

PATIENT INFORMATION LEAFLET

PINIX 40 mg/80 mg Film Coated Tablets

Oral use.

- **Active ingredient:** 40 mg Otilonium Bromide and 80 mg Simethicone
- **Excipients:** Microcrystalline Cellulose PH 102, Povidone K30, Lactose Monohydrate Spray Dried, Kolidon CL, Pregelatinized Starch, Colloidal Silicon Dioxide, Magnesium Stearate, Opadry II Yellow 85G32279 (Polyvinyl Alcohol, Talc, Titanium Dioxide, Macrogol/PEG, Lecithin, Quinoline Yellow Aluminum Lacquer)

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet because you may need to read it again.*
- *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.*
- *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital.*
- *Strictly follow these instructions. Do not take lower or higher doses than the recommended dose.*

What is in this leaflet:

1. **What PINIX[®] is and what it is used for?**
2. **What you need to know before you use PINIX[®]**
3. **How to use PINIX[®]?**
4. **Possible side effects**
5. **How to store PINIX[®]?**

1. What PINIX[®] is and what it is used for?

Otilonium bromide and simethicone are the active ingredients of PINIX[®]. Otilonium bromide belongs to a group of drugs called antispasmodics. It acts on the muscles in the digestive tract, alleviating intestinal spasms and regulating increased motility (such as controlling excessive contractions and speed of intestinal muscles). Simethicone is an anti-foaming agent used to relieve pain caused by excessive gas in the digestive tract.

PINIX[®] is in the form of yellow biconvex and oblong film-coated tablets and is offered in packages of 30 tablets.

PINIX[®] is used for conditions characterized by spasms and gas. Some of these conditions include:

- **Irritable Bowel Syndrome (IBS):** A group of diseases involving functional disturbances observed in the intestines without an organic cause, and spastic-painful conditions of the distal enteric (the latter parts of the intestines) region.
- **Effect on Digestive Tract Muscles:** PINIX[®] acts on the muscles in the digestive tract, alleviating intestinal spasms and regulating increased motility (such as controlling excessive contractions and speed of intestinal muscles).
- **Gas-Related Spasms:** It is used to relieve pain caused by excessive gas in the digestive tract, particularly in situations where spasms are caused or exacerbated by gas.

2. What you need to know before you use PINIX®

Do NOT use PINIX® in the following situations:

If you have:

- An allergy (hypersensitivity) to otilonium bromide, simethicone, or any of the excipients in PINIX®
- A suspicion of perforation or obstruction in the digestive system. Additionally, the use of PINIX® is not recommended for children.

Use PINIX® with CAUTION in the following situations:

If you have:

- Glaucoma (an eye disease where the pressure inside the eye is increased)
- An enlarged prostate gland (also known as prostatic hypertrophy)
- A narrowing in the passage from the stomach to the intestines (pyloric stenosis)
- Constipation due to intestinal laziness (atony) (e.g., due to diabetes). PINIX® relaxes the muscles in the digestive system. Therefore, if you have constipation or intestinal laziness (atony), which is more common in diabetics, use PINIX® with caution.

If these warnings apply to you at any time in the past, please consult your doctor.

Use of PINIX® with food and drink:

Take preferably 20 minutes before meals.

Pregnancy:

Consult your doctor or pharmacist before using the medicine.

Unless deemed necessary by your doctor, do not use PINIX® if you are pregnant. In such cases, use it under the supervision of your doctor.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breastfeeding:

Consult your doctor or pharmacist before using the medicine.

Unless deemed necessary by your doctor, do not use PINIX® if you are breastfeeding. In such cases, use it under the supervision of your doctor.

Driving and using machines:

No studies have been conducted on the effects of using vehicles and machines. Do not use dangerous machines, including motor vehicles, until you are sure that PINIX® does not adversely affect you.

Important information about some of the excipients in PINIX®:

PINIX® contains lactose monohydrate spray dried (bovine source). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

PINIX® contains lecithin (soy). Do not use this medicinal product if you are allergic to peanuts or soy.

Use with other medicines:

The absorption of medicines containing levothyroxine (used in the treatment of thyroid diseases) is impaired when taken with PINIX®, so the two medicines should be taken at least 2 hours apart.

If you are currently using or have recently used any prescription or non-prescription medicines, please inform your doctor or pharmacist.

3. HOW TO USE PINIX®

Instructions for proper use and dosage/frequency of administration:

Always use PINIX® as your doctor has instructed. If you are unsure about any aspect, please consult your doctor or pharmacist.

According to your doctor's recommendation: take 1 tablet 2-3 times a day.

Method and route of administration:

Take the tablets with a small amount of water without breaking, crushing, or chewing, preferably 20 minutes before meals.

Different age groups:

Use in children: Not suitable for use in children.

Use in the elderly: According to your doctor's recommendation: take 1 tablet 2-3 times a day.

Special usage situations:

Renal/Hepatic insufficiency: No dose adjustment is necessary in these patients.

If you have the impression that the effect of PINIX® is too strong or too weak, talk to your doctor or pharmacist.

If you use more PINIX® than you should:

No overdose effects have been reported with PINIX®.

However, if you have used more than you should and do not feel well, talk to your doctor or go to the nearest hospital, taking the medicine package or this leaflet with you if possible.

If you have used more PINIX® than you should, talk to a doctor or pharmacist.

If you forget to take PINIX®:

If you forget a dose, take it as soon as you remember.

Do not take a double dose to make up for a forgotten dose.

Effects that may occur when treatment with PINIX® is discontinued:

If you do not use your medication as prescribed, you may not benefit from the treatment. However, no side effects are expected due to the early termination of the treatment. If you have any further questions about the use of this product, consult your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, PINIX® can cause side effects, although not everybody gets them.

Very common	: in at least 1 patient of 10.
Common	: in less than 1 of 10 patients and more than 1 of 100 patients.
Uncommon	: in less than 1 of 100 patients but, more than 1 of 1000 patients.
Rare	: in less than 1 of 1000 patients but more than 1 of 10.000 patients.
Very rare	: in less than 1 of 10.000 patients.
Unknown	: Cannot be estimated based on available data

Stop using PINIX® and notify your doctor immediately or go to the nearest hospital emergency department if any of the following occur:

- Symptoms of an allergic reaction such as difficulty in breathing or swallowing, swelling of the face, lips, tongue, or throat, severe itching with a rash or hives.
- Widespread skin rash.
- Hives (Urticaria).

All of these are very serious side effects. You may need urgent medical intervention or hospitalization.

All of these very serious side effects are very rare.

Rare:

- Diarrhea
- Nausea
- Vomiting
- Stomach pain
- Runny nose, cold
- Throat inflammation
- Constipation

Unknown frequency:

- Headache

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting side effects:

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.

5. How To Store PINIX®

Store PINIX® in its original packaging and keep out of the reach and sight of children.

Store at room temperature, below 25°C.

Use in compliance with the expiry date.

Do not use PINIX® after the expiry date which is stated on the packaging.

If you notice any defects in the product and/or packaging, do not use PINIX®.

Do not throw away expired or unused medicines! Submit them to the collection system determined by the Ministry of Environment, Urbanization, and Climate Change.

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This leaflet has been approved <{DD month YYYY}>.

[To be completed nationally]