PROTUSS

(Levodropropizine)

30 mg / 5 ml syrup

Antitussive

پروٹس شربت

(لیووڈروپروپائیزین)

FORMULATION

Each 5 ml contains:

Levodropropizine (BP) ..... 30 mg

Product Complies Kaizen Specs.

Levodropropizine is new compound with an essentially peripheral action on the tracheobronchial tree.

INDICATIONS

For the symptomatic treatment of annoying and debilitating cough of any etiology. Pre-and post-op cough suppression for surgical procedure and bronchoscopy, smokers' cough primary and metastatic lung cancer cough.

DOSAGE AND ADMINISTRATION

• Individual and daily dosages for adults and children over 24 months measuring cup with markers for 3 ml, 5 ml and 10 ml are included in the package.

• **Adults and children over 12 years of age:** 2 teaspoonful (10 ml) (equivalent to 60 mg of levodropropizine) up to 3 times daily at intervals of at least 6 hours.

• **Children over 2 years of age:** The pediatric dose is 1 mg/kg 3 times daily, for a total daily dose of 3 mg/kg at intervals of at least 6 hours.

For convenience, the following approximate dosages can be used:

10-20 kg body weight: 3 ml up to 3 times daily

20-30 kg body weight: 5 ml up to 3 times daily

The preparation is administered orally.

The medication should be taken between meals, since the effect of concomitant food consumption has not yet been determined.

TREATMENT DURATION

The treatment should be taken until the cough clears up, or as directed by the physician, for a period not to exceed seven days. If symptoms persist after this period, treatment should be stopped and a physician should be consulted.

DRUG INTERACTIONS

No interactions with benzodiazepines were observed during clinical trials, however, care should be taken when sedative drugs are simultaneously administered to particularly sensitive individuals.

WARNING AND PRECAUTIONS FOR USE

• Care should be taken for patients with serious renal insufficiency.

• Notice to diabetics: 10 ml of **PROTUSS** contains 3.5 g sucrose (equal to 0.3 bread units).

• The safety and efficacy of levodropropizine in children less than 24 month has not yet been established.

• Drivers of vehicles and machine operators are warned of the possibility of drowsiness with the use of this drug.

SIDE EFFECTS

The following side effects sometimes occur:

• Gastrointestinal tract

- nausea
- vomiting
- heartburn
- abdominal discomfort
- diarrhea

• Central nervous system

- exhaustion, faintness
- somnolence, clouding of consciousness (stupor) - numbness
- dizziness
- headache

• Cardiovascular system

- palpitations

• Hypersensitivity reactions may occur in predisposed patients because **PROTUSS** contains parabens.

• Allergic skin reactions were observed in very rare cases.

• Consult your physician or the pharmacist in the event other side effects appear.

PRESCRIPTION STATUS

This product is sold only with a physician's prescription.

ATTENTION: Do not use the drug after the expiration date indicated on the box. • Store below 30°C in a dry place, protect from light. • Keep out of the reach of children.

AVAILABILITY: 120 ml, 60 ml (30 mg / 5 ml syrup)

Manufactured by:
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