

PHARMANIAGA DIPHENHYDRAMINE EXPECTORANT

Diphenhydramine hydrochloride / Ammonium chloride (12.5mg/135mg per 5ml)

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What **Pharmaniaga Diphenhydramine Expectorant** is used for

It is used for the symptomatic relief of cough, nasal and airway congestion.

Ask your doctor or pharmacist if you have any questions about why this medicine has been prescribed. Your doctor may have prescribed this medicine for another reason.

How **Pharmaniaga Diphenhydramine Expectorant** works

Pharmaniaga Diphenhydramine Expectorant contains diphenhydramine which belongs to a group of medicines called antihistamines which has properties to suppress the urge to cough. It also dries up secretions in the nose and chest.

Ammonium chloride is an expectorant that helps to loosen phlegm.

Before you use **Pharmaniaga Diphenhydramine Expectorant**

-When you must not use it

Do not take **Pharmaniaga Diphenhydramine Expectorant** if:

- You are allergic to diphenhydramine, ammonium chloride or any of the ingredients listed at the end of this leaflet
- You use in children less than 2 years of age.
- You use in premature and newborn infant.
- You have raised pressure in the eye, asthma, enlarged prostate, liver or kidney problems, monoamine oxidase inhibitor therapy.
- You are pregnant, breastfeeding or intend to become pregnant. Diphenhydramine should be avoided if you are breastfeeding.
- The expiry date printed on the pack has passed
- The packaging is torn, shows signs of tampering or it does not look right

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

-Before you start to use it

Tell your doctor if you have any allergies to any other medicines or food.

Tell your doctor or pharmacist if you have or have had any medical condition especially the following:

- Epilepsy
- Severe heart and blood vessel condition
- Gastric outlet and duodenum obstruction
- Difficulty passing urine.
- Skeletal muscle weakness
- Abnormal gland
- Has breathing problem and chronic cough
- Kidney or liver problem
- Vision problem

-Taking other medicines

Tell your doctor or pharmacist before taking **Pharmaniaga Diphenhydramine Expectorant** if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or any other source.

The effects of some medicines may be affected when used with **Pharmaniaga Diphenhydramine Expectorant** at the same time. These include:

- Medicines used to treat depression especially Monoamine oxidase inhibitors (MAOI)
- Sedative medicines
- Antimuscarinic medicines
- Aminoglycoside antibiotics (used to treat bacterial infection)
- Allergen extracts (for diagnostic skin test. It is recommended that medication can be discontinued at least 72 hours before testing begins)
- Medicines used to reduce blood pressure.

Your doctor or pharmacist can advise you on other medicines to be careful with while taking **Pharmaniaga Diphenhydramine Expectorant**.

How to use **Pharmaniaga Diphenhydramine Expectorant**

To be taken orally only. Shake well before use.

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

-How much to use

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

PHARMANIAGA DIPHENHYDRAMINE EXPECTORANT

Diphenhydramine hydrochloride / Ammonium chloride (12.5mg/135mg per 5ml)

Dosage

Adults and children above 12 years:
10ml every four to six hours. Do not take more than 60ml in one day.

Children 6 to 12 years:
5ml every four to six hours. Do not take more than 30ml in one day

Children 2 to 5 years:
2.5ml every four to six hours. Do not take more than 15ml in one day

It may be taken with or without food.

Do not give Pharmaniaga Diphenhydramine Expectorant to children under the age of two years. Use carefully and follow the advice from your doctor strictly for children aged 2-6 years, premature and newborn infant.

When administering Pharmaniaga Diphenhydramine Expectorant to children, it is advisable to use an oral syringe to measure the dose accurately.

-When to use it

Take with food or milk to minimise gastric irritation. Drink a glass of water after each dose to help loosen mucous in lungs.

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

-How long to use it

Follow the directions on the 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 the next dose, skip the dose you missed and take the 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 chances of getting unwanted side effects.

-If you use too much (overdose)

Overdose of antihistamines in infants and children is very dangerous and can be fatal.

If you or anyone else has taken too much of Pharmaniaga Diphenhydramine Expectorant immediately go to the Emergency Department at your nearest hospital even if there are no signs of discomfort or poisoning.

