

DICETEL[®] FILM COATED TABLET

Pinaverium bromide (50mg)

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What Dicetel[®] is used for

Dicetel[®] treats and relieves the symptoms associated with irritable bowel syndrome (IBS) such as abdominal pain, bowel disturbances (constipation and/or diarrhea) and intestinal discomfort (bloating). Dicetel is also used to help relieve symptoms caused by certain disorders of the gallbladder associated with secretion of bile.

How Dicetel[®] works

Dicetel[®] works by relaxing the muscles in the walls of the gut (also called intestine).

Before you use Dicetel[®]

- When you must not use it

- If you are allergic to pinaverium bromide or any of the ingredients listed at the end of this leaflet

- Before you start to use it

Discuss with your doctor or pharmacist before taking your medicine if:

- You have lesion on your esophagus and/or hiatus hernia (a condition where part of your stomach moves up into your chest)

- You have gastrointestinal movement disorder due to structural changes on organ or tissue

- Taking other medicines

It is particularly important to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also concerns medicines obtained without a prescription including herbal medicines.

How to use Dicetel[®]

- How much to use

Always take Dicetel[®] exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dosage is 1 tablet three times a day. If necessary, your doctor may increase this dosage to 6 tablets per day.

Swallow the tablets without chewing or sucking them.

- When to use it

Take the tablets with a glass of water in the middle of a meal.

- How long to use it

Continue using Dicetel[®] for as long as your doctor or pharmacist recommends.

- If you forget to use it

Do not take a double dose to make up for the forgotten tablet. Take the next tablet at your regular time on the next day. If you are worried about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you have taken more Dicetel[®] than you should or if someone else has

taken your medicine, tell your doctor or pharmacist or contact your nearest hospital.

While you are using it

- Things you must do

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

The tablet should not be swallowed when in the lying position or just before bedtime.

Pregnancy and breast feeding

There is insufficient information on the use of Dicetel[®] on pregnant and breast-feeding women. Your doctor will decide whether you are suitable for Dicetel[®].

Usage of Dicetel[®] at the end of pregnancy can affect the newborn to experience low eye pressure and sedation.

- Things to be careful of

Important information about some of the ingredients of Dicetel[®]

Dicetel[®] contains types of sugars called lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

This product contains sunset yellow as ingredient, which may cause allergic reactions.

The usage of this product in children (less than 18 years of age) is limited.

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Side effects

Like any other medicine, Dicetel[®] may cause side effects in some people. Some people may experience abdominal pain, nausea, vomiting, difficulty swallowing, or diarrhea.

Since these side effects are similar to the symptoms of IBS, it may be hard to tell the difference. Other side effects include rash, itching, hives, redness of skin and allergic reaction. Lesions on esophagus may occur if Dicetel[®] tablets are not taken as instructed.

If you get these or any other problems while you are taking Dicetel[®], consult 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 visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Dicetel[®]

- Storage

Keep this medicine out of the sight and reach of children. Do not use Dicetel[®] after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package and keep the blister in the outer carton in order to protect from light.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These

measures will help protect the environment.

- 25/03/2022

Product Description

- What it looks like

Dicetel[®] 50mg Film Coated Tablet is round, orange coloured with engraving of “50” on one side, and “S” on the other side.

Dicetel[®] is available in cartons of 5, 20, 25, 30, 40, 50, 60, 100 or 120 tablets. Not all pack sizes may be marketed.

- Ingredients

- Active ingredient(s)

Pinaverium Bromide

- Inactive ingredients

Microcrystalline cellulose, pre-gelatinised starch, lactose monohydrate, anhydrous colloidal silica, talc, magnesium stearate, basic butylated metacrylate copolymer, sodium laurylsulfate, stearic acid, hydroxypropyl methylcellulose, titanium dioxide, sunset yellow lake

- MAL number:

Dicetel[®] 50mg Film Coated Tablet:
MAL12045092ACZ

Manufacturer

Mylan Laboratories SAS
01400 Châtillon-sur-Chalaronne
France

Product Registration Holder

Abbott Laboratories (M) Sdn. Bhd.
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