AXCEL CHLORPHENIRAMINE SYRUP

Chlorpheniramine Maleate (2mg & 4mg)

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WHAT AXCEL CHLORPHENIRAMINE SYRUP IS USED FOR

Axcel Chlorpheniramine Syrup is used to treat allergic conditions including:

- Hay fever
- Urticaria (itchy rash resulting from an allergic reaction).
- Angioedema (swelling and itching of the skin and mucous membranes)
- Vasomotor rhinitis
 (inflammation of the membranes
 inside of the nose)
- Allergic eczema (itchy skin rash by allergen)
- Atopic and contact dermatitis (inflammation of the skin)
- Drug and serum reactions
- Insect bites
- Pruritus (itching)

HOW AXCEL CHLORPHENIRAMINE SYRUP WORKS

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. Chlorpheniramine 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 CHLORPHENIRAMINE SYRUP

When you must not use it

Do not take Axcel Chlorpheniramine Syrup if:

- If you are allergic or hypersensitive to antihistamines.
- If you have been receiving MAOI therapy within the previous 14 days.
- If the patient is a newborn or premature infants.

Before you start to use it

Tell your doctor if:

- If you have narrow angle glaucoma (eye pain), history of bronchial asthma, hvperthvroidism (overactive thyroid gland), cardiovascular disease, prostatic hypertrophy (enlargement of prostate), stenosing peptic ulcer (scarring and swelling due to ulcers cause narrowing in the duodenum and gastric outlet obstruction), pyloroduodenal obstruction (pyloric obstruction) and bladder neck obstruction (intermittent urine stream).
- 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 Chlorpheniramine Syrup:

- Ototoxic drugs (drugs that can damage the ear) such as aminoglycoside antibiotics
- Any Central Nervous System (CNS) depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers
- Monoamine Oxidase Inhibitors (MAOI)

HOW TO USE AXCEL CHLORPHENIRAMINE SYRUP

How much to use

For oral administration only.

Adult:

4 mg, 4 - 6 hourly, up to a maximum of 24 mg / 24 hrs.

Children:

6 – 12 years; 2 mg, 4 – 6 hourly, up to a maximum of 12 mg / 24 hrs.
2 – 5 years: 1 mg, 4 – 6 hourly, up to a maximum of 6 mg / 24 hrs.
(Use Axcel Chlorpheniramine – 2 Syrup for children)

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 Chlorpheniramine Syrup may give you unacceptable side effects.

<u>If you use too much (overdose)</u>

Symptoms of over dosage may vary from CNS depression including sedation. cardiovascular collapse (sudden development of circulatory failure) and stimulation including insomnia, hallucination, tremors Other convulsion. symptoms include dizziness. tinnitus (ringing noise in one or both ataxia (uncoordinated movement), blurred vision and blood hypotension (low pressure).

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It is advisable for you to contact and inform your doctor if you did take Axcel Chlorpheniramine 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 Axcel Chlorpheniramine 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 Chlorpheniramine Syrup.
- Be careful if you are pregnant, nursing mother, newborn or premature infant.

SIDE EFFECTS

Like all medicines, Axcel Chlorpheniramine 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 (lack of energy).
- 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 noise in one or both ears)
- Elation or depression
- Irritability
- Nightmares
- Anorexia (eating disorder)
- 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 CHLORPHENIRAMINE SYRUP

<u>Storage</u>

Keep Axcel Chlorpheniramine 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 Chlorpheniramine 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 requires. These measures will help to protect the environment.

PRODUCT DESCRIPTION

A) Axcel Chlorpheniramine-2 Syrup

What it looks like

Axcel Chlorpheniramine-2 Syrup is an orange coloured and orange flavoured syrup.

<u>Ingredients</u>

Active Ingredient (s): Chlorpheniramine Maleate

Inactive Ingredients:

Purified Water, Sodium Benzoate, Sunset Yellow Dye, Methylparaben, Refined Sugar, Orange Flavor and Propylene Glycol.

MAL Number

MAL19984390A

B) Axcel Chlorpheniramine-4 Syrup

What it looks like

Axcel Chlorpheniramine-4 Syrup is a yellow coloured and fruity flavoured syrup.

<u>Ingredients</u>

Active Ingredient (s): Chlorpheniramine Maleate

Inactive Ingredients:

Purified Water, Sodium Benzoate, Quinolline Yellow, Methylparaben, Refined Sugar, Orange Flavor, Strawberry Flavor and Propylene Glycol.

MAL Number

MAL19984391A

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

02/10/2014

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