

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PINIX® 40 mg/80 mg film coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Otilonium Bromide	40 mg / Tablet
Simethicone	80 mg / Tablet

Excipients:

Lactose Monohydrate Spray Dried	554.00 mg / Tablet
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For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet

Yellow, biconvex, and oblong film tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Used as an antispasmodic in irritable bowel syndrome (IBS) and spastic-painful conditions of the distal enteric region. It is used to relieve pain due to excessive gas in the gastrointestinal tract, particularly in situations where spasms are due to or increased by gas.

4.2. Posology and method of administration

Posology / Frequency and duration of administration:

As per your doctor's recommendation, take one tablet 2-3 times a day.

The duration of treatment should be decided by the physician.

After completing the specified treatment period, whether to continue treatment should be evaluated by the physician.

Method of Administration

Tablets should be swallowed whole with a small amount of water, preferably 20 minutes before meals.

Additional information on special populations:

Renal/Hepatic Impairment

PINIX® contains otilonium, which is systemically absorbed at 3% and acts locally, unaffected by renal or hepatic dysfunction. Simethicone is physiologically inert and has not shown any toxicity; it is excreted unchanged in the feces. Therefore, no dose adjustment is necessary for patients with renal or hepatic impairment.

Pediatric Population

There is no clinical data regarding use in pediatric populations, so PİNIX® is not recommended for use in children.

Geriatric Population

Take one tablet 2-3 times daily as recommended by your doctor.

4.3 Contraindications

- Known hypersensitivity to the active substance or any of the excipients.
- Should not be used in cases of intestinal perforation or colon obstruction.

4.4. Special warnings and precautions for use

Patients with glaucoma, prostatic hypertrophy, and pyloric stenosis should use this medicine with caution.

Due to the relaxing effect of otilonium bromide on gastrointestinal smooth muscles, caution should be exercised, especially in diabetic patients with constipation and bowel atony.

If symptoms do not improve or worsen despite treatment, the therapy should be re-evaluated.

PİNIX® contains lactose monohydrate spray dried (bovine source). Patients with rare inherited galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not use this medicine.

PİNIX® contains lecithin (soy). If you are allergic to peanuts or soy, do not use this medicinal product.

4.5. Interaction with other medicinal products and other forms of interactionSimethicone

The absorption of levothyroxine-containing medications can be impaired when taken with simethicone, so these drugs should be taken at least 2 hours apart.

Otilonium Bromide

No known interactions

4.6. Pregnancy and Lactation**General Advice**

Pregnancy category is C.

Women of Childbearing Potential/Contraception

Since the systemic absorption of the active ingredients in PİNIX® is very low, interaction with contraceptives is not expected. To date, no interactions with the active ingredients have been reported in clinical use.

Pregnancy

Studies in animals are insufficient regarding the effects on pregnancy, embryonal/fetal development, or postnatal development. The potential risk to humans is unknown.

PİNİX® should not be used during pregnancy unless necessary.

Lactation

PİNİX® should only be used in breastfeeding mothers if absolutely necessary and under medical supervision.

Fertility

No effects on fertility have been observed or are expected.

4.7 Effects on Driving and Machinery

There is no data on the effects of the active ingredients on the ability to drive or operate machinery.

4.8 Undesirable Effects

Adverse reactions

Frequency estimate: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1.000$ to $< 1/100$); Rare ($\geq 1/10.000$ to $< 1/1.000$); Very rare ($< 1/10.000$); frequency not known (cannot be estimated from the available data).

Immune System Disorders

Rare: Hypersensitivity reactions (such as rash, itching, swelling of the tongue, difficulty breathing)

Nervous System Disorders

Unknown: Headache

Respiratory, Thoracic, and Mediastinal Disorders

Rare: Pharyngitis, rhinitis

Gastrointestinal Disorders

Rare: Diarrhea, nausea, vomiting, epigastric pain, constipation

Skin and Subcutaneous Tissue Disorders

Unknown: Urticaria, skin rash

Therapeutic doses of the active ingredient, otilonium bromide, do not cause anticholinergic effects.

