

BEAMOTIL TABLET

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

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What Beamotil is used for

This medicine is used as adjunctive therapy to treat symptoms of diarrhoea.

Beamotil may also be used to reduce the frequency and fluidity of the stools in people with colostomies or ileostomies (part of your bowel removed causing you to use an external bag).

How Beamotil works

Beamotil contains diphenoxylate hydrochloride and atropine sulfate along with other ingredients. The diphenoxylate reduces diarrhoea by slowing down the movements of the intestines. Because diphenoxylate may be abused by taking it in doses that are larger than prescribed, this causes unpleasant effects. So, a small amount of atropine sulfate is included in Beamotil to discourage abuse.

Before you use Beamotil

- When you must not take it

Do not take this medicine if you:

- are allergic to diphenoxylate or atropine or any of the tablet ingredients listed at the end of this leaflet.

- have an allergic reaction (you may get a skin rash, difficulty in breathing, hay fever or faintness)
- have jaundice (yellowing of skin and whites of eye)
- have diarrhea caused by pseudomembranous colitis (a potentially serious infection of the gut) which may occur during or up to several weeks following antibiotic treatment
- have inflammatory bowel disease such as colitis.
- are breastfeeding

You should use an alternative form of infant feeding while taking Beamotil.

Beamotil passes into breast milk, so if you take Beamotil while breastfeeding, your baby may have some effects from it.

Studies in animals have not shown diphenoxylate and atropine to be teratogenic (disturb the development of foetus). However, risk-benefit must be considered as animal studies have shown that diphenoxylate may reduce maternal weight gain and fertility.

Beamotil is not recommended for children less than 6 years old.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

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

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Inhibition of muscle movements in oesophagus or digestive tract due to medicines may result in fluid detention in the intestine, which may aggravate and mask dehydration and depletion of electrolytes, especially in young children.

Atropine may aggravate conditions such as:

- acute angle-closure glaucoma (increased pressure in the eye)
- oesophageal reflux associated with backflow from the stomach to the chest cavity
- high blood pressure
- conditions characterised by increased heart rate such as overactive thyroid gland, heart failure and heart surgery where it may further accelerate the heart rate
- prostate enlargement, narrowing of urethra or urinary retention
- reduction in intestinal muscle tone in the elderly or debilitated and myasthenia gravis (muscle weakness).

How to use Beamotil

Tell your doctor if you have any of the following health problems:

- liver disease
- kidney disease
- diarrhoea caused by poisoning
- acute dysentery characterized by bloody stools and elevated temperature
- gastrointestinal obstruction
- underactive thyroid disease
- respiratory diseases
- overflow incontinence (loss of bladder control) secondary to constipation

If you have not told your doctor about any of the above, tell him/her before you start taking Beamotil.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Beamotil may interfere with each other.

- Antidepressants - medicines used to treat depression, such as tricyclic antidepressants and monoamine oxidase inhibitors (MAOI)
- Barbiturates - medicines used to treat epilepsy and to help you sleep.
- Some antihistamines - medicines for allergy

Other medicines not listed above may also interact with Beamotil. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

- How much to use

The dosage of Beamotil depends on the condition it is being used to treat.

Adult:

The recommended initial dose is 2 tablets. 3 - 4 times daily.

Maintenance dose: 2 tablets once daily as needed.

Never take more than 8 tablets in any 24 hour period.

Children:

Children under 6 years of age: Use is not recommended.

Children 6 - 9 years of age: 1 tablet 3 times daily

Children 9 - 12 years of age: 1 tablets 4 times daily

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

- When to use it

Take medicine with food or meals if gastrointestinal irritation occurs.

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

- If you forget to use it

You should only take this medicine as required following the dosage instructions given carefully.

If you forget to take a dose, take a dose after the next loose stool (bowel movement).

Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Taking too many of this tablet at one time may cause blurred vision, difficulty in breathing or swallowing.

Other symptoms include:

- constipation
- severe drowsiness
- coma
- irritability
- seizure
- hallucination (hear, smell, taste or feel things that do not exist)
- flushing
- restlessness
- abnormally low heart rate followed by high heart rate
- severe dryness of skin, mouth, nose, and throat

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Beamotil.

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

If you become pregnant while taking this medicine, tell your doctor immediately.

Drink plenty of liquids, such as an oral rehydration solution. Drinking plenty of liquids makes sure you do not become dehydrated (lose too much liquid from your body). If you have become very dehydrated, you should see your doctor to make sure this is corrected, before taking Beamotil.

Contact your doctor if diarrhoea is not controlled within 48 hours and/or fever develops.

- Things you must not do

Do not drink alcohol. Drinking alcohol can make your diarrhea worse.

Do not take Beamotil to treat any other complaints unless your doctor tells you to.

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

- Things to be careful of

Be careful driving or operating machinery until you know how Beamotil affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

These are the side effects of Beamotil:

- mild anticholinergic effects (blurred vision, difficult urination, dryness of skin and mouth, fever)
- Central Nervous System (CNS) depression (dizziness or lightheadedness, drowsiness, mental depression, restlessness)
- euphoria (a feeling or state of intense excitement and happiness)
- headache
- confusion

- numbness of hands and feet
- hypersensitivity reactions

If any side effects do not settle down during treatment and are a problem for you, or if you develop any new medical problem while you are taking Beamotil, tell your doctor.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Beamotil.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (conserve) or Vaccine (AEFI))

Storage and Disposal of Beamotil

- Storage

Keep your medicine in a dry place below 30°C. Protect from light.

Do not store Beamotil or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

- What it looks like

A 5.5mm diameter, round, convex, white tablet.

- Ingredients

- Active ingredient:

- Diphenoxylate Hydrochloride
- Atropine Sulfate

- Inactive ingredients:

- Corn starch
- Lactose monohydrate
- Magnesium stearate
- Microcrystalline cellulose

- MAL number

MAL19871646AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn. Bhd.
Lot No. 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi Selangor, Malaysia.

Product Registration Holder

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