

AXCEL DEXTROZINE SYRUP

Dextromethorphan Hydrobromide (15mg/5ml)

Promethazine Hydrochloride (3.6mg/5ml)

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WHAT AXCEL DEXTROZINE SYRUP IS USED FOR

Axcel Dextrozone Syrup is used to relief congestion and dry irritating cough, example on those associated with common cold, upper respiratory tract infection and allergic rhinitis (inflammation inside of the nose caused by an allergen).

HOW AXCEL DEXTROZINE SYRUP WORKS

Dextromethorphan Hydrobromide is a cough suppressant which has a central action on the cough centre in the medulla. Dextromethorphan has no analgesics properties and in general it has little sedative activity. It acts centrally to elevate the threshold for coughing. Promethazine Hydrochloride is a histamine H₁-receptor antagonist. It works by preventing the actions of histamine. Histamine is a substance produced by the body as part of its defence mechanisms which causes the symptoms of allergic reactions. Promethazine blocks histamine from binding to its receptors in various parts of the body and this stops it causing the symptoms of an allergic reaction. Promethazine Hydrochloride used in combination preparations with Dextromethorphan Hydrobromide for the treatment of coughs and colds.

BEFORE YOU USE AXCEL DEXTROZINE SYRUP

When you must not use it

Do not take Axcel Dextrozone Syrup if:

- If you are allergic or hypersensitive to Dextromethorphan.
- If you have respiratory failure or liver disease.
- If you are allergic or hypersensitive to any of the ingredients in this medicine.
- If you are known to be hypersensitive to bisulphites.
- If you are pregnant, nursing mother, newborn or premature infant or children less than 2 years of age.

Before you start to use it

Tell your doctor if:

- If you are pregnant, nursing mother, newborn or premature infant or children less than 2 years of age.
- If you have narrow angle glaucoma (buildup of pressure in the eye), hyperthyroidism (overproduction of thyroid hormones) or cardiovascular disease (disorders of the heart and blood vessels).

If the above situation is related to you, talk to your doctor and your doctor will be able to decide what is suitable for you.

Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Dextrozone Syrup:

- Quinidine
- Central nervous system (CNS) depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers
- Monoamine oxidase inhibitors (antidepressant)

HOW TO USE AXCEL DEXTROZINE SYRUP

How much to use

To be taken 6-8 hourly.

Adult & Children >12 years: 10ml (max. 40ml in 24 hours)

6-12 years: 5ml (max. 20ml in 24 hours)

2-6 years: 2.5ml (max. 10ml in 24 hours)

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

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)

- Symptoms of overdose may include excitation, confusion and respiratory depression.

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.

WHILE YOU ARE USING IT

Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Take the Axcel Dextrozone Syrup according to the recommended dosage.

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- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

Things to be careful of

- Avoid prolonged use with high dosage.
- No driving or operating machinery when feeling drowsy after taking the medicine.
- Use with caution upon the advice of a doctor/ pharmacist for children between the ages 2 to 6 years old.

SIDE EFFECTS

Like all medicines, Axcel Dextrozone Syrup can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

Very common side effects:

- Dizziness.
- Drowsiness.
- Gastrointestinal disturbances which may involve nausea, diarrhoea and epigastric pain.

Common side effects:

- Headache.
- Blurred vision.
- Dry mouth.
- Urinary retention.
- Constipation.
- Increased gastric reflux.
- Thickened respiratory tract secretions.
- Tightness of the chest.

Rare side effects:

In high doses, transient bradycardia (slow heart rate) may occur, followed by tachycardia (faster than normal heart rate at rest) with palpitation (abnormality of heartbeat), arrhythmias (irregular heart beat) and

central nervous system (CNS) stimulation.

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 AXCEL DEXTROZINE SYRUP

Storage

Keep Axcel Dextrozone Syrup out of reach of children.
Store below 30°C. Keep container well closed and protect from light.

Disposal

Do not use Axcel Dextrozone Syrup after the expiry date which is stated on the carton.

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

Axcel Dextrozone Syrup is a dark brown coloured syrup with sour plum flavour.

Ingredients

Active Ingredient (s):

Dextromethorphan Hydrobromide and Promethazine Hydrochloride

Inactive Ingredients:

Sour Plum Flavor, Sodium Metabisulfite, Purified Water, Methylparaben, Glucose Syrup, Citric Acid Anhydrous, Ammonium Chloride, Aspartame, Sorbitol, Propylene Glycol, Sodium Chloride, Saccharin Sodium, Refined Sugar, Menthol Crystal and Liquid Caramel.

MAL Number

MAL20012740A

MANUFACTURER AND PRODUCT REGISTRATION HOLDER

KOTRA PHARMA (M) SDN BHD
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

DATE OF REVISION

03/03/2015

SERIAL NUMBER

BPFK(R4/1)060215/00029