Micropride SR 75
- 6. Contents of the pack and other information

1. What Micropride SR 75 is and what it is used for

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

Gastroesophageal reflux disease (Acid reflux), Irritable bowel syndrome, Heartburn, Schizophrenia, Depression

2. What you need to know before you take Micropride SR 75

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

Precautions should be taken if patients have any history of renal or hepatic impairment.

Precautions should also be taken if patients having:

- Drowsiness
- Dizziness

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

Pregnancy

Sustained-release levosulpiride tablets are contraindicated during pregnancy.

Lactation

Sustained-release levosulpiride tablets are contraindicated during lactation.

Driving and using machines

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

3. How to take Micropride SR 75

The recommended dosage of Levosulpiride Sustained Release Tablets is 75 mg once daily. The medication must be swallowed whole, without being torn, crushed, or chewed before use.

Dose reduction is appropriate in elderly patients, and the drug should be taken exactly as prescribed by your doctor.

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

If you skip a dose, take it as soon as you remember. To make up for a missing dose, skip it and don't take two doses at the same time.

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

Report to the physician immediately if the patients are having any of these following symptoms:

- Headache
- Fatigue
- Sleepiness
- Increased prolactin level in blood
- Neuroleptic malignant syndrome

5. How to store Micropride SR 75

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 SR 75 contains

Active ingredient: Levosulpiride

The other ingredients are: Microcrystalline Cellulose, Hypromellose, Povidone (K-30), Colloidal Anhydrous Silica, Magnesium stearate, Instacoat White

What Micropride SR 75 looks like and contents of the pack

White to off white, Round shape, film coated tablet plain on both sides. Blister pack of 10 tablets

Manufacturer

MICRO LABS LIMITED

92, SIPCOT,

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Marketing Authorization Holder

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INDIA

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