Symptoms for antihistamines in infants and children, causing:

- Lack of muscle coordination
- Excitement
- Shaking
- Severe mental disorder and loss control with reality
- Hear, smell, taste or feel things that do not exist and seizure
- Extremely high body temperature
- Deepening coma and sudden loss of heart function and respiratory failure

While for adults, more common with:

- Respiratory failure
- Cardiovascular collapse (Disorder of the heart and blood circulation)
- Profound unbalanced body's acid- base and deficiency of potassium in the blood
- Sleepiness
- Irregular movement of the body

While you are using Pharmaniaga Diphenhydramine Expectorant

-Things you must do

- Talk to your doctor or pharmacist if your symptoms persist for more than 7 days, or if high fever, skin rash or continuing headache is present with cough.
- When seeking other medical treatment, inform all the doctors, dentists and pharmacists that you are taking Pharmaniaga Diphenhydramine Expectorant.

- If you become pregnant while taking Pharmaniaga Diphenhydramine Expectorant, inform your doctor immediately.

-Things you must not do

Do not give Pharmaniaga Diphenhydramine Expectorant to anyone else, even if their symptoms seem similar to yours.

Do not use Pharmaniaga Diphenhydramine Expectorant to treat any other complaints unless your doctor tells you to.

Do not drink alcohol while taking Pharmaniaga Diphenhydramine Expectorant. If you drink alcohol, the side effects of Pharmaniaga Diphenhydramine Expectorant such as drowsiness, dizziness or lightheadedness may become worse.

-Things to be careful of

Do not drive, operate machinery or engage in activities which require mental alertness if you feel sleepy or dizzy after taking Pharmaniaga Diphenhydramine Expectorant.

Side Effects

All medicines may have some unwanted side effects. Unwanted side effects do not always occur in every person. The following side effects may occur while you are using Pharmaniaga Diphenhydramine Expectorant:

- Drowsiness
- Blurred vision
- Confusion
- Dizziness
- Dryness of eye, mouth, nose or throat
- Increased sweating
- Loss of appetite
- Nightmares
- Irritability
- Oversensitivity of skin to the light

PHARMANIAGA DIPHENHYDRAMINE EXPECTORANT

Diphenhydramine hydrochloride / Ammonium chloride (12.5mg/135mg per 5ml)

- Impaired performance
- Tiredness
- Menstrual disease
- Low blood pressure
- Stomach discomfort
- Sleep disorder
- Coldness
- Anxiety
- Numbness
- Tremor
- Inflammation of nerve
- Low blood platelet count
- Abnormal breakdown of red blood cell
- Lack of white blood cell
- Redness and swelling
- Serious allergic reaction
- Ear problem
- Double vision
- Urinary problem
- Abnormal thickening of bronchial wall
- Muscle movement disorder
- Constipation
- Diarrhoea
- Vomiting and urge to vomit
- Sudden attack of illness

If you experience any of the following after taking Pharmaniaga Diphenhydramine Expectorant, inform your doctor and get medical treatment immediately:

- Wheezing or shortness of breath
- Fast, pounding heartbeat
- Skin rash
- Swelling of the face, lips, mouth, around the eyes, tongue or throat which causes difficulty in swallowing

These are very serious side effects and require urgent medical treatment.

Hyperexcitability may occur in older children taking antihistamines.

The elderly is more susceptible to many adverse effects of antihistamines including sedation and high blood pressure.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Pharmaniaga Diphenhydramine Expectorant

-Storage

Keep all medicines out of sight and reach of children.

Do not store in the bathroom or near a sink, or on a window sill.

Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

Do not take this medicine after the expiry date stamped on the pack. The expiry date refers to the last day of that month.

- Store below 30°C.
- Protect from light.
- Keep container tightly closed.

-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

Brown syrup.

-Ingredients

- Active ingredient:

Each 5mL of the syrup contains
Diphenhydramine hydrochloride: 12.5mg
Ammonium chloride: 135mg

- Inactive ingredients:

Raspberry Flavour, Menthol, Glycerin, Peppermint Oil, Refined Sugar, Citric Acid, Liquid Glucose, Sodium Benzoate, Sodium Saccharin, Purified Water, Caramel SD, Sodium Citrate, Xanthan Gum

-MAL Number:

MAL19971329AZ

Manufacturer

Idaman Pharma Manufacturing Sdn Bhd
Lot 24 & 25 Jalan Perusahaan Lapan
Bakar Arang Industrial Estate
08000 Sungai Petani
Kedah Darul Aman
Malaysia

Product Registration Holder

Pharmaniaga Manufacturing Berhad
No. 11A, Jalan P/1,
Kawasan Perusahaan Bangi,
43650 Bandar Baru Bangi,
Selangor Darul Ehsan
Malaysia

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