Dicetel® 50 mg
film-coated tablets

Dicetel® 100 mg
film-coated tablets

50 or 100 mg pinaverium bromide

Abbott

Read this entire leaflet carefully before you start taking this medicine.
Keep this leaflet. You may need to read it again. If you have questions not answered by this pamphlet, please ask your doctor or pharmacist. This medicine has been prescribed to you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Dicetel film-coated tablets are orange coloured film-coated tablets for oral administration, engraved with "50" or "100" on one side (depending on the tablet strength) and "S" on the other side. Each tablet contains 50 mg or 100 mg of pinaverium bromide.

Excipients (non-medicinal ingredients):

Core: microcrystalline cellulose, pre-gelatinised starch, lactose monohydrate, anhydrous colloidal silica, talc, magnesium stearate.

Coating: basic butylated metacrylate copolymer, sodium laurylsulfate, stearic acid, talc, microcrystalline cellulose, aluminium lake "sunset yellow" (E110), titanium dioxide (E171), hydroxypropyl methylcellulose.

Indications
- Symptomatic treatment of pain, transit disorders and intestinal discomfort related to functional intestinal disturbances;
- Symptomatic treatment of pain related to functional disturbances of the biliary tract;
- Preparation for a barium enema.

Dosage and administration

Always take Dicetel exactly as your doctor has prescribed. If you have any questions, contact your doctor or pharmacist.

If you forget to take your tablet(s), do not take a double dose to compensate for it. If you require further information, please ask your doctor or pharmacist for advice.

Adults:
- *Dicetel 50 mg, film-coated tablets:*
  The recommended dosage is 3 to 4 tablets per day. If necessary, your doctor may increase this dosage to 6 tablets per day.
  Information for doctors:
  In preparation for a barium enema, the dosage is 4 tablets per day, for the 3 days before the examination.
- *Dicetel 100 mg, film-coated tablets:*
  The recommended dosage is 2 tablets per day. If necessary, your doctor may increase this dosage to 3 tablets per day.
  Information for doctors:
  In preparation for a barium enema, the dosage is 2 tablets per day, for the 3 days before the examination.

Take your tablets in divided doses: i.e. one dose in the morning and one in the evening.

Method of administration

Swallow the tablets without chewing or sucking them. Take the tablets with a glass of water in the middle of a meal.

Paediatric population:

The experience in children is limited (see section "Warnings and special precautions for use").

Contraindications

Do not take Dicetel if you are hypersensitive to the active substance or to any of the excipients.

Warnings and special precautions for use

There is only limited experience with the use of Dicetel in children. Therefore, the doctor will only prescribe Dicetel to your child if it is clearly indicated.

This medicinal product contains lactose.

If you suffer from any of the following rare hereditary problems: galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, you should not take this medicine.

Interactions with other medications

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription. Furthermore, if you are taking any type of the medications listed below, or if you are unsure of the class of medication you are taking, you must inform your doctor before starting treatment with Dicetel.

Clinical trials have demonstrated the absence of any interaction between pinaverium bromide and digitalis drugs (heart medications), oral anti-diabetics, insulin, oral anticoagulants and heparin.

Co-administration of an anticholinergic drug may enhance spasmolysis.

No interference with laboratory tests for drug level detection was observed.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

There are no adequate data from the use of pinaverium bromide in pregnant women.

Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition (giving birth) and postnatal (following birth) development. The potential risk for humans is unknown. Dicetel should not be used during pregnancy unless your doctor decides it is clearly necessary.

Furthermore, the presence of bromine should be taken into account. Administration of pinaverium bromide at the end of pregnancy can affect the new-born neurologically (can cause hypotony (decreased muscle tone) and/or sedation (sleepiness)).

There is insufficient information on the excretion of pinaverium bromide in human and animal breast milk. Available research data, including physico-chemical and pharmacodynamic/toxicological data on Dicetel suggest that pinaverium bromide is excreted in breast milk and therefore a risk to the suckling child cannot be excluded. Dicetel should not be taken while breast-feeding.

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Important information about the ingredients

If you have been told by your doctor that you have an intolerance to some sugars, especially lactose, glucose or galactose, contact your doctor before taking this medicinal product.

This product contains sunset yellow (E110) as an excipient, which may cause allergic reactions.

Undesirable effects

Like all medicines, Dicetel may cause side effects, although not everybody experiences them. If you notice any side effects not mentioned in this leaflet, or if any of the side effects gets serious, please inform your doctor or pharmacist.

The following adverse events have been reported spontaneously during post-marketing use. A precise frequency can not be estimated from available data (not known).

Gastrointestinal disorders

Gastro-intestinal disturbances have been observed, e.g. abdominal pain, diarrhea, nausea, vomiting, and dysphagia (difficulty swallowing).

Skin and subcutaneous tissue disorders

Cutaneous (skin) effects have been observed, e.g. rash, pruritus (itchiness), urticaria (hives), and erythema (reddening of the skin).

Immune system disorders

Hypersensitivity reactions may occur.

Overdose

Currently there is no specific information on overdose related adverse reactions. No specific antidote is known; symptomatic treatment is recommended.

Pharmacodynamics

The following is a detailed description of how the active ingredients of Dicetel work. For further explanations please consult your doctor.

Pharmacotherapeutic group: Other drugs for functional bowel disorders

Pinaverium bromide is an antispasmodic selectively acting on the gastro-intestinal tract. It is a calcium antagonist which inhibits the influx of calcium into intestinal smooth muscle cells. In animals, pinaverium directly or indirectly reduces the effects of the stimulation of the sensitive afferences. It is free from anticholinergic effects. It is also devoid of effects on the cardiovascular system.

Pharmacokinetics

The following is a detailed description of how the active ingredients of Dicetel are metabolized by the body. For further explanations please consult your doctor.

After oral administration pinaverium bromide is rapidly absorbed with peak plasma concentrations occurring within one hour. The drug is extensively metabolised and eliminated via the liver. The elimination half-life is 1.5 hours.

Absolute bioavailability for the oral formulation is very low (< 1%). Major route of excretion is via the faeces.

Plasma protein binding of pinaverium bromide is high (95-96%).

Incompatibilities

Not applicable.

Shelf life and storage conditions

This product can be stored for up to 3 years.

Do not use the medicine after the expiry date stated on the carton.

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.

Keep this medicine out of the reach and sight of children.

Pack sizes

Dicetel 50mg: 15, 20, 25, 30, 40, 50, 60, 100 or 120 tablets per pack (not all pack sizes may be marketed). The blisters strips are made from PVC/aluminium.

Dicetel 100mg: 10, 15, 20, 25, 30, 50 or 100 tablets per pack (not all pack sizes may be marketed). The blisters strips are made from PVC/aluminium.

Further information

Any unused product or waste material should be disposed of in accordance with local requirements.

The information in this leaflet is limited. For further information, please contact your doctor or pharmacist.

Date of information

March 2009

Manufactured by:

Abbott Healthcare SAS - 01400 Châtillon-sur-Chalaronne - FRANCE

for:

Abbott Products SAS - 92151 Suresnes Cedex - FRANCE

THIS MEDICATION

is a product which affects your health and its use contrary to instructions is dangerous to you.

Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medication.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not interrupt the period of treatment prescribed without talking to your doctor first.
- Do not repeat the same prescription without first consulting your doctor.
- Keep all medications out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.