3. ***Smoking:*** increased metabolism of the drug may require higher dose.
4. ***Antihypertensive medications:*** concomitant use may enhance the hypotensive effect seen with the drug.
5. ***Anticholinergics:*** increased incidence of anticholinergic side effects.
6. ***Levo dopa:*** It may oppose the antipsychotic action of the drug, conversely levosulpiride can cause decrease the efficacy of levo-dopa in the management of Parkinsonism.
7. ***Arrhythmia*** especially prolonged QT interval with the concurrent use of

- Atomoxetine
- Antiarrhythmics
- Terfenadine
- Chloroquine, quinine
- Cisapride
- Drugs causing hypokalemia (corticosteroids, laxatives, diuretics like furosemide).

WARNINGS:

• Pregnancy warnings

• Use of this medicine during pregnancy is not recommended unless absolutely necessary. It is advised to use this medicine only when the benefits outweigh the risks involved.

• Breast-feeding warnings

• Use of this medicine by breastfeeding women is not recommended. However, if it is absolutely necessary to use this medicine, then breastfeeding should be discontinued. Consult your doctor before using this medicine.

• Heart disease

should be used with caution in patients having a history of stroke, blood clotting disorders or other ailments of the heart and blood vessels.

• Diabetes

should be used with caution in patients who are suffering from diabetes or are exposed to the risk factors.

• Hypokalemia

should be used with caution in patients having low potassium levels in the body

• Breast cancer

medicine is not recommended for use if the patient is suspected to have breast cancer associated with abnormally high levels of prolactin in the body.

• Drowsiness

This medicine is known to cause moderate to severe drowsiness and may the ability to perform tasks that require a high level of mental alertness.

• Leukopenia

This medicine is not recommended for use in patients who have a decreased white blood cell count characterized by frequent infections, fever with chills, sore throat, and mouth ulcers.

• Use in elderly

This medicine should be used with caution in the elderly as the risk of side effects are increasingly high.

• Menstrual abnormalities

Use of this medicine has been associated with abnormalities in menstrual period. Contact your doctor if the regular periods are excessively delayed.

PRECAUTIONS: Caution should be exercised in patients with history of neuroendocrine tumour, epilepsy, manic states, abnormally-high levels of prolactin in the blood, painful, lumpy breasts, heart disease, any allergy, during pregnancy and breastfeeding. It may cause dizziness or drowsiness, do not drive a car or operate machinery while taking this medication.

ADVERSE REACTIONS : Amenorrhoea, gynaecomastia, galactorrhoea, changes in libido.
Potentially Fatal: Neuroleptic malignant syndrome.

CONTRAINDICATIONS: The following are the conditions where the drug should either be used cautiously or is contraindicated:

- Elderly people
- Children less than 14 years of age
- Parkinson disease
- Severe renal or hepatic insufficiency
- History of epilepsy
- Porphyrias
- Breast cancer
- Alcohol intoxication
- Certain tumors like phaeochromocytoma and pituitary prolactinoma
- Hypokalemia
- 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).
- The drug is known to be secreted in breast milk, so, its use should be restricted in breastfeeding women

OVERDOSAGE : Contact a doctor if an overdose with Levosulpiride 25 mg Injection is suspected. Symptoms of an overdose may include excessive drowsiness, fall in blood pressure, agitation, coma etc.

HOW SUPPLIED : Levosulpiride 12.5 mg/ml, is supplied in: 2 ml amber glass ampoule and 10 ampoule in tray with one monocarton & 10 monocarton pack in one outer along with pack Insert.

Storage: Stored in a cool place below 25°C. Improper storage may deteriorate the product.

Manufactured by:

AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)

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WHO GMP CERTIFIED

For the use only of a registered medical practitioner or a hospital or a laboratory

℞ Levosulpiride Injection

AMERICAN VESOPRIDE Injection

FOR IM/IV USE ONLY

Composition:

Each 2 ml contains:

Levosulpiride		25 mg
Water For Injection	IP	q.s.

