SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PIVERTEL 100 mg film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

Pinaverium bromide 100 mg

Excipient(s):

Lactose monohydrate (obtained from cow's milk) 36,30 mg

See 6.1 for a list of excipients.

3. PHARMACEUTICAL FORM

Film-coated tablet.

White or slightly yellowish, round, biconvex tablets

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Symptomatic treatment of pain due to functional bowel disorders, movement disorders and gastrointestinal diseases,

4.2. Posology and method of administration

Posology/ frequency and duration of administration:

Adults

- The recommended dose of PİVERTEL is 1 tablet taken twice, in the morning and in the evening.
- In exceptional cases, this dose may be increased to 3 tablets per day.

Method of administration:

To prevent contact of pinaverium with the esophageal mucosa, the tablets should be swallowed whole, without chewing or sucking, with a large glass of water between meals. (risk of esophageal damage, see Section 4.8).

Do not swallow the tablets while lying down or just before going to bed.

Additional information about special populations:

Renal failure

The safety and effectiveness of PIVERTEL in patients with renal failure have not been studied. There is no specific data regarding the use of PIVERTEL in this patient group.

Liver failure

The safety and effectiveness of PIVERTEL in patients with liver failure have not been studied. There is no specific data regarding the use of PIVERTEL in this patient group.

Pediatric population

The efficacy and safety of pinaverium bromide have not been studied in children (see section 4.4).

Available data are described in section 5.1, but no recommendation on posology can be given.

Geriatric population

Geriatric patients can be administered the same dosage with adults.

4.3. Contraindications

PIVERTEL is contraindicated in patients with hypersensitivity to pinaverium bromide or any of the excipients (see section 6.1).

4.4. Special warnings and precautions for use

- Due to the risk of upper digestive tract disease, including esophageal ulcers, administration instructions should be followed with caution. Patients with previous esophageal lesions and/or hiatus hernia should pay particular attention to the correct administration of PIVERTEL.

- Tablets should be swallowed in a sitting position, without chewing or sucking, in the middle of a meal with a large glass of water. Do not lie down for 30 minutes after taking it.
- Since its safety and effectiveness in children have not been adequately determined and experience is limited, PİVERTEL is not recommended for use in this group of patients.
- Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption should not use this medicine.Instructions for administration should be followed with caution due to the risk of esophageal lesions.

4.5. Interactions with other medicinal products and other forms of interaction

Concomitant use with anticholinergic drugs may increase spasmolysis.

Additional information about special population

No interaction studies have been conducted on special populations.

Pediatric population

No interaction studies have been conducted on the pediatric population.

4.6. Pregnancy and lactation

General advice

Pregnancy category: C

Women with the potential to give birth/ Birth control (Contraception)

There is no sufficient data on the use of PİVERTEL in pregnant women.

Women of childbearing potential should use birth control methods that are medically accepted as effective during treatment.

Pregnancy period

There is no sufficient data regarding the use of pinaverium bromide in pregnant women. Animal studies are insufficient to determine the effects on pregnancy and/or embryonal/fetal development and/or parturition and/or post-natal development. The potential risk to humans is not known. PIVERTEL should not be used during pregnancy unless absolutely necessary.

Additionally, the presence of bromide should be taken into account. Administration of pinaverium bromide at the end of pregnancy may affect the newborn neurologically (hypotonia, sedation).

Lactation period

Data on the excretion of pinaverium bromide into breast milk in humans or animals are insufficient. Physico-chemical and available pharmacodynamic/toxicological data indicate that pinaverium bromide is excreted in breast milk and in this respect, the risk in breastfed children should not be excluded. Therefore, PIVERTEL should not be used in breastfeeding mothers.

Reproductive Ability/Fertility

Studies in rats evaluating the effect of pinaverium bromide on fertility and reproductive functions showed adverse effects on female fertility at a dose of 50 mg/kg, with the highest level at which no adverse effects were observed (NOAEL) at 25 mg/kg. The highest level at which no adverse effects on male fertility were observed (NOAEL) was 50 mg/kg.

4.7. Effects on ability to drive and use machines

No studies have been conducted on the effects of pinaverium bromide on the ability to drive and use machines.

