

Pr **DICETEL[®] Information for the Patient**
(Pinaverium bromide)
Film-coated Tablets
Gastrointestinal calcium antagonist

BGP Pharma ULC
85 Advance Road
Etobicoke, Ontario
M8Z 2S6

This information provides a summary on DICETEL and explains how to use it. For more information or advice, please ask your doctor or pharmacist.

What is DICETEL[®]?

DICETEL is the brand name for the medication, pinaverium bromide. It is available as a round, biconvex, yellowish-orange film-coated tablet containing either 50 mg or 100 mg of pinaverium bromide. The 50 mg tablets are engraved with “50” on one side and are 8 mm in diameter. The 100 mg tablets are engraved with “100” on one side and are 11 mm in diameter. In addition, the tablets also contain the following nonmedicinal ingredients: microcrystalline cellulose, pre-gelatinized starch, lactose monohydrate, anhydrous colloidal silica, talc and magnesium stearate, basic butylated methacrylate copolymer, sodium laurylsulphate, stearic acid, hydroxypropyl methylcellulose, iron oxide yellow, iron oxide red.

If you are allergic to any of these substances ask your doctor or pharmacist whether these ingredients may pose a problem.

How does DICETEL[®] work?

DICETEL works by relaxing the muscles in the walls of the gut (also called the intestine). 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).

What you should tell your doctor before you take DICETEL[®]:

- If you are pregnant or breast-feeding. DICETEL should not be used during breastfeeding.
- If you have any allergies or have had a reaction to any of the ingredients in DICETEL (see What is DICETEL?).
- If you are lactose intolerant, talk to your doctor, as this product contains lactose.
- If you have been told by your doctor that you have a rare condition of intolerance to some sugars or difficulty absorbing some sugars (galactose intolerance, Lapp lactase deficiency or glucose/ galactose malabsorption), do not take this medicinal product before talking to your doctor, as the product contains lactose.
- If you have lesions or damage to your esophagus, including hernia (rupture) affecting the esophagus.

- If you have other medical conditions and/ or are taking other medications.

How to take DICETEL[®] tablets:

- Take only as directed by your doctor. The dose-range for adults is DICETEL 50 - 100 mg three times a day.
- To avoid irritation to your esophagus (food pipe), the tablet should be swallowed whole with a glass of water during meals; do not crush, chew or suck the tablet.
- The tablet should not be swallowed when in the lying position or just before bedtime.
- DICETEL is not recommended for use in children.

What if you miss a dose?

If you miss the usual time for taking a DICETEL tablet, take it as soon as possible. If however, it is near the time of your next dose, skip the missed pill and return to your usual dosing schedule. Do not take double the dose.

What if you take too many tablets?

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Never change the amount of DICETEL you are taking unless instructed to do so by your doctor. If you have taken more DICETEL tablets than the recommended dose, tell a doctor immediately. Show the doctor your pack of tablets.

What are possible side effects with DICETEL[®]?

Most people tolerate DICETEL well. Like any other medicine, however, DICETEL may cause side effects in some people. These tend to be mild when they occur. Some people may feel stomach pain and/or fullness, abdominal pain, nausea, vomiting, difficulty swallowing, constipation, heartburn, bloating 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 headache, dryness of the mouth, drowsiness, dizziness, skin allergy, rash, itching, hives, redness of skin and allergic reactions. Lesions or damage to the 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.

Looking after your tablets.

- Store at room temperature (15°C to 30°C).
- Keep away from children.
- Don't take your tablets if they are past their expiry date.

Remember that this medication has been prescribed for you. Do not share your medications with others, even if they are experiencing similar symptoms. Only a doctor can prescribe DICETEL.

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