Description:

Levosulpiride is the levo enantiomer of sulpiride. It is a substituted benzamide antipsychotic, reported to be a selective antagonist of dopamine D2 receptor activity on both central & peripheral levels. It is an a typical neuroleptic and a prokinetic agent. Levosulpride is also claimed to have mood elevating properties. Chemically it is the stereo enantiomer of levosulpiride. It is physically present as a white crystalline powder.

Mechanism of Action: Levosulpride is an atypical antipsychotic agent that blocks the presynaptic dopaminergic D2 receptors.The preferential binding of the presynaptic dopamine receptors decreases the synthesis and release of dopamine at low doses whereas it causes postsynaptic D2 receptor antagonism at higher dose. This receptor profile of the drug along with its limbic selectivity explains its effectiveness in the management of both positive and negative symptoms of schizophrenia.

Pharmacodynamics: Levosulpiride is a substituted benzamide, which exerts antidopaminergic (selective dopamine D2 receptors) activity on both central and peripheral levels. It is an atypical neuroleptic and a prokinetic agent.

DOSAGE AND ADMINISTRATION: It is advised to take plenty of water while taking this injection. Levosulpiride is used in the treatment of psychosis, depression, frequent persistent heart burn, gastro-oesophageal reflux disease, irritable bowel syndrome, indigestion (dyspepsia). Do not prepare a supply in advance. Dosage is based on your age, medical condition, and response to therapy. It is administered by intramuscular or intravenous route.

Pharmacokinetics and Metabolism: The parent drug is given in a dose of 400-1800 mg orally daily although a much lower dose is effective for producing antidepressant effect (about 50-300 mg).The plasma t1/2 of the drug is about 6-8 hours & 4.3 hr (IV). The drug is chiefly excreted through the renal route

Absorption: Oral bioavailability is about 30%; peak plasma concentrations after about 3 hr.

INDICATION AND USAGE:.

1 ***Psychiatric illness:*** the primary indication of this drug is in the management of both positive and negative symptoms of schizophrenia. It is also used in patients of depression.

2 ***Burning mouth syndrome:*** Burning mouth syndrome (BMS) is a condition of a burning sensation in the mouth in the absence of any underlying medical or dental cause. The pain is predominantly localized to tongue or lips with minimal oral signs. Levosulpiride at a dose of 100 mg/day demonstrated beneficial effect (decreased burning or stinging oral sensation) in BMS.

3. ***Acute unilateral labyrinthine dysfunction:*** Levosulpride has been shown to induce recovery in unilateral labyrinthine dysfunction. When the drug was administered at a dose of 25 mg three times a day for a period of 10 days, it produced lesser residual labyrinthine dysfunction and reduction in the recurrence of attacks.

4. ***Cataplexy:*** Animal studies have demonstrated the beneficial effects of levosulpiride in the management of cataplexy without much adverse effects. Another advantage with the use this drug is non reduction of the REM sleep.

5. ***Premature ejaculation:*** Premature ejaculation is defined as a failure of the normal voluntary control over ejaculation. It is usually managed with the use of antidepressants and other adjuvant drugs. Dopamine has been shown to be facilitate sexual arousal and in decreasing ejaculatory threshold. So, levosulpiride being a dopamine antagonist may be responsible for the beneficial effect by this mechanism.

6. **Several indications:** depression, psychosis, somatoform disorders, emesis and dyspepsia.

Side effects

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

- Acute muscular dystonia characterized by abnormal movements (twitching, tremor etc.) of hands, leg, 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.
- Neuroleptic malignant syndrome (characterized by hyperpyrexia, muscle rigidity, increased myoglobin and creatine kinase;) the last two suggestive of muscle damage.
- Akathisia (uncontrollable desire to move about without any anxiety).
- Tardive dyskinesia, it occurs late in the therapy and its features include involuntary rhythmical movements of face, mouth and jaw. This causes a decrease in cholinergic activity in the striatum followed by decrease in GABA release. This decreased in inhibitory GABA is responsible for increased involuntary motor activity.
- Postural hypotension (because of autonomic blockade), tolerance develops to this effect after some time.
- Weight gain.
- Elevated liver transaminases.

Drug interactions

1. ***Antacids and Sucralfate:*** They can decrease the absorption of the drug from the intestine. So, these medicines should not be taken along with levosulpiride
2. ***Alcohol :*** there is increased chance of sedation.