LORATADINE PHENYLEPHRINE HCl

LORAPED®

5 mg/5 mg per 5 mL Syrup
Antihistamine/Nasal Decongestant

FORMULATION
Each 5 mL (1 teaspoonful) syrup contains:

Loratadine	5 mg
Phenylephrine HCl	5 mg

PRODUCT DESCRIPTION
Loratadine + Phenylephrine HCl (Loraped®) Syrup is a clear to slightly yellow-colored syrup with strawberry-mint odor and taste.

WHAT IS IN THE MEDICINE?
This medicine contains Loratadine and Phenylephrine HCl.
Loratadine, an anti-allergy, blocks the action of naturally occurring histamine, a substance that causes allergic symptoms. Loratadine is less likely to cause drowsiness and dizziness than the older class of anti-allergy medicines. Phenylephrine HCl, a nasal decongestant, clears obstructed air passages and nasal sinuses due to congestion making breathing easier. It also reduces postnasal drip.

STRENGTH OF THE MEDICINE
See Formulation.

WHAT IS THE MEDICINE USED FOR?
This medicine is used for the relief of clogged nose; sneezing; runny, itchy nose; and itchy, watery eyes associated with allergic rhinitis.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
This medicine should be taken orally (by mouth) every 12 hours, or, as directed by a doctor.

Children 2 years and older:

Body weight 30 kg or less	2.5 mL (1/2 teaspoonful)
Body weight more than 30 kg	5 mL (1 teaspoonful)

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
Do not give this medicine if the child:
- Is allergic to any ingredient in the product
- Is taking medicines for depression
- Has high blood pressure or severe heart disease

UNDESIRABLE EFFECTS
The following undesirable effects have been reported:

Loratadine
- Dizziness or drowsiness
- Insomnia/sleeplessness
- Nervousness
- Headache
- Increased or decreased blood pressure
- Palpitation (rapid and irregular pulse)
- Tachycardia (fast heart rate)
- Fatigue (excessive tiredness)
- Abdominal pain
- Diarrhea
- Nausea
- Vomiting
- Epistaxis (nose bleed)
- Dry mouth
- Sore throat
- Rash

Phenylephrine HCl
- Tremor (muscle shaking)
- Restlessness
- Anxiety (feeling of uneasiness)
- Insomnia/sleeplessness
- Nervousness
- Dizziness
- Increased blood pressure
- Palpitation
- Arrhythmia (irregular heart beat)
- Weakness

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Do not use this product together with medicines for depression (e.g., Amitriptyline, Imipramine, Sertraline, Moclobemide), sympathomimetic agents (e.g., Epinephrine) and general anesthetics (e.g., Halothane) because of the possibility for increased toxicity.
Taking an adrenergic-blocking agent (e.g., Phentolamine, Phenothiazine, Propranolol) before the administration of this product may decrease the effect of Phenylephrine.
Tell your doctor about the other medicines the child is taking, especially other medicines for cough, cold and allergy.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If the child misses a dose, just give the next dose if still needed for the condition being treated, and the subsequent doses at the recommended time or schedule (i.e., every 12 hours).
Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

Keep the product out of reach and sight of children.

Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Loratadine • Drowsiness • Headache • Decreased blood pressure • Tachycardia • Palpitation	• Extrapyramidal manifestations or movement disorders such as involuntary movements, tremors and rigidity, body restlessness, muscle contractions, and changes in breathing and heart rate • Nausea • Vomiting
Phenylephrine HCl • Increased blood pressure • Headache • Seizure	• Palpitation • Paresthesia (sensation of tingling, pricking, or numbness of the skin) • Vomiting

WHAT TO DO IF YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If the child has taken more than the recommended dosage, consult a doctor or contact a Poison Control Center right away, even if the child seems well.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

This medicine should be given with care to patients with kidney or liver disease including patients taking other drugs that affect the liver.
Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

- Before giving this medicine, tell your doctor if the child has:
  - High blood pressure or any type of heart problems
  - Glaucoma
  - Thyroid problems
  - Diabetes
  - Liver or kidney disease
  - Bladder problems or difficulty urinating
- If symptoms do not improve or new symptoms appear.

AVAILABILITY

Loratadine + Phenylephrine HCl (Loraped®) Syrup in amber bottle of 60 mL.

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): November 2013

Manufactured by
AMHERST LABORATORIES, INC.
UNILAB Pharma Campus, Barangay Mamplasan
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