

# PROMEDYL DM LINCTUS

Dextromethorphan hydrobromide/Chlorpheniramine maleate/Pseudoephedrine hydrochloride (15mg/2mg/30mg per 5ml)

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## What Promedyl DM Linctus is used for

Promedyl DM Linctus is used for the relief of dry irritating cough and nasal (nose) congestion.

## How Promedyl DM Linctus works

Dextromethorphan hydrobromide is a cough suppressant used for the relief on non-productive cough. It has a central action on the cough centre in the brain). Although structurally related to morphine, dextromethorphan has no classical analgesic (pain relief) properties and little sleep induce properties.

Chlorpheniramine maleate is an antihistamine which works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. It also helps to dry up the nasal lining.

Pseudoephedrine hydrochloride, a decongestant which works by reducing the swelling of blood vessels inside your nose. This helps to open up your nasal airway, making breathing easier.

## Before you use Promedyl DM Linctus

### - *When you must not use it*

Do not take Promedyl DM Linctus if you:

- are allergic to any medicine containing dextromethorphan, chlorpheniramine maleate, pseudoephedrine hydrochloride or any ingredients of this product.
- have heart disease.
- Have severe high blood pressure.
- are receiving monoamine oxidase inhibitors (MAOIs- medicines used to treat depression) therapy

When Promedyl DM Linctus is used for treatment of cough and cold, it is not to be used in children less than 2 years of age. It is needed to be used with caution and doctor's or pharmacist's advice in children 2 to 6 years of age.

Dizziness, sedation, confusion and low blood pressure may be more likely to occur in elderly people. Elderly people are more susceptible to the anticholinergic effects such as dry mouth and urinary retention (especially in males). If these side effects occur and continue or are severe, medications should probably be discontinued.

Do not take this medicine if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

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

### - *Before you start use it*

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you are sensitive to one antihistamines or similar medicines, you may be sensitive to others.

### *Pregnancy and breastfeeding*

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding. Antihistamines may cause excitement and irritability in nursing infant.

Care must be taken for the fetus or newborn infant, especially with high dose and/or long term usage.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

Tell your doctor if you have or have had any of the following medical conditions:

- asthma or other breathing problems
- bladder neck obstruction
- liver, kidney or heart disease
- glaucoma (high pressure in the eyes)
- pyloroduodenal obstruction (blockage of the junction between stomach and the first part of small intestine)
- stenosing peptic ulcer (scarring and swelling due to ulcers causes narrowing in the duodenum and gastric outlet obstruction.)
- enlarged prostate
- diabetes
- overactive thyroid gland

If you have not told your doctor about any of the above, tell him/her before you start taking Promedyl DM Linctus.

### - *Taking other medicines*

Tell your pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Promedyl DM Linctus may interfere with each other. These include:

- medicines to treat depression such as maprotiline, tricyclic antidepressants or monoamine oxidase inhibitors (MAOIs) including furazolidone and procabazine.
- anticholinergics

You need to report occurrence of gastrointestinal problems promptly since paralysis of intestinal muscle may occur with concurrent therapy.

These medicines may be affected by Promedyl DM Linctus or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

### How to use Promedyl DM Linctus

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 understand the directions on your prescription bottle, ask your pharmacist, nurse or doctor to explain the instructions to you.

To ensure that you get a correct dose, measure the liquid mixture with a special dose-measuring spoon or cup, not with a regular household spoon. If you do not have a dose-measuring device, ask your pharmacist where you can get one.

#### - How much to use

*Children under 2 years:*

Not recommended.

*Children 2 to 5 years:*

2.5ml three times daily.

*Children 6 to 12 years:*

5ml three times daily.

*Adults:*

10ml three times daily.

#### - When to use it

Medication should be taken with food, water or milk to minimize irritation. Drink a glass of water after each dose of medication to help loosen mucus in lungs.

To be taken undiluted three times daily.

#### - How long to use it

Continue taking Promedyl DM Linctus for as long as your doctor recommends.

#### - If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

#### - 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.

Symptoms of overdosing include:

- convulsions
- fast breathing
- hallucinations (hear, smell, taste or feel things that do not exist)
- increase in blood pressure

- irregular heart beat
- shortness of breath or troubled breathing
- unusual nervousness
- restlessness or excitement

### While you are using it

#### - Things you must do

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

Do not take Promedyl DM Linctus to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same conditions as you.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

#### - Things to be careful of

Be careful if you are driving or operating machinery until you know how Promedyl DM Linctus affects you.

The medicine may cause drowsiness, dizziness in some people. If this happens, do not drive or operate machinery.

### Side effects

Tell your pharmacist or doctor if you do not feel well while you are taking Promedyl DM Linctus. This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- fast heart beat
- increase in blood pressure
- anxiety
- restlessness
- mild fatigue
- dizziness
- diarrhoea
- constipation
- nausea
- vomiting
- drowsiness

The above list includes more common side effects of the medicine.

The side effects listed are rare. If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- low blood pressure
- tinnitus (noise or ringing in the ears)
- headache
- paraesthesia (prickling, burning, tickling, numbing sensation on the skin)
- hallucinations

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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 [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

## Storage and Disposal of Promedyl DM Linctus

### - Storage

Keep your medicine in a dry place where the temperature stays below 30°C. Protect from light. Keep container tightly closed.

Keep out of the reach and sight of children.

Do not use Promedyl DM Linctus after the expiry date which is stated on the carton and on the bottle. The expiry date refers to the last day of the month.

### - 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

A flavoured, clear, colourless to straw coloured syrup.

### - Ingredients

#### - Active ingredients

Each 5ml of Promedyl DM Linctus contains 15 mg Dextromethorphan hydrobromide, 2 mg Chlorpheniramine maleate and 30mg Pseudoephedrine hydrochloride.

#### - Inactive ingredients

- Saccharin sodium
- Polyvinyl pyrrolidone (Povidone)
- Propylparaben
- Sorbitol 70%
- Lychee flavour
- Citric acid
- Glycerin
- Methylparaben
- Menthol
- Propylene glycol

- MAL number:  
MAL05032522AZ

## Manufacturer

UPHA Pharmaceutical Mfg. (M) Sdn Bhd (53667-M)  
Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

## Product Registration Holder

CCM Pharmaceuticals Sdn Bhd (27754-W)  
Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

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