

# MOTROL

## COMPOSITION:

Motrol 25mg Tablets

Each tablet contains:

Levosulpiride ..... 25mg

Motrol 50mg Tablets

Each tablet contains:

Levosulpiride ..... 50mg

Motrol 100mg Tablets

Each tablet contains:

Levosulpiride .....100mg

Product conforms to the Manufacturer's Specifications.

## DESCRIPTION:

Levosulpiride is a substituted benzamide, it is a selective antagonist of dopamine D2 receptor activity on both central and peripheral levels. It is an atypical neuroleptic and a prokinetic agent. Chemically it is N-[[[(2S)-(-)-1-ethylpyrrolidin-2-yl]methyl]-2-methoxy-5 sulfamoylbenzamide. It has a molecular formula C<sub>15</sub>H<sub>23</sub>N<sub>3</sub>O<sub>4</sub>S and a molecular weight 341.43.

## PHARMACOKINETICS:

Oral absorption of Levosulpiride is found to be 35% ±5. Plasma protein binding is >40 % and metabolism is reported hepatic. Renal excretion accounts for unchanged 25% and plasma half-life is 8-9 hr.

## INDICATIONS:

Levosulpiride is primarily indicated in conditions like:

- Gastroesophageal Reflux Disease (GERD)
- Irritable Bowel Syndrome (IBS)
- Dyspeptic syndrome (Anorexia, Meteorism, Sense of epigastric tension, Postprandial cephalgia, Pyrosis, Eruptions, Diarrhea and Stipsis)
- Essential Cephalgia (Vasomotoric affections and Muscular tension conditions like nausea and vomiting)
- Vertigo of a Central and/or Peripheral Origin

## DOSAGE & ADMINISTRATION:

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

1 tablet of 50mg 2-3 times per day before meals, according to medical prescription.

1 tablet of 100mg 2-3 times per day before meals, according to medical prescription.

## CONTRAINDICATIONS:

The following are the conditions where the drug should be used cautiously:

- Elderly people
- Children less than 14 years of age
- Parkinson's disease
- Severe renal or hepatic insufficiency
- History of epilepsy



Sign of Health & Care

CONTINUE

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- Porphyrias
- Breast cancer
- Alcohol intoxication
- Certain tumors like pheochromocytoma and pituitary prolactinoma
- Hypokalemia

## WARNINGS:

Drug should not be given to Paediatrics, Cardiac / Hypertensive Patients, Patients suffering from Kidney dysfunction and Neonates. Caution should be exercised in patients with history of Neuroendocrine tumor, Epilepsy, Manic states, Abnormally high levels of prolactin in the blood, painful and lumpy breasts, heart disease and any allergy during pregnancy and breastfeeding.

## PRECAUTIONS:

Levosulpiride (Motrol) 100mg contains Lactose.

## PREGNANCY & LACTATION:

**Pregnancy:** The drug should be used cautiously in pregnancy (only when it is expected to benefit the mother more than the possibility of risking the fetus).

**Lactation:** The drug is known to be secreted in breast milk so, its use should be restricted in nursing mothers.

## DRUG-DRUG INTERACTIONS:

**Antacids and Sucralfate:** They can decrease the absorption of the drug from the intestine. So, these medicines should not be taken along with Levosulpiride. There should be a minimum 2 hour time lag between the two medicines.

**Alcohol:** There is increased chance of sedation.

**Antihypertensive medications:** Concomitant use may enhance the hypotensive effect seen with the drug.

**Anticholinergics:** Increased incidence of anticholinergic side effects.

**Levodopa:** It may oppose the antipsychotic action of the drug, conversely Levosulpiride can decrease the efficacy of Levodopa in the management of Parkinsonism.

Concurrent use of following drugs results in arrhythmia especially prolonged QT interval

- Atomoxetine
- Antiarrhythmics
- Terfenadine
- Chloroquine, Quinine
- Cisapride
- Drugs causing hypokalemia (Corticosteroids, Laxatives, Diuretics like Furosemide)

## ADVERSE DRUG REACTIONS:

The following side effects can occur with the use of this drug:

- Acute muscular dystonia characterized by abnormal movements (twitching, tremor etc.) of hands, legs, tongue and facial muscles.
- Sedation or drowsiness (because of decrease in sensory inputs to reticular activating system)
- Increase in plasma prolactin levels manifested by breast enlargement, production of milk and stopping of menstrual periods.



Sign of Health & Care

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- Neuroleptic malignant syndrome characterized by hyperpyrexia, muscle rigidity, increased myoglobin and creatine kinase; the last
- Postural hypotension (because of autonomic blockade), tolerance develops to this effect after some time.
- Weight gain
- Elevated liver transaminases

## OVER DOSAGE:

In internal medicine neither extrapyramidal nor sleep disturbances have ever been observed, which may eventually occur at very high dosages. Interrupting the therapy or reducing the dosages depending on the physician's judgment will be sufficient in this case.

## STORAGE:

Store in a cool & dry place below 30°C.  
Protect from light, heat and moisture.  
Keep out of reach of children.

## PRESENTATION:

Motrol 25mg tablets are available in a blister pack of 20's.  
Motrol 50mg tablets are available in a blister pack of 20's.  
Motrol 100mg tablets are available in a blister pack of 20's.

