

# DHAMOTIL TABLET

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

## What is in this leaflet

1. What Dhamotil is used for
2. How Dhamotil work
3. Before you use Dhamotil
4. How to take Dhamotil
5. While you are using Dhamotil
6. Side Effects
7. Storage and Disposal of Dhamotil
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What Dhamotil is used for

Dhamotil is used as adjunctive therapy in the management of diarrhoea.

When you have diarrhoea, your body loses water and important salts. Consequently, your doctor may also give you other medicines to help replace the water and salts that you have lost. In some cases the doctor will not give you Dhamotil until after the water and salts have been replaced.

## How Dhamotil work

Dhamotil contains diphenoxylate hydrochloride and atropine sulphate.

Diphenoxylate is the active ingredient of Dhamotil. It has the effect of slowing down the activity of the intestines.

## Before you use Dhamotil

### -When you must not take it

Do not take Dhamotil if:

- You are allergic (hypersensitive) to diphenoxylate hydrochloride, atropine sulphate and any of the other ingredients in the tablets.
- You have jaundice (yellowing of your skin or the whites of your eyes caused by liver disease).
- You have an obstruction of the bowels which prevents food from moving through your digestive system.
- You have diarrhoea resulting from some types of bacteria called enterotoxin-producing bacteria, or from a severe disease of the bowels called

pseudomembranous enterocolitis (inflammation of colon), which may be caused by certain antibiotics.

- your child taking the medicine is below 6 years old

### -Before you start to take it

You should check with your doctor or pharmacist before taking Dhamotil if:

- you are pregnant or breast-feeding
- you have severe dehydration or electrolyte (minerals in the body) imbalance
- kidney or liver disease

Diphenoxylate HCl and Atropine Sulphate are found in breast milk. Atropine Sulphate can cross the placenta. DHAMOTIL should only be used if the potential benefit justifies the risk to the foetus.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Dhamotil.

### Driving and operating machine

This medicine may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink.

### -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. This includes:

- Medicines for depression known as monoamine oxidase inhibitors (MAOIs)
- Medicines to treat anxiety and tension such as barbiturates and tranquilizers.

## How to take Dhamotil

### -How much to take

Adults:

1 to 2 tablets three or four times a day or as directed by the physician.

### -When to take it

Take Dhamotil at the same time every day. If you are not sure, check with your doctor or pharmacist.

### -How long to take it

Always take Dhamotil exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

### -If you forget to take it

If you forget to take a dose, take it as soon as you remember it and then take the 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 (or someone else) took a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

Taking too many tablets can be very serious, and may cause unconsciousness or difficulty breathing.

Other symptoms include:

- dry skin
- tachycardia (an abnormally rapid heart rate)
- flushing
- hyperthermia (body temperature above normal)
- miosis (excessive constriction of the pupil of the eye)
- hypotonia (a state of low muscle tone, often involving reduced muscle strength)
- nystagmus (involuntary eye movement)
- seizures
- tiredness

## While you are taking Dhamotil

### -Things you must do

Stop treatment when bowel movements return to normal. Consult the doctor if diarrhoea is bloody or persists for more than 3 days.

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## -Things you must not do

Do not exceed 8 tablets in 24 hours.

## -Things to be careful of

Dhamotil is not recommended for children under 6 years of age.

## **Side Effects**

Like all medicines, Dhamotil 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.

This includes:

- Numbness of extremities e.g. in the fingers, hands, arm, feet, leg
- drowsiness
- headache
- allergic reactions e.g. itchiness, redness, swelling
- vomiting
- nausea
- anorexia (eating disorder)
- abdominal discomfort.

If any of the side effects become 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 [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

## **Storage and Disposal of Dhamotil**

### -Storage

Keep all medicines out of the reach of children.

Store below 30°C and protect from light.

### -Disposal

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

Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets 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

Round, green film-coated tablets, 6 mm diameter without score-line and logo.

### -Ingredients

Active Ingredient

Each tablet contains:

- 2.5mg Diphenoxylate Hydrochloride BP
- 0.025mg Atropine Sulphate BP

Inactive ingredients

Povidone 30, corn starch, magnesium stearate, titanium dioxide, FDC Blue no. 1 aluminium lake, lactose mesh 30, propylene glycol, hydroxypropylmethylcellulose, quinoline yellow E104 aluminium lake

### -MAL Number

MAL19890376AZ

## **Manufacturer**

Drug Houses of Australia Pte. Ltd.

#09-01/02 Haw Par Tiger Balm Building,  
No. 2, Chia Ping Road,  
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## **Product Registration Holder**

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## **Date of Revision**

16/02/2016

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