

AXCEL DIPHENHYDRAMINE PAEDIATRIC SYRUP

Diphenhydramine hydrochloride / Ammonium chloride (7mg /67.5mg per 5ml)

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What Axcel Diphenhydramine Paediatric Syrup is used for

Axcel Diphenhydramine Paediatric Syrup is used for relief of cough and alleviation of nasal (nose) and bronchial (airways) congestion.

How Axcel Diphenhydramine Paediatric Syrup works

Axcel Diphenhydramine Paediatric Syrup contains Diphenhydramine Chloride, which is a form of antihistamine. It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. Its drying effects on such symptoms as watery eyes and runny nose are caused by blocking another natural substance made by your body (acetylcholine). Ammonium chloride is used as an expectorant. It helps loosen up phlegm making it easier to cough it up.

Before you use Axcel Diphenhydramine Paediatric Syrup

When you must not use it

Do not take Axcel Diphenhydramine Paediatric Syrup if:

- You are allergic or hypersensitive to antihistamines.
- You are receiving MAOI (monoamine oxidase inhibitor) therapy for depression.

- You have impaired liver or kidney function.

Before you start to use it

Tell your doctor if:

- You have narrow angle glaucoma (increased pressure inside the eye), history of bronchial asthma (breathing problem), hyperthyroidism (overactive thyroid gland which can cause increased appetite, weight loss or sweating), cardiovascular disease (disease of the heart or blood vessels), stenosing peptic ulcer (scarring and swelling due to ulcers cause narrowing in the duodenum and gastric outlet obstruction), pyloroduodenal obstruction (gastric outflow obstruction), bladder neck obstruction (intermittent urine stream) or prostatic hypertrophy (enlargement of prostate).
- You have G6PD (glucose-6-phosphate deficiency).

It is not recommended for children below 2 years old. To be used with caution upon the advice of a doctor/ pharmacist for children between the age of 2 to 6 years old.

Taking other medicines

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

- Antihistamines
- Hypnotics, sedatives and tranquilizer
- MAOI (monoamine oxidase inhibitors), aminoglycosides, antibiotics and antimuscarinics

How to use Axcel Diphenhydramine Paediatric Syrup

How much to use

To be taken 4-6 hourly.

Children 2-5 years: 5ml, not to exceed 40ml in 24 hours.

Children 6-12 years: 5-10ml, not to exceed 60ml in 24 hours.

Children above 12 years: 10-20ml, not to exceed 120ml 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

- 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 double up the dosage as Axcel Diphenhydramine Paediatric Syrup may give you undesirable side effects.

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 overdosage may vary from central nervous system (CNS) depression including sedation, cardiovascular collapse (sudden loss of blood flow to the brain and other organs) and stimulation including insomnia, hallucination, tremors or convulsion.
- Other symptoms include dizziness, tinnitus (ringing in the ears), ataxia (lack of voluntary coordination of muscle movements), blurred vision and low blood pressure.

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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 Diphenhydramine Paediatric Syrup according to the recommended dosage.
- 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 overdosage 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.
- Avoid drinking alcoholic beverages when taking this syrup.

Side effects

Like all medicines, Axcel Diphenhydramine Paediatric 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:

Most common side effects:

- Sedation, varying from drowsiness to deep sleep, including inability to concentrate.
- Fatigue.
- Dizziness.
- Hypotension (low blood pressure).
- Muscular weakness and inco-ordination.

Other side effects:

- Gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, colic and epigastric pain
- Headache
- Blurred vision
- Tinnitus (ringing in the ear)
- Elation or depression
- Irritability
- Nightmares
- Anorexia
- Difficulty in urination
- Dryness of the mouth
- Tightness of the chest
- Tingling
- Heaviness and weakness of the hands
- Fits

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 Dipheniramine Paediatric Syrup

Storage

Keep Axcel Diphenhydramine Paediatric Syrup out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

Disposal

Do not use Axcel Diphenhydramine Paediatric 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 Diphenhydramine Paediatric Syrup is brown colour liquid with caramel flavour.

Ingredients

Active Ingredient (s):

Ammonium Chloride and Diphenhydramine Hydrochloride

Inactive Ingredients:

Saccharin Sodium, Caramel flavor, Citric Acid, Carboxymethyl Cellulose Sodium, Purified Water, Sodium Citrate, Liquid Caramel, Sodium Benzoate, Refined Sugar and Glycerine

MAL Number

MAL20021157AZ

Manufacturer and product registration holder

KOTRA PHARMA (M) SDN BHD
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Cheng Industrial Estate,
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