UNILAB

LEVODROPROPIZINE

LEVARE® 60 mg Tablet

Cough Suppressant

FORMULATION
Each tablet contains:
Levodropropizine.....60 mg

PRODUCT DESCRIPTION
Levodropropizine (Levare) 60 mg is a white, round tablet.

PHARMACODYNAMICS
Levodropropizine, the S-isomer of dropropizine, has a predominant peripheral antitussive action which acts by inhibiting the sensory C-fiber activation and the release of neuropeptides. It is a cough sedative with bronchial muscle relaxant action, thus improving pulmonary ventilation. However, it is exempted from secondary reactions of central antitussive action.

PHARMACOKINETICS
Levodropropizine is rapidly absorbed after oral administration and peak plasma concentration occurred within 40 minutes. The bioavailability of levodropropizine is more than 75%.
Levodropropizine is 11 to 14% bound to plasma proteins.
It is unknown whether levodropropizine is metabolized in the liver.
The plasma elimination half-life of levodropropizine is 1 to 2 hours. Approximately 35% of levodropropizine is excreted unchanged in the urine within 48 hours.

INDICATION
For the symptomatic relief of cough.

DOSAGE AND MODE OF ADMINISTRATION
Adults and Children 12 years and older: 1 tablet. Or, as prescribed by a physician.
- Levodropropizine should be taken orally, 3 times a day with at least 6-hour intervals, in between meals.
- This medicine should not be taken for more than 7 days. If symptoms persist after this period, the treatment should be stopped and a physician should be consulted.

CONTRAINDICATIONS
- Hypersensitivity to levodropropizine or to any component of the product
- Patients with bronchorrhea and reduced mucociliary function (e.g., Kartagener syndrome or bronchial cilia dyskinesia)
- Severe hepatic impairment
- Pregnancy
- Breastfeeding

WARNINGS AND PRECAUTIONS
Coexisting Conditions: Levodropropizine should be administered with caution in patients with severe heart failure, diabetes, and severe renal impairment (creatinine clearance < 35 mL/min).
Effects on Ability to Drive and Use Machines: Levodropropizine may cause somnolence, dizziness, and vertigo. Patients should exercise caution when driving vehicles or operating machinery.

INTERACTIONS WITH OTHER MEDICAMENTS
Benzodiazepines: No interaction has been observed between benzodiazepines (e.g., alprazolam, diazepam, clonazepam) and levodropropizine. However, caution should be exercised when concomitantly administered in sensitive patients.

STATEMENT ON USAGE FOR HIGH RISK GROUPS
Pregnancy: There are no adequate and well-controlled studies in pregnant women. Levodropropizine should not be used during pregnancy.
Lactation: Levodropropizine is excreted in breast milk. Therefore, it is not recommended in breastfeeding women.
Children: The safety and efficacy of levodropropizine have not been established in children below 2 years old.

UNDESIRABLE EFFECTS
The most frequently reported adverse effect with levodropropizine is somnolence.
Immune system disorders: Allergic skin reaction, angioedema, hypersensitivity reaction
Metabolism and nutrition disorders: Generalized edema, hypoglycemia
Psychiatric disorders: Depersonalization, nervousness, stupor
Nervous system disorders: Coma, clouding of consciousness, dizziness, epilepsy, faint, headache, hypoglycemic coma, impaired consciousness, paresthesia, tremors, vertigo
Eye disorders: Bilateral blindness, mydriasis, palpebral edema, temporary loss of vision
Cardiac disorders: Arrhythmia, palpitations, tachycardia
Vascular disorders: Hypotension
Respiratory, thoracic and mediastinal disorders: Cough, dyspnea, pulmonary edema
Gastrointestinal disorders: Abdominal distress, abdominal discomfort, aphthous fever, diarrhea, dyspepsia, glossitis, heartburn, nausea, vomiting
Hepatobiliary disorders: Cholestatic hepatitis
Skin and subcutaneous tissue disorders: Epidermolysis, erythema, exanthema, itching, urticaria
Musculoskeletal and connective tissue disorders: Hypotonia
General disorders and administration site conditions: Asthenia, exhaustion, fatigue, malaise, irritability, weakness

OVERDOSE AND TREATMENT
There is limited information on levodropropizine overdose. No significant side effects have been reported after a single dose administration of up to 240 mg and multiple administration (thrice a day) of up to 120 mg for 8 consecutive days.
In cases of overdose, symptomatic and supportive treatment should be given.

STORAGE CONDITIONS
Store at temperatures not exceeding 30°C.
Keep the product out of sight and reach of children.

AVAILABILITY
Alu/PVC blister pack x 10 tablets (box of 100 tablets)

CAUTION: Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

Manufactured by Sinil Pharmaceutical Co., Ltd.
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For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at +632-8-**UNILAB**-1 (+632-8-**864522**-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph.

By reporting undesirable effects, you can help provide more information on the safety of this medicine.

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