



**MEDLEY PHARMACEUTICALS**

## **Le-Ride 100mg** Capsules

*Levosulpiride*

---

### **COMPOSITION:**

Each Capsule contains:

*Levosulpiride*.....100mg (Medley's Specs)

### **CHEMICAL CLASSIFICATION:**

Levosulpiride is a substituted benzamide. Chemically it is S-(-)...N (1-ethylpyrrolidine 2 -ylmethyl-1-5- ) sulfamoyl benzamide.

### **PHARMACOLOGICAL CLASSIFICATION:**

Antidopaminergic (a selective D2 receptor antagonist) in the central nervous system and in the peripheral sub mucosal and myenteric plexus of the gastrointestinal tract.

### **PROPERTIES:**

The biochemical, pharmacological and clinical data obtained from two sulpiride isomers indicate that the antidopaminergic action, on both central and peripheral level is due to the levogyre enantiomer (Levosulpiride).

**Le-Ride capsules** increases the tone and range of gastric contractions in patients affected by gastric stasis and consequently retarded gastric voiding relaxes the pyloric sphincter and increases the duodenal and jejunal peristalsis leading to the accelerated gastric voiding and intestinal transit owing to these peculiar features, the Patient may be employed in endoscopic studies for overcoming spastic and primary or reflected pyloric hypermyotonia, in the radiology of the digestive tract for shortening examination time, for promotion enteral ejection of the contrasting medium and for avoiding troublesome compressive motions.

**Le-Ride (Levosulpiride)** Capsules exerts regulation action both on the central and peripheral circuits controlling the dynamics of the digestive system. Controlled clinical studies demonstrate that Levosulpiride (Le-Ride) is active for digestive disturbances (anorexia, nausea, vomiting etc.) of an organ functional and heterogeneous nature. **Le-Ride (Levosulpiride)** considerably reduces the emesis induced by the most powerful antitubercular agent (Cisplatin). Alone or in combination in patients affected by metopodinia it exerts a considerable pharmacological influence, by reducing the frequency, duration and intensity of crises periods.

**Le-Ride (Levosulpiride)** Capsules will generally not alter the cardiac-respiratory parameters, the kidney or bladder functions or the emetic crises.

### **PHARAMCOKINETICS:**



Manufactured by:  
ISO 9001-2008 Certified Company  
**Medley Pharmaceuticals**  
41-A, P.S.I.E. Jhang Bahtar Road,  
Wah Cantt- Rawalpindi



## MEDLEY PHARMACEUTICALS

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 hours. It is mostly eliminated by the kidneys in the urine.

### INDICATIONS:

1. **Gastroesophageal reflux diseases (GERD)**
2. **Irritable Bowl Syndrome (IBS)**
3. **Dyspeptic syndrome** (anorexia, meteorism sense of epigastric tension, postprandial cephalgia, pyrosis, erupticos, and diarrhea) due to retarded gastric voiding related to organic factors (diabetic gastroparesis, neoplasia etc.) and or functional factors (visceral somalization in anxious depressive individuals).
4. **Essential Cephalgia:** Vasomotor affections (classic, common ophthalmic cluster type migraine and muscular tension conditions, vomiting and nausea, post operational vertigo of a central and /or peripheral origin.

### DOSGE AND ADMINISTRATION:

25mg to 100mg PO daily in divided doses. Under the strict supervision of Registered Medical Practitioner as prescribed.

### CONTRANIDICATIONS:

**Le-Ride** (Levosulpiride) capsules are contraindicated in patients affected by pheochromocytoma, as it may cause hypertensive crises, probably due to release of catecholamines from the tumor. Such hypertensive crises may be controlled by phentolamines. **Le-Ride (Levosulpiride)** is contraindicated in patients with a known hypersensitivity or intolerance to the drug. It must not be used in the epilepsy, in manic conditions and in the manic stages of manic depressive psychosis. In regard to the supposed correlations between the hyper prolactinemyzing affect of most psychotropic drugs and mammary dysplasia. It will not be appropriate to administer

**Le-Ride (Levosulpiride)** in subjects affects by malignant mastopathies.

### SIDEE FFECTS:

For prolonged administration, certain disturbances such as amenorrhea, dysneocomastia, glactorrhea and alteration of libido, observed in particular occasions or deferrable to a reversible effect of Levosulpiride on the functionality of the hypothalamus-pituitary-gonadal axis, similar to that known for many neuroleptics.

### PRECAUTIONS:



Manufactured by:  
ISO 9001-2008 Certified Company  
**Medley Pharmaceuticals**  
41-A, P.S.I.E. Jhang Bahtar Road,  
Wah Cantt- Rawalpindi



## MEDLEY PHARMACEUTICALS

No secondary effect has been observed at the dosage recommended in internal medicine, however at higher doses 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 operations requiring total attentions

**Le-Ride (Levosulpiride)** must not be used when stimulating gastro intestinal motility may be harmful, for instance in presence of gastrointestinal bleeding, mechanical obstructions and perforations.

### USE DURING PREGNANCY AND LACTATION:

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

### DRUG INTERACTIONS:

The effect of Levosulpiride on the gastrointestinal motility may be opposed by anticholinergic, narcotic analgesic drugs.

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

### OVERDOSAGE:

In internal medicine no extra pyramidal or sleep disturbances have been observed, which may eventually occur at very high doses. Interrupting the therapy or reducing the dosage depending on the physician judgment will be sufficient in this case.

### STORAGE:

Store at room temperature (15-30°C) away from the children.

### SHELF LIFE:

Two years in undamaged packing when stored properly.

### PRESENTATION:

Pack of 2×10's capsules in blister packing



Manufactured by:  
ISO 9001-2008 Certified Company  
**Medley Pharmaceuticals**  
41-A, P.S.I.E. Jhang Bahtar Road,  
Wah Cantt- Rawalpindi