DEXTRODYL LINCTUS

Dextromethorpan hydrobromide / Promethazine hydrochloride (15mg / 3.6mg per 5ml)

What is in this leaflet

- 1. What Dextrodyl Linctus is used for
- 2. How Dextrodyl Linctus works
- 3. Before you take Dextrodyl Linctus
- 4. How to take Dextrodyl Linctus
- 5. While you are using Dextrodyl Linctus
- 6. While you are Dextrody Linctus
- 7. Side effects
- 8. Product description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

What Dextrodyl Linctus is used for

The combination of dextromethorphan and promethazine is used for the short term symptomatic relief, particularly at night, of troublesome cough associated with the upper respiratory tract infections, catarrh (an excessive build-up of thick phlegm or mucus in an airway or cavity of the body) and congestion.

How Dextrodyl Linctus works

Dextrodyl Linctus contains dextromethorphan and promethazine. Dextromethorphan is a cough suppressant and is used to reduce cough frequency and promethazine is an antihistamine.

Dextromethorphan affects the signals in the brain that trigger cough reflex. Promethazine blocks the effects of the naturally occurring chemical histamine in your body.

Before you use Dextrodyl Linctus

- When you must not use it

Do not take Dextrodyl Linctus if you:

 are allergic to any medicine containing dextromethorphan or promethazine. • Using or have used an MAO inhibitor, medicines used to treat depression, within the past 14 days.

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

To be used with caution and doctor's or pharmacist's advice in children 2 to 6 years of age.

- <u>Before you start to use it</u>

Tell your doctor or pharmacist if you have allergies to any other medicines, food, preservatives or if you have any medical conditions such as:

- coughing accompanied by excessive secretions
- impaired liver function
- asthma

If you have any of these conditions, you may not be able to use dextromethorphan and promethazine, or you may need a dosage adjustment.

This medication may be harmful to an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant during treatment.

Do not use dextromethorphan and promethazine without telling your doctor if you are breast-feeding a baby.

Taking other medicines

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

Avoid taking Monoamin Oxidase Inhibitor (MAOI) (medicine for depression) together as the combination with dextromethorphan may cause a toxic reaction. Avoid taking anticholinergic medicines, tricyclic antidepressant, sedative and hypnotic.

How to take Dextrodyl Linctus

- 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 take

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 take it

Take this medication exactly as it has been prescribed by your doctor.

To take every 6 - 8 hours daily.

How long to take it

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

A persistent cough may be a sign of a serious condition. If cough persists for more than 7 to 10 days, tends to recur or is accompanied by high fever, rash or persistent headache, a physician should be consulted.

- If you forget to take 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 confusion, excitation, convulsion and breathing difficulty.

While you are using Dextrodyl Linctus

- 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

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 may cause drowsiness that may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be awake and alert.

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.

Keep taking dextromethorphan and promethazine and talk with your doctor if you have any of these less serious side effects:

- dizziness
- gastro-intestinal disturbances
- blurred vision
- dry mouth
- urinary retention

Side effects other than those listed above 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: 0378835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and disposal of Dextrodyl Linctus

- Storage

Keep your medicine in its original packaging until it is time to take them.

Keep out the reach and sight of children.

Store in a dry place below 30°C.

- <u>Disposal</u>

If your doctor tells you to stop taking Dextrodyl Linctus or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment

Product description

- What it looks like

Dextrodyl Linctus:

A brown, flavored, homogenous, viscous syrup.

- Ingredients

- Active ingredient:

Each 5ml of Dextrodyl Linctus contains Dextromethorpan hydrobromide 15mg, Promethazine hydrochloride 3.6 mg.

- Inactive ingredients:
- cherry essence
- chloroform spirit
- raspberry essence
- preservatives (methylparaben and propylparaben)
- propylene glycol
- sugar
- menthol
- sodium chloride
- liquid glucose
- citric acid
- liquid caramel
- saccharin sodium
- glycerine

- <u>MAL Number:</u> MAL19962569AZ

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

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