

Lampsow

(Levosulpiride)

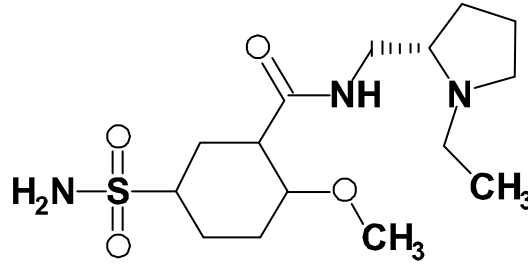
لیمپسو گولیاں
(لیوسلپرائیڈ)

۲۵ ملی گرام ۵۰ ملی گرام اور ۱۰۰ ملی گرام

25mg, 50mg & 100mg Tablets

1. DESCRIPTION :

Levosulpiride tablets for oral administration contain 25mg, 50mg and 100mg of Levosulpiride, an antidopaminergic (A Selective DA₂ receptors antagonist) in the central nervous system and in the peripheral submucosal and myoenteric plexus of the gastrointestinal tract. It is chemically described as S-(-)-N(1-methylpyrrolidine-2-yl-methyl 1-5-) sulfamoyl-benzamide, and its structural formula is; molecular formula is C₁₅H₂₃N₃O₄S and molecular weight is 341.4258.



2 COMPOSITION:

Lampsow 25mg Tablet

Each tablet contains:

Levosulpiride 25mg

(As per Innovator's Specification)

Lampsow 50mg Tablet

Each tablet contains:

Levosulpiride 50mg

(As per Innovators Specification)

Lampsow 100mg Tablet

Each tablet contains:

Levosulpiride 100mg

(As per Innovators Specification)

3 DOSAGE & ROUTE OF ADMINISTRATION

The normal dose in adults is 1 tablet (25 mg of levosulpiride) every 8 hours, i.e. 3 tablets (75 mg of levosulpiride) per day taken orally, distributed in three doses, at least 20 minutes before meals. Use in children: The use of levosulpiride in children is not indicated. Use in the elderly: In elderly patients, the daily dose of Lampsow will be established by the doctor according to the patient's needs. As directed by the physician.

4 CONTRAINDICATIONS

- If you are allergic (hypersensitive) to levosulpiride or any of the other ingredients of Lampsow.
- If you are epileptic or have a history of seizures or manic-depressive psychosis.
- If you have or are at risk of gastrointestinal bleeding, obstructions or perforations.
- If you have pheochromocytoma (tumour of the adrenal gland).
- If you have been diagnosed with malignant mastopathy (breast condition).
- If you are pregnant or breast-feeding.

4.1. Special warnings and precautions for use

o Painkillers (narcotics, analgesics).

o Anticholinergic and antidopaminergic drugs, ask your doctor if you have any questions.

4.2. Paediatric population

Not recommended in children under 18 years.

4.3. Interaction with other medicinal products and others forms of interaction

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Certain medicines may interact with Lampso. In such cases, it may be necessary to change the dose or stop the treatment with one of these medicines.

4.4. Additional information on special populations

Use in the elderly: in elderly patients, the doctor according to the patient's needs will establish the daily dose of Lampso.

4.5. Fertility, pregnancy and lactation

i. General principles

Ask your doctor or pharmacist for advice before taking any medicine. This medicine should not be used during pregnancy or breast-feeding.

ii. Women of childbearing potential / Contraception in males and females

This medicine should not be used during pregnancy or breast-feeding.

iii. Pregnancy

This medicine should not be used during pregnancy.

iv. Breastfeeding

This medicine should not be used during breast-feeding..

v. Fertility

This medicine should not be used during pregnancy or breast-feeding.

4.6. Effects on ability to drive and use machines

Levosulpiride can cause symptoms such as drowsiness, dizziness, visual disturbances and decreased ability to react. These effects and the digestive disorder itself may hamper your ability to drive or operate machines. Therefore, do not drive or operate machines or do other activities that require special attention until your doctor assesses your response to this medication.

4.7. Undesirable effects

a) Summary of the safety profile

Like all medicines, Lampso can cause side effects, although not everybody gets them. Very common (at least 1 in 10 patients): hoarseness, abdominal cramps, weight gain, hyper salivation (increase in saliva secretion), insomnia, constipation, vertigo and/or fatigue. Common (at least 1 in 100 patients) drowsiness, sedation, breast swelling and tenderness, menstrual disorders, galactorrhoea (nipple discharge), gynecomastia (increased breast size). If you consider that any of the side effects is serious or if you notice any possible side effect not listed in this leaflet, tell your doctor or pharmacist.

b) Tabulated list of adverse reactions

Very common	Common
Hoarseness	Drowsiness
Abdominal Cramps	Sedation
Weight Gain	Breast Swelling And Tenderness
Hyper salivation	Menstrual Disorders
Insomnia	Galactorrhea
Constipation	Gynecomastia
Vertigo	
Fatigue	

c) Description of selected adverse reactions

- Hoarseness: the quality of a person's voice when it sounds rough.
- Abdominal cramps: a sudden painful tightening in the abdominal.
- Hyper salivation: Increase In Saliva Secretion
- Insomnia: the condition of being unable to sleep, over a period of time.
- Constipation: a condition which makes someone unable to empty their bowels as often as they should.
- Vertigo: a feeling of spinning around and being unable to balance, often caused by Looking down from a height.
- Fatigue: extreme tiredness.
- Drowsiness: a tired state, between sleeping and being awake.
- Sedation: a state of calm or sleep produced by a sedative drug.
- Breast Swelling And Tenderness
- Menstrual Disorders
- Gynecomastia: increased breast size.
- Galactorrhea: Spontaneous flow of milk from the breast, unassociated with childbirth or nursing.

d) Pediatric population

The use of levosulpiride in children is not indicated.

e) Other special populations

In elderly patients, the daily dose of Lampso will be established by the doctor according to the patient's needs.

4.8. Overdose

The symptoms of Lampso overdose are mainly drowsiness and tremors. If this occurs, you should contact your doctor.

5. SHELF LIFE

2 years

6. STORAGE CONDITION

Store at 30°C.

Protect form sunlight and moisture

Keep out of reach of children.

7. HOW SUPPLIED

Lampso Tablet 25mg.

Alu-Alu blister Packs of 2x10 Tablets

Lampso Tablet 50mg.

Alu-Alu blister Packs of 2x10 Tablets

Lampso Tablet 100mg.

Alu-Alu blister Packs of 2x10 Tablets

MANUFACTURED BY:



NAWAN
LABORATORIES (PVT) LTD.

136, Sector 15, Korangi Industrial
Area, Karachi-74900, Pakistan.

لیمپسو گولیاں

(لیوسلپرائیڈ)

۲۵ ملی گرام اور ۵۰ ملی گرام اور ۱۰۰ ملی گرام

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

۳۰ ڈگری پر محفوظ کریں۔

دھوپ اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف مشورہ ڈاکٹر کے نسخے پر فروخت کی جائے۔