

HOSEDYL DM COUGH LINCTUS

Dextromethorphan Hydrobromide/Promethazine Hydrochloride (15mg/3.6 mg per 5 ml)

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What Hosedyl DM is used for

It is used for the short term symptomatic relief of non-productive cough and common cold, particularly at night.

How Hosedyl DM works

This medicine contains promethazine hydrochloride and dextromethorphan hydrobromide as the active ingredients.

Dextromethorphan hydrobromide is a cough suppressant. It inhibits the signals in the brain that causes cough.

Promethazine is an antihistamine. Promethazine blocks the effects of the naturally occurring chemical histamine in your body. It has anticholinergic action that provides drying effect on the nasal and oral mucosa.

Before you use Hosedyl DM

- When you must not use it

Do not take this medicine if:

- you are allergic to dextromethorphan, promethazine or any of the ingredients listed at the end of this leaflet.
- you are at risk of developing respiratory failure
- you are having acute asthma attack
- you are breastfeeding or plan to breastfeed
- you are pregnant, think you are pregnant, or plan to get pregnant.

Do not give this medicine to children under 2 years of age.

Do not give this medicine to teenagers with signs and symptoms suggestive of Reye's syndrome (fatal disease that

affects brain and liver especially). The common symptoms are unusual sleepiness, heavy and persistent vomiting and liver damage.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

- Before you start to use it

Tell your doctor/pharmacist if:

- you have allergies to any other medicines, foods, dyes or preservatives
- you have problem urinating
- you have symptomatic prostatic hypertrophy (enlargement of prostate)
- you have bone marrow depression
- you have heart disease
- you have coma
- you have eye disorder called glaucoma (increased pressure inside the eye)
- you have yellowing of the skin (jaundice)
- you have Reye's syndrome
- you have lung disease which includes symptoms such as shortness of breath, wheezing and cough that produces sputum
- you have respiratory depression (inadequate ventilation)
- you have history of asthma
- you have liver problem
- you have diabetes

Consult your doctor before using this medicine in children 2 to 6 years of age

Use in elderly

Elderly taking promethazine are more likely to experience dizziness, sedative, confusion, low blood pressure and paradoxical reaction (an opposite effect to that which would normally be expected from a medicine)

Use in children

Not recommended in newborn or premature infants as they are more susceptible to effects such as excitation and increased tendency towards convulsions.

Pregnancy and breastfeeding

This medication should not be taken during pregnancy especially 2 weeks before delivery to avoid inhibition of platelet aggregation (prevent blood clotting).

It is not recommended in breastfeeding because of adverse effects like unusual excitement or irritability in infants. Promethazine may inhibit lactation.

- Taking other medicines

Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtained without a prescription.

Tell the doctor if you are taking the following medicines:

- alcohol
- central nervous system (CNS) depressants
- monoamine oxidase (MAO) inhibitors including furazolidone, phenelzine, procarbazine, selegiline and tranylcypromine
- other enzyme inhibitors like amiodarone or fluoxetine or quinidine
- anticholinergics medications
- epinephrine
- levodopa (to treat Parkinson's disease)
- intrathecal metrizamide
- medication that causes extrapyramidal effects (e.g. haloperidol, metoclopramide, tricyclic antidepressants)

Tell the doctor that you are taking Hosedyl DM if you are going to perform the following laboratory tests:

- glucose tolerance test
- immunologic urine pregnancy tests
- skin tests using allergen extracts

Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to use Hosedyl DM

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not

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understand the instructions on the label, ask your doctor or pharmacist for help.

Oral

Adults 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- 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 - 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.

You 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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

You are advised to take Hosedyl DM as long as your doctor tells you to.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much may cause restlessness, nervous or irritable, severe unusual excitement, severe drowsiness, dizziness, dry mouth, large pupils, flushing, nausea, vomiting, shallow breathing, and fainting, severe low blood pressure, blurred vision, coma, confusion, movement disorders, uncoordinated movement, insufficient ventilation and urinary retention

While you are using Hosedyl DM

- Things you must do

Tell your doctor:

- If you experience allergic reactions/ any of the unwanted side effects while taking the medicine.
- If you become pregnant while taking this medication

Tell all the doctors, dentists and pharmacists treating you that you are taking Hosedyl DM.

Take your medicine exactly as your doctor has told you.

- Things you must not do

Do not:

- give your medicine to anyone else even if they have the same condition as you
- take your medicine to treat any other complaints unless you are told by your doctor or pharmacist
- take more than the recommended dose unless your pharmacist or doctor tells you to
- stop taking the medicine unless advised by your doctor.

- Things to be careful of

Be careful when driving or operating machinery because Hosedyl DM may make you feel drowsy, dizzy or less alert. You should know how you react to this medicine before you do anything that could be dangerous. Children should be supervised to avoid potential harm in bike riding or other dangerous activities.

Side effects

Like all medicines, Hosedyl DM can cause side effects, although not

everybody gets them. These effects can be serious.

Tell your doctor if you think you are experiencing any of the following possible side effects while taking the medicine.

Common side effects:

- skin rash
- dizziness
- headache
- drowsiness
- confusion
- increased sweating
- ringing in your ears
- dry mouth, nose or throat
- blood disorder called blood dyscrasias
- difficult or painful urination
- low blood pressure
- loss of appetite
- paradoxical reaction (effects opposite to the expected effect of Hosedyl to relieve cough)
- sensitive to light
- abnormal increase of heart rate

Other unwanted side effects not listed may occur. Tell your doctor immediately if you experience any side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)

Storage and disposal of Hosedyl DM

- Storage

Keep out of reach of children.

Store below 25°C. Protect from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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Product description

- What it looks like

Brown, plum flavoured, viscous liquid

- Ingredients

- Active ingredients

Each 5 ml contains:

Promethazine HCl 3.6 mg

Dextromethorphan HBr 15 mg

- Inactive ingredients

Propylene Glycol

Syrup Simplex

Methyl Hydroxybenzoate

Propyl Hydroxybenzoate

Saccharin Sodium

Purified Water

Glycerine

Malic Acid

Potassium Citrate

Caramel Liquid

Plum Essence

Liquid Glucose

Citric acid

- MAL Number:

MAL05051077A

Manufacturer

HOVID Bhd.

121, Jalan Tunku Abdul Rahman,

30010 Ipoh, Malaysia.

Product Registration Holder

HOVID Bhd.

121, Jalan Tunku Abdul Rahman,

30010 Ipoh, Malaysia.

Date of revision

19/10/2015

Serial Number

BPFK(R4/1)130815/00245