SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

Levosulpiride sustained release tablets

MICROPRIDE SR 75

2. Quality and Quantitative Composition

Each film coated sustained release tablet contains

Levosulpiride …….. 75 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Sustained release tablets

White to off white, Round shape, film coated tablet plain on both sides.

4. Clinical Particulars

4.1 Therapeutic indications:

Levosulpiride is used to prescribe for the treatment of:

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

4.2 Posology and method of administration:

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.

Missed Dose: 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.

4.3 Contraindications:

Levosulpiride must not be used in the following conditions:

- Hypersensitivity to the active ingredient(s) or to any of the excipients of the medicine
- Phaeochromocytoma
- Epilepsy
- Manic states
- Hyperprolactinemia
- Mammary dysplasia
- Malignant mastopathies
- Cardiac impairment

4.4 Special warning 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

4.5 Interactions with Other Medicaments

- Reduced bioavailability is seen with sucralfate, aluminium- and magnesium-containing antacids. Effect on gastrointestinal motility may be antagonised by anticholinergic agents, narcotics and analgesics.
- Additive sedative effects can occur when levosulpiride is given with alcohol, sedatives, hypnotics, narcotics or tranquilizers.

- Levosulpiride releases catecholamines in patients with essential hypertension. So it should be used cautiously, if at all, in patients receiving monoamine oxidase inhibitors.
- The risk of cardiac arrhythmias increases on combined use with other drugs that prolong the QT interval including certain anti-arrhythmics, other antipsychotics, some non-sedating anti-histamines, antimalarials and cisapride.
- Levosulpiride should be avoided with drugs that cause electrolyte abnormalities such as diuretics

4.6 Pregnancy and lactation:

Pregnancy

Sustained-release levosulpiride tablets are contraindicated during pregnancy.

Lactation

Sustained-release levosulpiride tablets are contraindicated during lactation.

4.7 Effects on ability to drive and use machine:

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

4.8 Undesirable 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

4.9 Overdose:

An accidental overdose of Levosulpiride in a small amount may not be dangerous. High doses, on the other hand, can cause sleep disturbances, restlessness, excessive muscle movements,

tremors, and other side effects. If you have any of these signs, contact your doctor right away or seek medical help.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties:

Pharmacotherapeutic group: Psycholeptics, antipsychotics, ATC code: N05AL07.

Levosulpiride is the (-)-enantiomer of sulpiride. It is a selective dopamine D2-receptor antagonist with pro-kinetic activity, is therapeutic option in the management of functional dyspepsia. It has shown greater central antidopaminergic activity, anti-emetic and anti-dyspeptic effects and lower acute toxicity than both the racemic and dextro forms. The main mechanism of action of levosulpiride consists of blocking the D2 dopaminergic receptors, preferentially located on the presynaptic membranes in the dopaminergic pathways of the brain, which means that sulpiride is a selective autoreceptor blocker. On the other hand, the serotonergic (5HT-4) component of levosulpiride may enhance its therapeutic efficacy in functional dyspepsia.

5.2 Pharmacokinetic Properties:

After oral administration the bioavailability of levosulpiride is about 30%. Peak plasma concentration occurs after about 3 hours and it has plasma half-life of about 9.7 hours. It is mostly eliminated by the kidneys in the urine.

5.3 Preclinical safety Data:

None stated

6. Pharmaceutical Particulars

6.1 List of excipients:

Microcrystalline Cellulose

Hypromellose

Povidone (K-30)

Colloidal Anhydrous Silica

Magnesium stearate

Instacoat White

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

36 Months from the date of Manufacturing.

6.4 Special precautions for storage:

Store below 30°C. Keep medicine away from the reach of children

6.5 Nature and contents of container:

Blister pack of 10 tablets

7. Marketing Authorization Holder:

MICRO LABS LIMITED

31, Race Course Road

Bangalore-560001

INDIA

8. Marketing Authorization Numbers

--

9. Date of first authorization

--

10. Date of revision of the text

July 2022