

# PHARMANIAGA DIPHENOXYLATE A TABLET

Diphenoxylate Hydrochloride/Atropine Sulphate (2.5mg/0.025mg)

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## What Pharmaniaga

### Diphenoxylate A Tablet is used for

Pharmaniaga Diphenoxylate A Tablet is used in the treatment of diarrhoea.

When you have diarrhoea, your body loses water and important salts. Therefore, your doctor may also give you other medicines to help replace the water and salts that you have lost which you may need to take before using Pharmaniaga Diphenoxylate A Tablet.

Your doctor may also give you Pharmaniaga Diphenoxylate A Tablet to reduce the number of stools and make them less watery if you have had a colostomy (part of your bowel removed causing you to use an external bag) or ileostomy.

## How Pharmaniaga

### Diphenoxylate A Tablet works

Pharmaniaga Diphenoxylate A Tablet contains the ingredients diphenoxylate and atropine sulphate.

Diphenoxylate hydrochloride works by slowing down the activity of the intestines and therefore reduces the diarrhoea.

When given by mouth, atropine sulphate reduces smooth-muscle contraction and diminishes gastric and intestinal motility.

## Before you use Pharmaniaga

### Diphenoxylate A Tablet

#### -When you must not use it

You should not use Pharmaniaga Diphenoxylate A Tablet if you are allergic to diphenoxylate hydrochloride and atropine sulphate or any of the other ingredients of Pharmaniaga Diphenoxylate A tablet as listed at the end of this leaflet.

You should not use Pharmaniaga Diphenoxylate A Tablet if you are treated for diarrhea caused by antibiotics such as clindamycin or lincomycin.

#### -Before you start to use it

Check with your doctor or pharmacist before taking Pharmaniaga Diphenoxylate A Tablet if you have ulcer and inflammation in the large intestine or obstructive bowel disorder.

#### -Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

This is because Pharmaniaga Diphenoxylate A Tablet can affect the way some other medicines work or those medicines may affect the way Pharmaniaga Diphenoxylate A tablet works.

## How to use Pharmaniaga Diphenoxylate A Tablet

### -How much to use

Follow all directions given to you by doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist to help.

The standard dose for Pharmaniaga Diphenoxylate A Tablet is as follows:

#### Adult:

Initial dose of two tablets four times a daily, later reduced when the diarrhoea is controlled.

#### Children:

6-8 years: one tablet three times daily.

9-11 years: one tablet four times daily.

Over 12 years: two tablet three times daily.

Pharmaniaga Diphenoxylate A Tablet should not be used in children under 6 years of age.

### When to use it

Use as directed by your doctor or pharmacist.

If your diarrhoea contains blood or still does not stop, you should go back to see the doctor.

### -How long to use it

Continue taking Pharmaniaga Diphenoxylate A Tablet for as long as your doctor recommends.

Your doctor may advise you to stop taking Pharmaniaga Diphenoxylate A Tablet when your diarrhoea stops or has improved.

### -If you forget to use it

Take the missed dose as soon as you remember. If it is almost time

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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.

### -If you use too much (overdose)

Symptoms of overdosage include dryness of the skin, flushing, feeling unusually warm with a high temperature and fast heartbeat, pinpoint pupils, poor reflexes, tiredness, coma and severe breathing difficulty.

Go to the Emergency Department of your nearest hospital if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

### **While you are using it**

#### -Things you must do

Take your medicine exactly as your doctor or pharmacist has told you.

When seeking other medical treatment, tell all the doctors, dentists and pharmacists treating you that you are taking Pharmaniaga Diphenoxylate A Tablet.

#### -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 or pharmacist

Do not drink alcohol while you are taking Pharmaniaga Diphenoxylate A Tablet.

Do not give Pharmaniaga Diphenoxylate A Tablet to anyone else, even if they have the same symptoms or conditions as you.

### -Things to be careful of

#### **Pregnancy and breast feeding**

Pharmaniaga Diphenoxylate A Tablet should not be used during pregnancy or breast feeding. Ask your doctor or pharmacist for advice before taking any medicine.

#### **Driving and using machines**

Pharmaniaga Diphenoxylate A Tablet may make you feel drowsy or dizzy or affect your concentration. You should not drive or use machines when you first start to take this medicine until you are certain that you are not getting these side effects. If in any doubt, speak to your doctor or pharmacist before you drive or use machines.

This medicine may result in fluid retention in the intestines, which may aggravate and mask dehydration and depletion of electrolytes, especially in young children. If severe dehydration or electrolyte imbalance is present, diphenoxylate should be withheld until appropriate corrective therapy has been initiated by doctor.

#### **Side effects**

Like all medicines, Pharmaniaga Diphenoxylate A Tablet can sometimes cause side effects, although not everybody gets them.

If you experience any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face, gum or lips, rash or itching (especially affecting your whole body) you should see a doctor immediately.

The following side effects may occur:

- Nausea and vomiting.
- Sleeping difficulty.
- Drowsiness and headaches.
- Reduced appetite and constipation.

- Flushing and dryness of your skin and mouth.
- Chest pain.
- Transient slow heartbeat followed by fast heartbeat, with strong and irregular heartbeat.
- Difficulty passing urine.
- Increased pressure in the eye causing changes to vision.
- Sensitivity towards light.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

### **Storage and Disposal of Pharmaniaga Diphenoxylate A Tablet**

#### -Storage

Keep the medicines in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store it or any other medicine 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 use this medication after the expiry date which is printed on the product packaging. The expiry date refers to the last day of that month.

Keep it where children cannot reach it.

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## -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

White, round, biconvex tablet with Pharmaniaga icon on one side and scoreline on the other.

### -Ingredients:

-Active ingredient(s):

Diphenoxylate Hydrochloride  
2.5mg & Atropine Sulphate  
0.025mg

-Inactive ingredient(s):

Talcum, Povidone, Lactose  
Monohydrate, Starch,  
Croscarmellose Sodium, Purified  
Water and Stearic Acid

### -MAL number(s):

MAL19880347AZ

## **Manufacturer**

Pharmaniaga Manufacturing  
Berhad (60016-D),  
11A, Jalan P/1, Kawasan  
Perusahaan Bangi, 43650 Bandar  
Baru Bangi, Selangor Darul  
Ehsan, Malaysia.

## **Product Registration Holder**

Pharmaniaga Manufacturing  
Berhad (60016-D),  
11A, Jalan P/1, Kawasan  
Perusahaan Bangi, 43650 Bandar  
Baru Bangi, Selangor Darul  
Ehsan, Malaysia.

## **Date of Revision**

01/11/2017

## **Serial Number**

NPRA(R4/1)241017/00280