DICETEL
PINAVERIUM BROMIDE

PRODUCT NAME
Dicetel 100mg Film-Coated Tablet

BRAND NAME
Dicetel

QUALITATIVE AND QUANTITATIVE COMPOSITION
Active ingredient: pinaverium bromide.
Each film-coated tablet contains 100mg of pinaverium bromide

For full list of excipients, see section list of excipients.

PHARMACEUTICAL FORM
Round biconvex, yellowish-orange coloured film-coated tablet for oral administration, engraved with "100" on one side and 11mm in diameter.

INDICATIONS
- Treatment and relief of symptoms associated with irritable bowel syndrome (IBS): abdominal pain, bowel disturbances and intestinal discomfort.
- Treatment of symptoms related to functional disorders of biliary tract.

DOSAGE AND ADMINISTRATION
Adults
- The recommended dosage is 1 tablet twice a day
- If necessary, this dosage may be increased to 1 tablet three times a day

Paediatric population
The safety and efficacy of Dicetel have not sufficiently been established in children and experience is limited (see section warning and precautions).

Method of administration
The tablets must be swallowed without being chewed or sucked, with a glass of water in the middle of a meal in order to avoid contact of pinaverium with the oesophageal mucosa (risk of oesophageal lesion, see section side effects).
The tablet should not be swallowed when in the lying position or just before bedtime.

CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the excipients.

WARNING AND PRECAUTIONS
- Because of a risk of oesophageal lesion, instructions on the methods of administration should be carefully adhered to. Patients with pre-existing oesophageal lesion and/or hiatus hernia should pay special attention to correct application of Dicetel.

- The safety and efficacy of Dicetel have not sufficiently been established in children and experience is limited. Therefore, Dicetel is not recommended for use in children.

- This medicinal product contains Lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

- Dicetel should not be administered for the relief of motility dysfunction due to underlying organic disease.

DRUG INTERACTIONS
Clinical trials have demonstrated the absence of any interaction between pinaverium bromide and digitalis drugs, oral anti-diabetics, insulin, oral anticoagulants (i.e., acenocoumarol [anti vitamin K] 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
There are no adequate data from the use of pinaverium bromide in pregnant women. Animal studies are insufficient with respect to effects on pregnancy or embryonal/foetal development or parturition or postnatal development. The potential risk for humans is unknown. Dicetel should not be used during pregnancy unless clearly necessary.

Furthermore, the presence of bromine should be taken into account. Administration of pinaverium bromide at the end of the pregnancy can affect the new-born neurologically (hypotony, sedation).

There is insufficient information on the excretion of Dicetel in human or animal breast milk. Physico-chemical and available pharmacodynamic/toxicological data on Dicetel point to excretions in breast milk and a risk to the suckling child cannot be excluded. Dicetel should not be used during 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.

Adverse drug reactions such as somnolence may occur (see section 4.8). Under this condition the ability to react may be decreased.

SIDE EFFECTS
Based on the pooled data from 46 company-sponsored patient studies including 3755 patients who received pinaverium bromide, the following undesirable effects have been reported. Adverse reactions listed below are classified according to frequency and SOC. Frequencies are defined as very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), or very rare (<1/10,000).

MedDRA SOC	Frequency category	
	Common	Uncommon
Gastrointestinal disorders	Abdominal pain*# Constipation#, Dry mouth#, Dyspepsia, Nausea	Diarrhea, Vomitting
General disorders and administration site conditions		Asthenia
Nervous system disorders	Headache	Somnolence

* combination of PT's: 'abdominal pain', 'abdominal pain lower' and 'abdominal pain upper'

Gastrointestinal disorders are mainly associated with the underlying disease. Similar of lower incidences compared to placebo were reported for Abdominal pain, Constipation and Dry mouth.

The following adverse reactions 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. Oesophageal lesion may occur when not applied as advised (see section dosage and administration)

Skin and subcutaneous tissue disorders
Cutaneous effects have been observed, e.g. rash, pruritus, urticaria, and erythema.

Immune system disorders
Hypersensitivity.

OVERDOSAGE
Overdose may lead to gastrointestinal complaints, such as nausea, flatulence and diarrhoea. No specific antidote is known; symptomatic treatment is recommended.

PHARMACOLOGIC PROPERTIES
Pharmacodynamics
Pharmacotherapeutic group: Other drugs for functional bowel disorders, ATC code: A03AX04.
Pinaverium bromide is an antispasmodic which selectively acts on the gastro-intestinal tract. It is a calcium antagonist which inhibits the influx of calcium into intestinal smooth muscle cells. In animal pinaverium directly or indirectly reduces the effects of the stimulation of the sensitive afferences. It is free from significant anticholinergic effects. It is also devoid of effects on the cardiovascular system.

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

Plasma protein binding of pinaverium bromide is high (95-97%).

PRE-CLINICAL SAFETY DATA
The oral LD50 in animals ranges from 153.6 to 2153 mg/kg body weight. Toxicity of pinaverium bromide after oral administration was low. Signs of toxicity were mostly limited to general signs of toxicity, gastrointestinal symptoms and CNS symptoms. Pinaverium bromide did not display genotoxic or carcinogenic properties and had no teratogenic potential. At higher dose levels pinaverium bromide decreased pregnancy performance, but no relevant effect on pre- or post-natal development. Placental transfer of pinaverium bromide was not studied.

Based on toxicity studies, the lowest NOAEL was 300, 100 and 25 mg/kg for mice, rats and dogs, representing 50, 20 and 5 multiples of the human dose, respectively.

LIST OF EXCIPIENTS

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

Composition of the coating:
basic butylated metacrylate copolymer
sodium laurylsulfate
stearic acid
talc
hydroxypropyl methylcellulose.
Iron oxide yellow E172
Iron oxide red E172

STORAGE

- 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.

SHELF LIFE

36 months

HOW SUPPLIED

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.

MANUFACTURED AND PACKED BY:

Mylan Laboratories SAS
01400 Châtillon-sur-Chalaronne
France

PRODUCT REGISTRATION HOLDER & IMPORTER:

Abbott Laboratories (M) Sdn. Bhd.
27-02, Level 27, Imazium,
8, Jalan SS21/37, Damansara Uptown,
47400 Petaling Jaya,
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