

# AXCEL PROMETHAZINE SYRUP

Promethazine Hydrochloride (5mg/5ml & 10mg/5ml)

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## WHAT AXCEL PROMETHAZINE SYRUP IS USED FOR

Axcel Promethazine Syrup is used in the symptomatic relief of allergy or hypersensitivity reactions such as hay fever, urticaria (raised, itchy rash on the skin), angioedema (swelling under the skin), rhinitis (inflammation of the membrane inside the nose), conjunctivitis (inflammation of the eye) and pruritic (itching) skin disorders, night sedation, treatment and prevention of motion sickness and vertigo (dizziness) of various causes.

## HOW AXCEL PROMETHAZINE SYRUP WORKS

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. It 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.

## BEFORE YOU USE AXCEL PROMETHAZINE SYRUP

### When you must not use it

Do not take Axcel Promethazine Syrup if:

- If you are allergic or hypersensitive to propylene glycol.
- If you have been taking monoamine oxidase inhibitors (MAOI) within 14 days.
- If you suffer central nervous system (CNS) depression of any cause.
- If you are hypersensitive to bisulphites.
- If you are hypersensitive to phenothiazines.
- If it is not prescribed by a qualified doctor or pharmacist for you.
- Do not take Axcel Promethazine Syrup if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Axcel Promethazine Syrup 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 you:

- If you are phenylketouric (inability to properly break down an amino acid called phenylalanine).
- If you are allergic to any medicines, food and dyes.
- If you are taking any other medicines (including those not prescribed by your doctor).
- If you have narrow angle glaucoma (buildup of pressure in the eye), hyperthyroidism (a raised level of thyroid hormone), cardiovascular (heart / blood vessels) disease, prostatic hypertrophy (enlargement of the prostate), stenosing peptic ulcer (scarring and swelling due to ulcers cause narrowing in the duodenum and gastric outlet obstruction), pyloroduodenal obstruction (pyloric obstruction), bladder neck obstruction (intermittent urine system).
- Pregnancy and lactation.

Promethazine should not be used in paediatrics less than 2 years old. It is

to be used with caution and doctor's advice in children 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 Promethazine Syrup:

- MAO inhibitors.
- CNS depressant including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilisers.
- Ototoxic drugs (agents that can cause damage to hearing) such as aminoglycoside antibiotics.

## HOW TO USE AXCEL PROMETHAZINE SYRUP

### How much to use

#### A) Axcel Promethazine-5 Syrup

*For allergic conditions*

#### Children:

2-5 years: 5-15ml single dose at night or 5ml two times daily (maximum 15ml daily).

6-12 years: 10-25ml single dose at night or 5-10ml two times daily (maximum 25ml daily).

#### Adults:

10ml two times daily. May be increased to 20ml three times daily.

*For nausea and vomiting*

#### Children:

2-5 years: 5ml every 4-6 hours (maximum 15ml daily).

6-12 years: 10ml every 4-6 hours (maximum 25ml daily).

#### Adults:

25ml every 4-6 hours (maximum 100ml daily).

*For travel sickness (the night before travel and repeated after 6-8 hours if required)*

#### Children:

2-5 years: 5ml

6-12 years: 10ml

Adults: 25ml.

# AXCEL PROMETHAZINE SYRUP

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B) Axcel Promethazine-10 Syrup

Adults:

*As a hypnotic:*

10 ml at night. May be increased to 25 or 37.5 ml as required.

*Treatment for nausea and vomiting:*

12.5 ml 4-6 hourly, not to exceed 50 ml in 24 hours.

*In allergic condition:*

5-10 ml, 2-3 times a day, up to 30 ml a day.

Children:

*For hypersensitivity reactions:*

2-5 years: 2.5 to 7.5 ml daily.

5-10 years: 5-12.5 ml daily.

In case where 2 doses in 24 hours are required, the lower amount stated should be given.

*For the prevention of motion sickness (dose to be taken the night before the journey and repeated the following morning if required):*

2-5 years: 2.5 ml

5-10 years: 5ml

When to use it

Your doctor will decide when it is appropriate for you to take Axcel Promethazine Syrup according to the type of condition you have.

How long to use it

Continue taking Axcel Promethazine Syrup 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 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)

Symptom of overdosage:

- Sedation
- Heart failure

- Inability to fall asleep
- Hallucinations
- Tremors
- Convulsions
- Dizziness
- Tinnitus (ringing in the ear)
- Ataxia (uncoordinated movement)
- Blurred vision
- Low blood pressure

You must inform your doctor immediately if you have taken too much Axcel Promethazine Syrup.

### 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 Promethazine Syrup.
- 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 Promethazine Syrup to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- Axcel Promethazine Syrup may cause drowsiness and hence impair ability to drive vehicles or operate machinery.
- Pregnancy and nursing mother.
- Avoid giving to newborn and premature infants.

### SIDE EFFECTS

Like all medicines, Axcel Promethazine Syrup can cause side effects although not everybody gets them. The following side effects have been reported:

- Sedation varying from drowsiness to deep sleep, and

including inability to concentrate, lassitude (weakness), dizziness, hypotension (low blood pressure), muscular weakness and inco-ordination.

- 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 (loss of appetite).
- 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](http://portal.bpfk.gov.my) (Consumers -> Reporting).

### STORAGE AND DISPOSAL OF AXCEL PROMETHAZINE-5 SYRUP

Storage

Keep Axcel Promethazine Syrup out of reach children. Keep container well closed. Store below 30°C. Protect from light.

Disposal

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

A) Axcel Promethazine-5 Syrup

How it looks like

Axcel Promethazine-5 Syrup is brown colour syrup with sarsi flavour.

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## Ingredients

Active Ingredient:

Promethazine Hydrochloride

Inactive Ingredients:

Refined Sugar, Methylparaben, Aspartame, Sodium Metabisulphate, Sarsaparilla Flavour, Caramel Liquid, Citric Acid Anhydrous, Ammonium Chloride, Sorbitol 70%, Glycerin, Propylene Glycol, Sour Plum Flavour and Purified Water.

## MAL Number

MAL20020811A

B) Axcel Promethazine-10 Syrup

## How it looks like

Axcel Promethazine-10 Syrup is brown colour syrup with liquorice flavored.

## Ingredients

Active Ingredient:

Promethazine Hydrochloride

Inactive Ingredients:

Refined Sugar, Sodium Metabisulphate, Liquid Caramel, Citric Acid, Liquorice Flavour, Polysorbate 20, Glycerin, Sorbitol 70%, Methylparaben, Propylene Glycol, Sodium Saccharin, Xanthan Gum, Chloroform Spirit and Purified Water.

## MAL Number

MAL20013575A

## **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**

03/12/2014

## **SERIAL NUMBER**

BPFK(R4/1)271114/00059