

AXCEL FLEMIN EXPECTORANT

Diphenhydramine Hydrochloride /Ammonium Chloride (12.5mg/130mg per 5ml)

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WHAT AXCEL FLEMIN EXPECTORANT IS USED FOR

Axcel Flemin Expectorant is used to relieve cough and alleviation of nasal (nose) and bronchial (tubes that carry air into the lungs) congestion.

HOW AXCEL FLEMIN EXPECTORANT WORKS

Diphenhydramine hydrochloride is a histamine H1-receptor antagonist. It is an antihistamine which works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. Ammonium chloride is used as an expectorant. It helps loosen up phlegm making it easier to cough it up.

BEFORE YOU USE AXCEL FLEMIN EXPECTORANT

When you must not use it

Do not take Axcel Flemin Expectorant if:

- If you are hypersensitive to diphenhydramine or other antihistamines.
- If you are receiving monoamine oxidase inhibitors (MAOIs) (for depression) therapy.
- If you are having impaired liver or kidney function.
- If it is not prescribed by a qualified doctor or pharmacist for you.
- Do not take Axcel Flemin Expectorant if you are pregnant,

trying to get pregnant or think you may be pregnant.

- Do not take Axcel Flemin Expectorant if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

Tell your doctor if:

- If you are having narrow angle glaucoma (a buildup of pressure in the eye), history of bronchial asthma, hyperthyroidism (a raised level of thyroid hormone), cardiovascular (heart and blood vessel) disease and prostatic hypertrophy (enlargement of the prostate), peptic ulcer (sore in the lining of the stomach or duodenum, the first part of the small intestine), pyloroduodenal obstruction (gastric outlet obstruction) and bladder neck obstruction (intermittent urine stream).
- If you are taking any other medicines (including those not prescribed by your doctor).
- If you are pregnant and nursing babies.

Axcel Flemin Expectorant should not be given to newborns or infants. It is not recommended for children below 2 years old.

To be used with caution upon the advice of a doctor or pharmacist for children between the age of 2 to 6 years old.

Taking other medicines

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Flemin Expectorant:

- Hypnotics, sedatives and tranquilizers.
- monoamine oxidase inhibitors (MAOIs) (for depression), aminoglycosides, antibiotics and antimuscarinics.

HOW TO USE AXCEL FLEMIN EXPECTORANT

How much to use

Doses to be taken 4 – 6 hourly.

Adults & children >12 years old: 5-10ml (1-2 teaspoonful), not to exceed 60ml (12 teaspoonful) in 24 hours.

Children 6-12 years old: 2.5-5ml (half-1 teaspoonful), not to exceed 30ml (6 teaspoonful) in 24 hours.

Children 2-5 years old: 2.5 (half teaspoonful), not to exceed 15ml (3 teaspoonful) in 24 hours.

When to use it

Your doctor will decide when it is appropriate for you to use Axcel Flemin Expectorant according to the type of condition you have.

How long to use it

Continue taking Axcel Flemin Expectorant for as long as doctor recommends.

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.

Symptoms of overdose:

- sedation
- cardiovascular (heart and blood vessel) collapse
- insomnia
- hallucination
- tremors
- convulsions
- dizziness
- tinnitus (ringing in the ears)
- ataxia (lack of muscle coordination)
- blurred vision
- hypotension (low blood pressure)

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WHILE YOU ARE USING IT

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 Axcel Flemin Expectorant.
- Tell your doctor immediately if you become pregnant while talking this medication.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Flemin Expectorant to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- This product may cause drowsiness.
- Caution while doing activity required mental alertness.
- Pregnancy and lactation.
- Use with caution in children and elderly.
- Avoid prolonged usage with high dosage.
- Avoid drinking alcoholic beverages when taking this medicine.

SIDE EFFECTS

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

- Sedation (including drowsiness, inability to concentrate, lassitude (weakness), dizziness, hypotension (low blood pressure), muscular weakness, and inco-ordination).
- Gastrointestinal disturbances (such as nausea, vomiting, diarrhea or constipation, colic and epigastric pain).
- Headache, blurred vision, tinnitus, elation or depression,

irritability, nightmares, anorexia, difficulty in urination, dryness of mouth, tightness of chest, tingling, heaviness and weakness of the hands.

This is not a complete list of side effects. Contact your doctor or pharmacist 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 AXCEL FLEMIN EXPECTORANT

Storage

Keep Axcel Flemin Expectorant out of reach of children. Keep container well-closed. Store below 30°C. Protect from light.

Disposal

Do not use Axcel Flemin Expectorant 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 Flemin Expectorant is brown color syrup with caramel flavor.

Ingredients

Active Ingredients:

Diphenhydramine HCl and Ammonium Chloride.

Inactive Ingredients:

Refined Sugar, Sodium Benzoate, Liquid Caramel, Sodium Citrate, Citric Acid Anhydrous, Caramel Flavor, Saccharin Sodium, Glycerin, Aspartame, Sorbitol 70%, Purified water.

MAL Number

MAL19991903AZ

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

10/06/2015

SERIAL NUMBER

BPFK(R4/1)190515/00110