4.8. Undesirable effects

Adverse events are listed in the following order: Very common (≥1/10); common (between ≥1/100 and <1/10); uncommon (between ≥1/1000 and <1/100); rare (between ≥1/10.000, and <1/1000); very rare (<1/10.000), not known (cannot be estimated with the available data)

The following undesirable effects have been reported spontaneously during post-marketing use. An exact frequency cannot be estimated (not known) from available data.

Immune system diseases

Not known: Hypersensitivity

Gastrointestinal diseases

Unknown: abdominal pain, diarrhoea, nausea, vomiting and dysphagia.

Dermatological and subcutaneous tissue diseases

Unknown: rash, itching, urticaria and redness on the skin (erythema).

4.9. Overdose and its treatment

In case of overdose, gastrointestinal complaints such as nausea, flatulence and diarrhea may occur. It has no specific antidote, symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Other Drugs Used in Functional Intestinal Disorders

ATC Code: A03AX04

Pinaverium bromide is an antispasmodic substance that acts selectively on the gastrointestinal tract. It is a calcium antagonist, thus preventing the entry of calcium into intestinal smooth muscle cells. In animal studies, stimulation of sensitive afferent pathways has been shown to reduce related effects directly or indirectly. Pivertel does not have significant anticholinergic-type effects. It does not have any effect on the cardiovascular system.

5.2. Pharmacokinetic properties

General features

Absorbation

After oral administration, pinaverium bromide is rapidly absorbed, reaching peak plasma concentration within one hour.

Distribution

It is highly (95-97%) binds to plasma proteins.

Biotransformation

It is extensively metabolized and eliminated via the liver.

Elimination

Elimination is largely through the liver. The elimination half-life is 1.5 hours. The absolute bioavailability for oral formulation is very low (< 1%). The main route of excretion is faeces.

5.3. Preclinical safety data

Toxicity

Pinaverium bromide has low toxicity after oral administration. Toxicity symptoms are mostly limited to general toxicity symptoms, gastrointestinal symptoms and central nervous system (CNS) symptoms.

Genotoxicity, carcinogenic potential, teratogenicity

Pinaverium bromide has not shown genotoxic or carcinogenic properties.

Reproductive toxicity

Studies in rats evaluating the effect of pinaverium bromide on fertility and reproductive functions showed adverse effects on female fertility at a dose of 50 mg/kg, with the highest level at which no adverse effects were observed (NOAEL) at 25 mg/kg. The highest level at which no adverse effects on male fertility were observed (NOAEL) was 50 mg/kg.

Pinaverium bromide showed no significant effects on pre- and postnatal development. Studies on embryo-fetal development in rats and rabbits did not show teratogenic effects. The noxious dose (NOAEL) at which no adverse effects were observed was 50 mg/kg in rats and 60 mg/kg in rabbits.

Doses above 150 mg/kg in rats and 180 mg/kg in rabbits showed significant maternal toxicity.

The transport of pinaverium bromide across the placenta and its passage into milk have not been examined.

6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

Substrate

Lactose monohydrate (Obtained from cow's milk.)

Microcrystalline cellulose

Pregelatinised Starch

Talc

Anhydrous colloidal silica

Magnesium stearate

Coating

Basic butylated methacrylate copolymer

Stearic acid
Talc
Simethicone
Sodium lauryl sulfate
Hydroxypropyl methyl cellulose

6.2. Incompatibilities
There is no data.

6.3. Shelf life
24 months

6.4. Special precautions for storage
Store at room temperature below 25°C.

6.5. Nature and contents of container
PİVERTEL 100 mg Film-Coated Tablet; It is presented in 250/40 PVC/PVDC transparent foil and Gray Aluminum (20 µm) foil packaging, in a cardboard box with instructions for use (40 tablets/box and 80 tablets/box).

6.6. Special precautions for disposal and other handling
Unused products or waste materials should be disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulation".

7. MARKETING AUTHORISATION HOLDER
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06520 Balgat-ANKARA
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8. MARKETING AUTHORISATION NUMBER(S)
2022/484

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First license date: 29/08/2022

License renewal date:

10. DATE OF REVISION OF SPC

05.09.2022