

# Sapride

[Levosulpiride]

TABLETS

## COMPOSITION

### Sapride Tablets 25mg

Each tablet contains:

Levosulpiride (SPL. Specs.).....25mg

### Sapride Tablets 50mg

Each tablet contains:

Levosulpiride (SPL. Specs.).....50mg

## DESCRIPTION

Chemically Levosulpiride is a substituted benzamide. Its chemical formula is S-(-)-N (1-ethylpyrrolidine-2-yl-methyl 1-5) sulfamoyl-benzamide. The biochemical, pharmacological and clinical data obtained from the two sulpiride isomers indicate that the anti-dopaminergic action, both on a central and peripheral level is due to the levogyre enantiomer (levosulpiride).

## PHARMACOLOGICAL CLASSIFICATION

Sapride (Levosulpiride) is an Anti-Dopaminergic (A Selective DA2 receptors antagonist) in the central nervous system and in the peripheral sub mucosal and myoenteric plexus of the gastrointestinal tract.

## PROPERTIES

Sapride (Levosulpiride) increases the tone and range of gastric contractions in patient affected by gastric stasis and consequently retarded gastric voiding, relaxes the pyloric sphincter and increases the duodenal and jejunal peristalsis leading to accelerated gastric voiding and intestinal transit. Owing to these peculiar features, the pharmaceutical may be employed in endoscopic studies for overcoming spasm and primary or reflected pyloric hepermyotonia, in the radiology of the digestive tract for shortening examination time for promoting antral ejection of the contrasting medium and for avoiding troublesome compressive motions.

Sapride (Levosulpiride) exerts a regulation action both on the central and peripheral nervous circuits controlling the dynamics of the digestive system. Controlled clinical studies demonstrate that Sapride (Levosulpiride) is active for digestive disturbances (anorexia, nausea, vomit etc.) of an organic, functional and heterogeneous nature. Sapride (Levosulpiride) considerably reduces the emesis induced by the most powerful antiblastic agents (cisplatin, antracycline). Alone or in combination, in patients affected by metopodynia it exerts in a considerable pharmacological influence by reducing the frequency duration and intensify of crisis periods. Sapride (Levosulpiride) will generally not alter the cardiac-respiratory parameters the kidney or bladder functions or the emetic crisis.

## PHARMACOKINETICS

After oral administration the bioavailability of Sapride (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.

## INDICATIONS

- 1) GASTROESOPHAGEAL REFLUX DISEASE (GERD)
- 2) IRRITABLE BOWEL SYNDROME (IBS)
- 3) DYSPEPTIC SYNDROME (Anorexia, meteorism, sense of epigastric tension, postprandial cephalgia, pyrosis, eruptions, diarrhoea, stipsis) due to retarded gastric voiding related to organic factors (diabetic gastroparesis, neoplasia etc) and /or functional factors (visceral somatization in anxious depressive individuals):
- 4) ESSENTIAL CEPHALGIA: Vasomotoric affections (classic, common, ophthalmic, cluster type migraine) and muscular tension conditions, vomit and nausea (post operational or induced by anti-blastic pharmaceuticals).
- 5) VERTIGO OF A CENTRAL AND/OR PERIPHERAL ORIGIN

## DOSAGE AND ADMINISTRATION

### 25mg tablets:

1 tablet of 25mg 3 times per day before meals or according to medical prescription.

### 50mg tablets:

1 tablet of 50mg 2-3 times daily.

## CONTRAINDICATIONS

Sapride (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 phentolamine. Sapride (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 psychosis. In regard to the supposed correlations between the hyperprolactin enzyming effect of most psychotropic drugs and mammary dysplasia. It will be appropriate not to administer Sapride (Levosulpiride) in subjects affected by malignant mastopathies.

## SIDE EFFECTS

For prolonged administration certain disturbances such as amenorrhea, gynecomastia, galactorrhea and alteration of the libido, observed in particular occasions, are preferable to a reversible effect of Sapride (Levosulpiride) on the functionality of the hypothalamus-pituitary gonadal axis, similar to that known for many neuroleptics.

## PRECAUTIONS FOR USE

No secondary effects 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. Sapride (Levosulpiride) must not be used when stimulating gastrointestinal motility may be harmful, for instance in 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.

## DRUG INTERACTIONS

The effects of Sapride (Levosulpiride) on the gastrointestinal motility may be opposed by anti-cholinergic, narcotic or analgesic drugs. The association with psychopharmacological agents requires particular care and vigilance by the physician. In order to avoid any unexpected side effect due the interaction simultaneous intake of alcohol must be avoided.

## OVER DOSAGE

In internal medicine nor extra-pyramidal or sleep disturbances have ever been observed; which may eventually occur at very high dosages. Interrupting the therapy or reducing the dosage depending on the physician's judgment will be sufficient in this case.

## INSTRUCTIONS

Store below 30°C. Protect from heat, light and moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

## PRESENTATION

Sapride Tablets 25mg are available in Alu-Alu pack of 2x10s.

Sapride Tablets 50mg are available in Alu-Alu pack of 2x10s.

سپرائید ٹیبلٹس  
[لیووسلپیرائیڈ]

ہدایات: دوا کو 30° سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے محفوظ رکھیں۔  
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹرز کے نسخہ پر فروخت کریں۔



Manufactured by:

**STANDPHARM PAKISTAN (PVT) LTD**

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