AXCEL DEXCHLORPHENIRAMINE FORTE SYRUP

Dexchlorpheniramine Maleate (2mg/5ml)

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WHAT AXCEL DEXCHLORPHENIRAMINE FORTE SYRUP IS USED FOR

Axcel Dexchlorpheniramine Forte Syrup is used to treat allergic conditions including:

- Hav fever
- Urticaria (a raised, itchy rash that appears on the skin)
- Angioedema (swelling in the skin)
- Vasomotor rhinitis (inflammation of the membranes inside of the nose not caused by allergy)
- Allergic eczema (inflammation of the skin)
- Atopic and contact dermatitis (inflammation of the skin)
- Drug and serum reactions
- Insect bites
- Pruritus (itching)

HOW AXCEL DEXCHLORPHENIRAMINE FORTE SYRUP WORKS

Dexchlorpheniramine Maleate is an alkylamine derivative with antihistamine and anticholinergic effects. Histamine is a substance produced by the body that binds to its receptor (H1 receptor) as part of the

body defense system. The binding of histamine and H1 receptor causes allergic symptoms. Dexchlorpheniramine Maleate prevents histamine action by blocking the binding of H1 receptor – histamine. However, it does not prevent the production of histamines. This antagonism is competitive and reversible.

BEFORE YOU USE AXCEL DEXCHLORPHENIRAMINE FORTE SYRUP

When you must not use it

Do not take Axcel Dexchlorpheniramine Forte Syrup:

- If you are allergic or hypersensitive to antihistamines.
- If you have been receiving monoamine oxidase inhibitor (MAOI) therapy.
- If the patient is a newborn or premature infants.
- If the child is younger than 2 years of age.

Before you start to use it

Tell your doctor if:

- If you have narrow angle glaucoma (a buildup of pressure in the eye), history of bronchial asthma (chronic inflammatory disease of the airways), hyperthyroidism (a raised level of thyroid hormone), cardiovascular (heart) disease, and prostatic hypertrophy (enlargement of the prostate).
- If you are pregnant, nursing mother, newborn or premature infant.

Taking other medicines

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

- Ototoxic drugs (drugs that can damage hearing) such as aminoglycoside antibiotics
- Any central nervous system (CNS) depressants including alcohol, barbiturates, hypnotics,

- narcotic analgesics, sedatives and tranquillisers
- Monoamine oxidase inhibitors (MOAIs) (antidepressants).

HOW TO USE AXCEL DEXCHLORPHENIRAMINE FORTE SYRUP

How much to use

For oral administration only. *Adult*:

2.5 to 5 ml (1 to 2 mg), 4-6 hourly, up to a maximum of 30 ml (12 mg) / 24 hours.

Children:

6 - 12 years; 2.5 ml (1 mg), 4 - 6 hourly, up to a maximum of 15 ml (6 mg) / 24 hrs.

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.
- Do not double up the dosage as Axcel Dexchlorpheniramine Forte Syrup may give you unacceptable side effects.

If you use too much (overdose)

- Excitation, occurs particularly in children.
- Convulsions
- Hypotension (low blood pressure)

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It is advisable for you to contact and inform your doctor if you did take Axcel Dexchlorpheniramine Forte Syrup too much.

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 Dexchlorpheniramine 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 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 Axcel Dexchlorpheniramine Forte Syrup.

SIDE EFFECTS

Like all medicines, Axcel Dexchlorpheniramine Forte Syrup 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:

Very common side effects:

- Sedation, varying from drowsiness to deep sleep, including inability to concentrate.
- Lassitude (weakness).
- Dizziness.
- Hypotension (low blood pressure).

 Muscular weakness and incoordination.

Common 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

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 DEXCHLORPHENIRAMINE FORTE SYRUP

Storage

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

<u>Disposal</u>

Do not use Axcel Dexchlorpheniramine Forte 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 Dexchlorpheniramine Forte Syrup is red coloured and strawberry flavoured syrup.

Ingredients

Active Ingredient:

Dexchlorpheniramine Maleate

Inactive Ingredients:

Purified Water, Sodium Benzoate, Methylparaben, Refined Sugar, Xanthan Gum, Ponceau 4R, Strawberry Flavor and Propylene Glycol.

MAL Number

MAL19984387A

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

02/03/2015

SERIAL NUMBER

BPFK(R4/1)200115/00020