HOSEDYL DM COUGH LINCTUS

VIHOS10-var

DESCRIPTION
Brown, plum flavoured, viscous liquid.

COMPOSITION
Each 5 ml contains:

Promethazine Hydrochloride	3.6 mg
Dextromethorphan Hydrobromide	15.0 mg

ACTIONS AND PHARMACOLOGY
Promethazine, a phenothiazine derivative, is a sedating antihistamine with antimuscarinic, significant sedative, and some serotonin-antagonist properties. It is usually given as the hydrochloride or teoclate. Promethazine hydrochloride has anticholinergic actions of most antihistamines which provide a drying effect on the nasal and oral mucosa.

Dextromethorphan hydrobromide is a cough suppressant used for the relief of non-productive cough. It has a central action on the cough centre in the medulla. It is also an antagonist of N-methyl-D-aspartate (NMDA) receptors. Dextromethorphan has no classical analgesic properties and little sedative activity.

PHARMACOKINETICS
Promethazine is well absorbed after oral administration. Peak plasma concentrations have been observed 2 to 3 hours after administration. Onset of action occurs 15 to 60 minutes after oral administration and may have the duration of action from 4 to 12 hours. Promethazine crosses the blood-brain barrier and the placenta, and is distributed into breast milk. Values ranging from 76 to 93% have been reported for plasma-protein binding. It is excreted slowly via the urine and bile. Elimination half-lives of 5 to 14 hours have been reported.

Dextromethorphan hydrobromide is rapidly absorbed from the gastrointestinal tract. It is metabolized in the liver excreted in the urine as unchanged dextromethorphan and demethylated metabolites including dextrorphan. It is reported to act within half an hour of administration by mouth and to exert an effect for up to 6 hours.

INDICATIONS
For short term symptomatic relief of troublesome non-productive cough and common cold, particularly at night.

CONTRAINDICATIONS
This medication is contraindicated with patients with sensitivity to promethazine and dextromethorphan or other components of the formulation.

The presence of other medical problems may affect the use of this medication. A doctor should be consulted before using this medicine if any other medical problems exist, especially: bladder neck obstruction, symptomatic prostatic hypertrophy, urinary retention, bone marrow depression, cardiovascular disease, coma, glaucoma, jaundice, Reye's syndrome, asthma, chronic bronchitis, productive cough, emphysema, diabetes, hepatic function impairment and respiratory depression.

WARNING AND PRECAUTIONS
- Caution should be exercised to patients sensitive to promethazine or to other phenothiazine medications.
- **For pediatrics:** Use of promethazine is not recommended in newborn or premature infants because this age group has an increased susceptibility to anticholinergic side effects, such as central nervous system (CNS) excitation, and an increased tendency toward convulsions.
- This product contains promethazine hydrochloride. It should not be used in pediatric patients less than 2 years of age because of the potential for fatal respiratory depression.
- **For adolescents:** Promethazine should not be used in adolescents with signs and symptoms suggestive of Reye's syndrome since extrapyramidal symptoms may occur.
- **For geriatrics:** Dizziness, sedation, confusion, hypotension and paradoxical reaction may be more likely to occur in geriatric patients taking promethazine.
- Prolonged use of promethazine may decrease or inhibit salivary flow. Involuntary orofacial muscle movements may result from extrapyramidal effects.
- To be use with caution and doctor's advice in children 2 to 6 years of age.

Dextromethorphan should not be given to patients at risk of developing respiratory failure and caution is needed in patients with a history of asthma and should not be given during an acute attack.

** This medicine may cause drowsiness and dizziness, less alert than normal or to feel a false sense of well being. Patients should know how they react to this medicine before they drive, use machines or doing anything that could be dangerous if they are dizzy or are not alert and clearheaded. Children should be supervised to avoid potential harm in bike riding or other dangerous activities.*

USE IN PREGNANCY AND LACTATION
This medication should not be taken by pregnant patients especially during the 2 weeks before delivery to avoid possible inhibition of platelet aggregation in newborn. Jaundice and extrapyramidal effects also may occur in infants.

This medication is not recommended for nursing mothers because of adverse effects like unusual excitement or irritability in infants. The nursing infants may be associated with the sudden infant death syndrome (SIDS) and an increase in sleep apnea. Promethazine may also inhibit lactation because of their anticholinergic actions.

MAIN SIDE / ADVERSE EFFECTS

The side effects with this medication appear to be rare and may include drowsiness, blood dyscrasias, dizziness, gastrointestinal disturbances and other common side effects of sedating antihistamines like headache, confusion, difficult or painful urination, dryness of mouth, nose or throat, hypotension, increased sweating, loss of appetite, paradoxical reaction, photosensitivity, ringing or buzzing in ears, skin rash and tachycardia.

DRUG INTERACTIONS

Concurrent use of this medication with combination products containing any of the following medications, may interact with promethazine and dextromethorphan: alcohol or central nervous system (CNS) depressants, anticholinergic medications, epinephrine, extrapyramidal reaction-causing medication, levodopa, intrathecal metrizamide, monoamine oxidase (MAO) inhibitors including furazolidone, phenelzine, procarbazine, selegiline and tranylcypromine; other enzyme inhibitors like amiodarone or fluoxetine or quinidine; and smoking tobacco.

The diagnostic test results for the following laboratory tests may be affected in patients receiving promethazine: Glucose tolerance test, Immunologic urine pregnancy tests and skin tests using allergen extracts.

OVERDOSE

Symptoms of overdose:
Anticholinergic effects, CNS depression (severe drowsiness), CNS stimulation, extrapyramidal effects, severe hypotension, ataxia, blurred vision, coma, confusion, drowsiness or dizziness, respiratory depression, severe nausea or vomiting, severe unusual excitement, nervousness, restlessness or irritability and urinary retention.

Treatment for overdose:
Treatment is symptomatic and supportive with possible utilization of the following:

- induction of emesis and gastric lavage to decrease absorption.
- saline cathartics (milk of magnesia) are sometimes used to enhance elimination.
- assisted respiration, vital sign monitoring and intravenous naloxone.

DOSAGE AND ADMINISTRATION

Oral.

Adult and children over 12 years:
5 - 10 ml (1 to 2 teaspoons), 3 to 4 times daily, not to exceed 40 ml in a day.

Children 6 to 12 years:
2.5 - 5 ml ($^1/_2$ to 1 teaspoon), 3 to 4 times daily, not to exceed 20 ml in a day.

Children 2 to 6 years:
1.25 - 2.5 ml ($^1/_4$ to $^1/_2$ teaspoon), 3 to 4 times daily, not to exceed 10 ml in a day. It is also advised that the dose of promethazine for this age group be under the direction of a doctor.

Children below 2 years:
Not recommended.

Patients are advised to use a calibrated measuring device as 5 ml is a rough approximation of one teaspoon and different teaspoons differ in their volume.

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

Storage: Store below 30°C. Protect from light.
Presentation/Packing: Bottle of 60ml and 120 ml

Product Registration Holder / Manufactured by: HOVID Bhd.
121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

Revision date: March 2025