

# PROMETHAZINE SYRUP

Promethazine 5mg/5ml, Promethazine 15mg/5ml

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## What Promethazine Syrup are used for

Promethazine syrup is used for symptomatic treatment of allergic reactions, nausea and vomiting.

## How Promethazine Syrup work

Promethazine is an antihistamine which helps to reduce allergic symptoms by preventing the effects histamine reacts with H<sub>1</sub>-receptor sites on effector cells. Histamine is produced when body response to substances that the body is allergic to. Promethazine help to reduce nausea and vomiting by diminishing vestibular (body balance system in brain area) stimulation and depressing labyrinthine function.

## Before you use Promethazine Syrup

### When you must not take it

Promethazine syrup should not be used in paediatric patients less than 2 years of age because of the potential for fatal respiratory depression.

You are allergic to any medicine containing promethazine hydrochloride.

You are allergic to any of the ingredients listed at the end of this leaflet.

Do not drink alcoholic beverages during treatment.

## Before you start to take it

Always take Promethazine syrup exactly as your doctor or Pharmacist has told you. You should check with your doctor or pharmacist if:

- you are allergic to any other medicines
- you are allergic any other orally consumed substances
- you have any medical conditions like e.g. glaucoma etc.
- you are pregnant or breast-feeding

## Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Promethazine syrup may increase the sedative effect of some drugs. These include:

- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to help you sleep or relax (sedatives and hypnotics)
- other antihistamines
- alcohol

## How to take Promethazine Syrup

### How much to take

For adults and children over 12 years:

Usual dose: 25 to 50mg at bedtime for allergic conditions or 10 to 20mg 2 to 3 times daily.

### Children:

2 to 5 years : 5 to 15mg

6 to 12 years : 10 to 25mg

Doses to be given in 1 or 2 divided doses daily after food.

### When to take it

Read the label on the carton or follow what your doctor has told you.

### How long to take it

Take Promethazine Syrup for as long as your doctor recommends. If the symptom still persists or not lighten after

a few days, please consult your doctor.

### If you forget to take it

If you forget to take Promethazine Syrup take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

### If you take too much (overdose)

If you take more Promethazine Syrup than you should, tell a doctor or go to a hospital straight away.

Take the medicine pack with you. This is so the doctor knows what you have taken.

If you take too much Promethazine Syrup, you may experience:

Muscular twitching, convulsions, coma, restlessness and irritability, mental confusion and possibly hallucinations.

## While you are taking Promethazine Syrup

### Things you must do

Tell your doctors, dentists, and pharmacists who are treating you that you are taking Promethazine Syrup.

If you are about to be started on any new medicine, tell your pharmacist or doctor that you are taking Promethazine Syrup.

Talk to your pharmacist or doctor if your symptoms do not improve.

### Things you must not do

Do not give Promethazine Syrup to anyone else, even if they have the same condition as you.

Do not take Promethazine Syrup to treat any other complaints unless your pharmacist or doctor tells you to.

Do not drink alcohol while taking Promethazine Syrup. The sedation effects of alcohol may be increased.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

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## Things to be careful of

Promethazine Syrup may cause drowsiness. If affected, do not drive or operate machinery.

Dizziness, sedation, confusion and hypotension may be more likely to occur in geriatric patients taking antihistamines.

Avoid alcoholic drinks.

## Side Effects

Like all medicines, Promethazine Syrup may cause side effects, although not everybody gets them.

Consult doctor or pharmacist for further information if you notice any of the following and they worry you:

Drowsiness, dryness of mouth, blurred vision.

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 Promethazine Syrup

### Storage

Keep all medicines out of the reach of children.

Promethazine Syrup 5mg/5ml : Store below 30°C. Protect from light.

Promethazine Syrup 15mg/5ml : Store below 25°C. Protect from light.

### Disposal

Do not take this medicine after the expiry date stamped on the pack/bottle.

Return any unused syrup to your pharmacist to be disposed of. Only keep the syrup if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

## Product Description

### What it looks like

Promethazine Syrup 5mg/5ml : Clear brown syrup with sweet taste and prune flavour.

Promethazine Syrup 15mg/5ml : Clear green syrup with sweet taste and banana flavour.

## Ingredients

### Active Ingredient

Promethazine syrup 5mg/5ml:  
Each 5ml contains  
Promethazine HCl BP 5mg/5ml.

Promethazine syrup 15mg/5ml:  
Each 5ml contains  
Promethazine HCl BP  
15mg/5ml.

### Inactive ingredients

Promethazine HCl BP 5mg/5ml:  
Citric acid monohydrate,  
Granulated fine white sugar,  
Sodium benzoate, Sodium  
saccharin, Sodium citrate  
dihydrate, Sodium  
metabisulphite, Di-sodium  
EDTA, Prune HC 3995,  
Propylene glycol, Glycerin,  
Liquid caramel, Purified water.

Promethazine syrup 15mg/5ml:  
Citric acid monohydrate,  
Sodium citrate dihydrate,  
Granulated fine white sugar,  
Sodium benzoate, Sodium  
metabisulphite, Di-sodium  
EDTA, Banana Flavour PCA  
5639, Propylene glycol,  
Glycerin, Quinoline yellow  
E104, FDC Blue No.1, Purified  
water.

## MAL Number

Promethazine syrup 5mg/5ml :  
MAL19920202A

Promethazine syrup 15mg/5ml :  
MAL 19890529A

## Manufacturer

### Drug Houses of Australia Pte. Ltd.

#09-01/02 Haw Par Tiger Balm  
Building,  
No. 2, Chia Ping Road,  
Singapore 619968

## Marketing Authorization Holder

### Ascent Pharmahealth Malaysia Sdn Bhd

Unit 304, Level 3, Uptown 2, 2  
Jalan SS21/37, Damansara  
Uptown, 47400 Petaling Jaya,  
Selangor Darul Ehsan, Malaysia

## Date of Revision

18-06-2013