

PHARMANIAGA DEXTROMETHORPHAN COMPOUND

Dextromethorphan Hydrobromide/ Promethazine Hydrochloride (15mg/4mg per 5ml)

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What Pharmaniaga Dextromethorphan Compound is used for

Pharmaniaga Dextromethorphan Compound is indicated for the temporary relief of coughs and upper respiratory symptoms associated with allergy or common cold.

How Pharmaniaga Dextromethorphan Compound works

Dextromethorphan is an antitussive (cough suppressant) agent. It acts on the cough center in the brain and elevates the threshold for coughing.

Promethazine is an antihistamine which blocks the effects of the naturally occurring chemical in the body known as histamine. It also provides a drying effect on the nasal and oral mucosa.

Before you take Pharmaniaga Dextromethorphan Compound

-When you must not take it

- Do not take Pharmaniaga Dextromethorphan Compound if you are allergic to any medicine containing dextromethorphan or promethazine.
- Do not use dextromethorphan and promethazine if you have asthma or other lung disease.
- Do not use this medicine if you are receiving monoamine oxidase inhibitor (MAOI) therapy used to treat depression
- Do not use if you are known to be hypersensitive to bisulphites as this preparation contains sodium metabisulphite.

This product contains Promethazine hydrochloride. It should not be used in paediatric patients less than 2 years of age because of the potential for fatal respiratory depression. Use carefully and follow the advice from doctor or pharmacist for children aged 2 to 6 years.

-Before you start to take it

Before taking dextromethorphan and promethazine, tell your doctor if you are allergic to any medicines. Before taking dextromethorphan and promethazine, tell your doctor if you have:

- epilepsy or another seizure disorder
- sleep apnea (breathing stops during sleep)
- a stomach ulcer or digestive obstruction

If you have any of these conditions, you may not be able to use dextromethorphan and promethazine, or you may need a dosage adjustment or special tests during treatment. Dextromethorphan should be used with caution in atopic children (children with itchy skin).

Pregnancy and breastfeeding

This medication may be harmful to an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant during treatment. Small amount of antihistamines may be distributed into breast milk causing adverse effect such as unusual excitement or irritability in infants. Antihistamines may also inhibit production of breastmilk. Do not use dextromethorphan and promethazine without telling your doctor if you are breast-feeding a baby.

Paediatrics

Use is not recommended in children under 2 years of age due to the central nervous system (CNS) side-effects and an increased tendency towards convulsions caused by promethazine.

Geriatrics

Dizziness, sedation, confusion and low blood pressure may be more likely to occur in elderly taking antihistamines. The elderly are especially susceptible to the anticholinergic side-effects of promethazine such as dryness of the mouth and urinary retention (especially in males). If these side-effects occur and continue or are severe, the medication should be discontinued.

-Taking other medicines

Tell your doctor or pharmacist any medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Talk to your doctor or pharmacist before taking **Pharmaniaga Dextromethorphan Compound** if you are taking any particularly alcohol or other CNS depressants (including narcotic analgesics, sedatives, hypnotics and tranquilizers), anticholinergics, epinephrine (treat severe allergic reaction), levodopa (treatment of Parkinson disease) or monoamine oxidase (MAO) inhibitors.

How to use **Pharmaniaga Dextromethorphan Compound**

Take this medication exactly as it has been prescribed by your doctor. Do not use the medication in larger amounts, or use it for longer than recommended. Follow the directions on your prescription label.

Always ask a doctor before giving cough or cold medicine to a child. Death can occur from the misuse of cough or cold medicine in very young children.

Measure the liquid form of this medicine with a special dose-measuring spoon or cup, not a regular table spoon. If you do not have a dose-measuring device, ask your pharmacist for one.

-How much to use

Adults: 10 mL every six to eight hours.

Maximum of 40 mL daily

Children:

6-12 years: 5mL every six to eight hours. Maximum of 20 mL daily.

2-6 years: 2.5 mL every six to eight hours. Maximum 10 mL daily.

Children under 2 years: use is not recommended.

When to use it

Every 6 – 8 hour daily.

-How long to use it

Cough or cold medicine is usually taken only for a short time until your symptoms clear up.

-If you forget to use it

Since cough and cold medicine is usually taken only as needed, you may not be on a dosing schedule. If you are taking the medication regularly, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time. Do not take extra medicine to make up the missed dose.

-If you take 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.

Symptoms of a dextromethorphan and promethazine overdose may include low blood pressure, excitement, mental confusion, nightmares, severe drowsiness, dizziness, dry mouth, large pupils, flushing, nausea, vomiting, shallow breathing, and unconsciousness.

While you are using **Pharmaniaga Dextromethorphan Compound**

-Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking **Pharmaniaga Dextromethorphan Compound**.

- Tell your doctor immediately if you become pregnant while taking this medication.

Talk to your pharmacist or doctor if your symptoms do not improve. Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

-Things you must not do

Avoid drinking alcohol. It can increase some of the side effects of dextromethorphan and promethazine.

Do not use any other over-the-counter cough, cold, or allergy medication without first asking your doctor or pharmacist. Dextromethorphan is contained in many medicines available over the counter. If you take certain products together you may accidentally take too much of this medicine. Read the label of any other medicine you are using to see if it contains dextromethorphan.

-Things to be careful of

This medication can cause drowsiness or may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be awake and alert. Children should be supervised to avoid potential harm in bike riding or in other hazardous activities.

Avoid drinking alcohol. It can increase some of the side effects of dextromethorphan and promethazine.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the times they are not. Your doctor or pharmacist has weighed the risk of using this medicine against the benefit they expect it will have for you. Some of the side-effects include:

- dizziness, drowsiness, sleepiness, or confusion
- thickening of mucous
- difficult or painful urination
- increased sweating
- loss of appetite
- skin rash
- increased heart rate
- blurred vision
- dry mouth, nose or throat
- ringing in your ears
- nausea or vomiting

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

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 Dextromethorphan Compound

-Storage

Keep container tightly closed. Protect from light.

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the outer bottle.

Do not store above 25°C.

-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.

Product description

-What it looks like

Clear brown syrup.

-Ingredients:

-Active ingredient:

Each 5 mL of Pharmaniaga Dextromethorphan Compound

contains Dextromethorphan hydrobromide 15 mg and Promethazine HCl 4 mg,

-Inactive ingredients:

Refined Sugar, Menthol Crystals
Caramel, Xanthum Gum
Sodium Citrate, Sodium Metabisulfite, Citric Acid Anhydrous, Raspberry Flavour
Ascorbic Acid, Purified Water, Glycerin, Sodium Benzoate, Sodium Sulphite, Peppermint Oil

-MAL NO:

MAL19986509A

Manufacturer:

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1,
Kawasan Perusahaan Bangi,
43650 Bandar Baru Bangi,
Selangor Darul Ehsan,
Malaysia.

Product Registration Holder:

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