

Sulprisel^{Tablet}

(Levosulpiride)

سیلپری سیل
(لیووسلپیرید)

COMPOSITION:

Sulprisel 25mg Tablet

Each tablet contains:

Levosulpiride25mg
(Innovator's specs.)

Sulprisel 50mg Tablet

Each tablet contains:

Levosulpiride50mg
(Innovator's specs.)

DESCRIPTION:

Levosulpiride is a substituted benzamide antipsychotic, which is reported to be a selective antagonist of central dopamine (D-2, D-3 and D-4) receptors. Levosulpiride is also calimed to have mood elevating properties.

THERAPEUTIC INDICATIONS

Levosulpiride falls under a class of medication known as antipsychotic (also familiar as neuroleptics or tranquilizers) medicines.

It is mainly used for mental disorders such as hallucinations, schizophrenia, bipolar disorder, anxiety disorder, vertigo and irritable bowel syndrome.

Other conditions may include:

- Dyspeptic syndrome (anorexia, bloating, a feeling of epigastric tenderness, postprandial headache, heartburn, belching, diarrhea, constipation) from delayed gastric emptying related to organic factors (diabetic gastroparesis, cancer, etc.) and / or functional factors (visceral somatisation in anxious subjects - depressants).
- Essential headache: vasomotor forms (classical, common, ophthalmic, hemiplegic, cluster migraine) and muscle-tensive forms.
- Nausea and vomiting (post-operative or induced by anticancer drugs).
- Dizziness, by central or peripheral origin.

DOSAGE AND ADMINISTRATION:

1 tablet of 25mg 3 times per day before meal.

2 tablets of 50mg per day or according to medical prescription.

PRECAUTIONS FOR USE:

No secondary effect have been observed at the dosage recommended in internal medicine, however at higher dosages somnolence, numbness and dyskinesia may occur, due to their potential dangers, patients under treatment must be made aware of these risks in order to avoid driving vehicles and attending to operations requiring total attention.

Levosulpiride must not be used when stimulating gastrointestinal motility may be harmful, for instance presence of gastrointestinal bleeding, mechanical obstructions or perforations.

Use During Pregnancy And Lactation:

Not to be used during presumed or confirmed pregnancy and during the lactation period.

PHARMACOKINETICS:

After oral administration, the bio-availability of Levosulpiride is about 30%. Peak-plasma concentration occurs after about 3 hours and it has plasma half life of about 8-9 hours. It is mostly

eliminated by the kidneys in the urine and faeces, mainly as unchanged drug.

SIDE EFFECTS:

For prolonged administration, certain disturbances such as amenorrhea, Gynecomastia, Galactorrhea and alteration of the libido, observed in particular occasions are referable to a reversible effect of levosulpiride on the functionality of the hypothalamus pituitarygonadal axis, similar to that known for many neuroleptics.

DRUG INTERACTIONS:

The effects of levosulpiride on the gastrointestinal motility may be opposed by anti cholinergic, narcotic or analgesic drugs.

The association with psychopharmacological agents required particular care and vigilance by the physician, in order to avoid any unexpected side effects due to interaction. The simultaneous intake of alcohol must be avoided.

CONTRAINDICATIONS:

Levosulpiride is contraindicated to patients affected by pheochromocytoma, as it may cause a hypertensive crisis, probably due to the release of catecholamines from the tumor. Such hypertensive crisis, may be controlled by phenolamine, levosulpiride is contraindicated in patients with a known hypersensitivity or intolerance to the drug. It must not be used in epilepsy, in manic conditions and in the manic stages of manic-depressive psychoses, in regard to the supposed co-relations between the hyperprolactinemia of most psychotropic drugs and mammary dysplasias, it will be appropriate not to administer levosulpiride in subjects affected by malignant mastopathies.

OVERDOSAGE:

In internal medicine extrapyramidal or sleep disturbances have ever been observed, which may eventually occur at very high dosage. Interrupting the therapy or reducing the dosage depending on the physician's judgement will be sufficient in this case.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight & moisture.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:

Sulprisel 25mg Tablet

10's, 20's Tablets.

Sulprisel 50mg Tablet

20's Tablets.

خوراک و طریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا ۱۵-۲۵°C درجہ حرارت کے درمیان رکھیں۔

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

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:

PHARMASOL
PRIVATE LIMITED
Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.