# Pinaverium bromide

# Eldicet®

**50mg** Film-Coated Tablet

Spasmolytic

Rx

## QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: pinaverium bromide

Each film-coated tablet contains 50 mg of Pinaverium bromide.

## PHARMACEUTICAL FORM

Round, biconvex, yellowish-orange colored film-coated tablet for oral administration, engraved with "50" on one side and 8 mm in diameter.

## CLINICAL PARTICULARS

### Therapeutic 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.

### Posology and Method of Administration

**Posology**

Adults:

- The recommended dosage is 1 tablet three times a day up to 2 tablets twice a day.
- If necessary, this dosage may be increased to 2 tablets three times a day.
- In preparation for a barium enema, the dosage is 2 tablets twice a day, for the 3 days before the examination.

**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 esophageal mucosa (risk of esophageal lesion, see "**Undesirable Effects**").

Pediatric population:

The safety and efficacy of Pinaverium bromide (Eldicet®) have not sufficiently been established in children and experience is limited (see "**Special Warnings and Precautions for Use**"). Currently available data are described in "**Pharmacodynamic properties**" but no recommendation on a posology can be made.

### Contraindications

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

### Special Warnings and Precautions for Use

- Because of a risk of esophageal lesion, instructions on the methods of administration should be carefully adhered to. Patients with pre-existing esophageal lesion and/or hiatus hernia should pay special attention to the correct application of Pinaverium bromide (Eldicet®).
- The safety and efficacy of Pinaverium bromide (Eldicet®) have not sufficiently been established in children and experience is limited. Therefore, Pinaverium bromide (Eldicet®) 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.

### Interaction with Other Medicinal Products and Other Forms of Interaction

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.

### Fertility, 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/fetal development or parturition or postnatal development. The potential risk for humans is unknown. Pinaverium bromide (Eldicet®) 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 pregnancy can affect the new-born neurologically (hypotony, sedation).

There is insufficient information on the excretion of Pinaverium bromide (Eldicet®) in human or animal breast milk. Physico-chemical and available pharmacodynamic/toxicological data on Pinaverium bromide (Eldicet®) point to excretions in breast milk and a risk to the suckling child cannot be excluded. Pinaverium bromide (Eldicet®) 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 "**Undesirable Effects**"). Under this condition the ability to react may be decreased.

### Undesirable 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 (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), or very rare (<1/10,000).

| MedDRA SOC | Frequency category | |
|---|---|---|
| | Common | Uncommon |
| Gastrointestinal disorders | Abdominal pain*#,<br>Constipation#,<br>Dry mouth#,<br>Dyspepsia,<br>Nausea | Diarrhea,<br>Vomiting |

| | | |
|---|---|---|
| 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'<br># Gastrointestinal disorders are mainly associated with the underlying disease. Similar or 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 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. Esophageal lesion may occur when not applied as advised (see "**Posology and Method of Administration**").

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

Immune system disorders
Hypersensitivity.

**Overdose and Treatment**

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

**PHARMACOLOGICAL PROPERTIES**

**Pharmacodynamic Properties**

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.

*Pediatric Population*
Pharmacodynamic and efficacy studies have mainly been conducted in adults. In one open, baseline-controlled clinical study the efficacy and safety have been assessed in 29 children aged 5 to 15 over a period of 7-15 days with a daily dose of 100-150 mg. The safety and tolerability was shown to be good. Efficacy was analyzed only for the subset of patients (N=17) suffering from abdominal pain associated to an organic lesion or to previous pathological symptomatology. Overall clinical responses were considered good in 9 patients (53%), partial in 6 patients (35%) and nil in 2 patients (12%).

**Pharmacokinetic properties**

After oral administration Pinaverium bromide is rapidly absorbed with peak plasma concentrations occurring within one hour. The drug is extensively metabolized 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 feces.

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

**Preclinical Safety Data**

Toxicity
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.

Genotoxicity, carcinogenic potential, teratogenicity
Pinaverium bromide did not display genotoxic or carcinogenic properties. At doses 2fold the maximal recommended clinical dose pinaverium had no teratogenic potential.

Reproductive toxicity
At doses 2fold the maximal recommended clinical dose pinaverium bromide decreased gravidity performance, but had no relevant effect on the pre- or post-natal development. Placental transfer of pinaverium bromide and transfer into the milk were not studied.

**PHARMACEUTICAL PARTICULARS**

**Incompatibilities**
Not applicable

**Shelf Life**
36 months

**Special Precautions for Storage**
Store at temperatures not exceeding 30°C. Protect from light.

**Nature and Contents of Container**
Alu/PVC blister pack x 20 tablets (box of 20 tablets)
Alu/PVC blister pack x 25 tablets (box of 25 and 100 tablets)

**Caution**
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph".** Seek medical attention immediately at the first sign of any adverse drug reaction.

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