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 “3” on the other side. Each tablet contains 50 mg or 100 mg of pinaverium bromide.

Excipients (non-medicinal ingredients):
Core: microcrystalline cellulose, pregelatinised starch, lactose monohydrate, anhydrous colloidal silica, talc, magnesium stearate.
Coating: basic butylated metacrylate copolymer, sodium lauryl sulfate, 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.

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 glucosegalactose 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-diabet-
cics, 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 tak-
ing any medicine during pregnancy.
There are no adequate data from the use of pinaver-
ium bromide in pregnant women.
Animal studies are insufficient with respect to effects
on pregnancy, embryonal/foetal development, partur-
tion (giving birth) and postnatal (following birth) deve-
lopment. 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 leaf-
let, 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 cannot 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 ery-
thema (reddening of the skin).

Immune system disorders
Hypersensitivity reactions may occur.

Overdose
Currently there is no specific information on over-
dose 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 expla-
nations please consult your doctor.
Pharmacotherapeutic group: Other drugs for func-
tional 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, pinaver-
ium 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 rap-
idly 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 5 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 50 mg: 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 100 mg: 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