

METARYL SYRUP

Promethazine hydrochloride (5mg/5ml)

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What Metaryl is used for

Metaryl is used for:

- the symptomatic relief of allergy or hypersensitivity reactions such as hay fever, urticaria (a red, raised, itchy rash), angioedema (swelling of the deeper layers of the skin), rhinitis (inflammation of the mucous membrane inside the nose), conjunctivitis (eye inflammation), itchiness
- night sedation
- treatment and preventions of motion sickness
- vertigo (sensation of spinning) of various causes.

How Metaryl works

Metaryl is an antihistamine which helps to reduce allergic symptoms by blocking certain natural substance (histamine) that your body makes during an allergic reaction. Metaryl helps to reduce nausea and vomiting by inhibiting the chemoreceptor trigger zone located in the medulla (part of the brain).

Before you use Metaryl

When you must not use it

Tell your doctor if:

- You are hypersensitive to promethazine or other similar antihistamines.
- You are allergic to any of the ingredients listed at the end of this leaflet.
- You have lower airway symptoms including asthma.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

- a) Not to be used in children less than 2 years of age
- b) To be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age

Before you start to use it

Always take Metaryl exactly as your doctor or pharmacist has told you.

You should check with your doctor or pharmacist if you have any medical conditions such as epilepsy, severe heart disorders, liver disorders, narrow angle glaucoma (increased pressure inside the eye), stenosing peptic ulcer (ulcer of the upper digestive tract), pyloroduodenal obstruction (blockage of passage from stomach to intestine) and urinary bladder obstruction due to enlargement of prostate and narrowing of the bladder neck.

Pregnancy and breastfeeding

Promethazine should be used in pregnancy only if potential benefit justifies the potential risk to the fetus. Small amount of antihistamine is excreted in breast milk. Use is not recommended during breastfeeding due to risk of adverse effects such as unusual excitement or irritability in infants.

Taking other medicines

Tell your doctor or pharmacist before taking Metaryl, if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. The effects of some medicines may be affected if other medicines are used at the same time. They include:

- central nervous system depressants such as alcohol, barbiturates, hypnotics, opioid pain killer, anxiolytic sedatives and neuroleptics.
- monoamine oxidase inhibitors (antidepressant)
- atropine
- tricyclic antidepressants
- ototoxic medications (medications that cause damage to hearing) such as aminoglycoside antibiotics

How to use it

Always take the medicine exactly as your doctor or pharmacist has told you. Read the direction labels carefully. If you have any concerns about how to take this medicine, talk to your doctor or pharmacist.

Shake the syrup well before use.

How much to use

Your doctor will advise you how many doses are needed each day, and for how long you will need to take. This depends on your condition and whether or not you are taking any other medicines.

Recommended Dosage:

Adults:

10mg – 20mg two to three times daily.

Children 5 – 10 years :

10mg – 25mg daily in one or two divided doses.

Children 2 – 5 years :

5mg – 15mg daily in one or two divided doses.

Note : Do not use in children less than 2 years old because of the potential for fatal respiratory depression.

When to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist.

How long to use it

Follow the direction label carefully and as instructed by 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, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting unwanted side effects.

If you use too much (overdose)

Immediately call your doctor or go to the emergency department at your nearest

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hospital if you or anyone else has taken a large amount of this medication.

If you take too much Metaryl, you may experience:

- Drowsiness
- Ataxia (lack of muscular coordination)
- Excitement
- Tremors
- Psychoses (mental illness)
- Hallucinations
- Convulsion
- Coma
- Respiratory failure
- Cardiovascular (involving the heart or blood vessels) failure

While you are using Metaryl

Things you must do

Take the medication exactly as your doctor prescribed.

- Tell your doctor or pharmacist if you have allergies to Promethazine or other phenothiazine.
- Tell your doctor or pharmacist what other prescription and non-prescription medicines that you are taking.
- Tell your doctor if you are pregnant, planning to get pregnant or breastfeeding. If you are pregnant when taking Metaryl, contact your doctor.

Things you must not do

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

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

Avoid alcohol and alcoholic beverages.

Things to be careful of

If you are pregnant, trying to get pregnant or are breast-feeding, you should not take Metaryl without discussing it with your doctor first.

This medication is likely to cause marked drowsiness. If so avoid all activities requiring mental alertness such as driving or operating heavy machineries.

Dizziness, sedation, confusion and low blood pressure may be more likely to

occur in elderly patients taking antihistamines.

Side effects

All medicines may have some unwanted side effects. Unwanted side effects do not always occur in every person. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Metaryl. Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

- **Nervous system:** Sedation, drowsiness, sleepiness, dizziness, occasional blurred vision, dry mouth.
- **Dermatologic:** Rash.
- **Gastrointestinal:** Nausea, vomiting, diarrhea, epigastric pain.
- **Cardiovascular:** Increased or decreased blood pressure.

Other side effects not listed above may occur in some people. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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 Metaryl

Storage

Keep all medicines out of sight and reach of children.

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

Keep container tightly closed in a dry place, below 25°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

What it looks like

A clear, mobile, light brown liquid with odour of orange.

Ingredients

-Active ingredient :

Each 5ml contains: Promethazine Hydrochloride 5mg.

-Inactive ingredients :

FD & C Yellow, Anhydrous Citric Acid, Orange Flavour, Methyl paraben sodium, Propyl paraben sodium, Liquid Sorbitol, Purified Water, Sucrose, Vanillin, Caramel, Saccharin Sodium.

MAL Number

MAL06051321AZ

Manufacturer

Idaman Pharma Manufacturing Sdn Bhd (661901-P),
Lot 24 & 25, Jalan Perusahaan Lapan, Bakar Arang Industrial Estate, 08000, Sungai Petani, Kedah Darul Aman, Malaysia.

Product Registration Holder

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Lot 24 & 25, Jalan Perusahaan Lapan, Bakar Arang Industrial Estate, 08000, Sungai Petani, Kedah Darul Aman, Malaysia.

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