Reporting Suspected Adverse Reactions

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9. Overdose and Treatment

In case of overdose, symptomatic and supportive treatment should be applied.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Other Drugs Used in Functional Bowel Diseases

ATC code: A03AX13

Otilonium Bromide exhibits a strong antispasmodic effect on the smooth muscles of the digestive system. Its mechanism of action is complex: Otilonium bromide primarily alters the flow of Ca^{2+} from cellular and extracellular areas by binding to Ca^{2+} channels, muscarinic, and tachykinin receptors, thus preventing the entry of Ca^{2+} into smooth muscle cells. The activity of otilonium bromide can be explained by the combination of blocking the Ca^{2+} channel and a mild anti-muscarinic effect.

Simethicone is an activated dimethicone with an anti-foaming effect; it relieves bloating by dispersing gas bubbles in the gastrointestinal tract and preventing the formation of gas bubbles covered with mucus.

5.2. Pharmacokinetic properties

General properties

Absorption:

Studies have shown that after oral administration, otilonium bromide has extremely low systemic absorption (3%). Therefore, plasma concentration is low. Simethicone is physiologically inert. Its absorption is negligible after oral administration.

Distribution:

Otilonium bromide is highly distributed in the colon smooth muscles. There is insufficient information regarding the distribution of simethicone.

Biotransformation:

Otilonium bromide has extremely low systemic absorption and is not metabolized in the body. Simethicone is not metabolized in the body.

Elimination:

Most of otilonium bromide (95-97%) is excreted via bile. Simethicone is mainly excreted in the feces without participating in enterohepatic circulation.

Linearity/Non-linearity:

Since otilonium is not systemically absorbed, linearity cannot be assessed. There is insufficient data on whether simethicone exhibits linear or non-linear behavior.

5.3. Preclinical Safety Data

Otilonium

Bromide:

Acute Toxicity: The LD₅₀ for rats is 1500 mg/kg. No fatal cases were reported when administered at 1000 mg/kg to dogs.

Chronic Toxicity: In animal studies, no histological or hematological abnormalities were observed with 80 mg/kg doses of otilonium bromide administered for 180 days.

Teratogenicity: No embryotoxic or teratogenic effects were observed at doses of 60 mg/kg in rats and rabbits.

Mutagenicity: Various tests have shown no mutagenic effects.

Simethicone:

Preclinical studies have been conducted with oral, intravenous, intramuscular, intraperitoneal, inhalational, and topical applications in mice, rats, rabbits, and cats. No significant changes were detected in acute and chronic toxicity studies. There is no evidence of mutagenic potential in mice, rats, and rabbits. Studies in rabbits and rats do not provide evidence for simethicone's potential to promote tumor development.

Reproductive Toxicology: In animal studies (mice, rats, rabbits), simethicone has not shown teratogenic effects.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Microcrystalline Cellulose PH102
Povidone K30
Lactose Monohydrate Spray Dried
Kolidon CL
Pregelatinized Starch
Colloidal Silicon Dioxide
Magnesium Stearate
Opadry II Yellow 85G32279

Opadry II Yellow 85G32279 composition: Polyvinyl Alcohol, Talc, Titanium Dioxide, Macrogol, Lecithin, Quinoline Yellow Aluminum Lake

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store in the original package, at room temperature below 25°C.

6.5. Nature and contents of container

30 film-coated tablets in opaque PVC/PE/PVDC/Aluminum foil blister packs in a cardboard box.

6.6. Disposal of unused medicinal products and other special precautions:

Unused products or waste materials should be disposed of in accordance with the "Regulation on the Control of Medical Wastes" and the "Regulations on the Control of Packaging and Packaging Waste."

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION /RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]