

## PATIENT INFORMATION LEAFLET

### PIVERTEL 100 mg Film Coated Tablet

It is taken orally.

- **Active ingredient:** Each tablet contains 100 mg pinaverium bromide.
- **Excipient(s):**

**Core ingredients:** Lactose monohydrate (obtained from cow's milk), microcrystalline cellulose, pregelatinized corn starch, talc, colloidal anhydrous silica, magnesium stearate,

**Coating ingredients:** Basic butylated methacrylate copolymer, stearic acid, talc, simethicone, sodium lauryl sulfate, hydroxypropyl methyl cellulose.

**Before you start using this medicine, read this PATIENT INFORMATION LEAFLET carefully because it contains important information for you.**

- *Keep this leaflet. You may need to read again*

- *If you have other questions, please talk your doctor or pharmacist.*

- *This medicine has been prescribed for you personally, do not give it to others.*

- *During the use of this medicine, tell your doctor that you are using this medicine when you go to the doctor or hospital.*

- *Follow exactly what is written in this instruction. Do not use **high or low** doses other than the dose recommended to you about the medicine.*

### **In this leaflet:**

1. *What is PIVERTEL and what is it used for?*
2. *Things to consider before using PIVERTEL*
3. *How to use PIVERTEL?*
4. *What are the possible side effects?*
5. *Storage of PIVERTEL*

**Headings are included.**

### 1. *What is PIVERTEL and what is it used for?*

- PIVERTEL is presented in a blister foil package and a cardboard box with instructions for use (40 tablets/box and 80 tablets/box). Tablets are white or slightly yellowish, round, biconvex.

- PIVERTEL is used to relieve pain, transit disorders and intestinal discomfort complaints due to functional bowel disorders.

## ***2. Things to consider before using PIVERTEL?***

### **DO NOT USE PIVERTEL in the following situations:**

If you are hypersensitive to pinaverium bromide or any ingredient of PIVERTEL.

### **USE PIVERTEL WITH CARE in the following situations:**

- PIVERTEL is not recommended for use in children.
- It is important that you take PIVERTEL correctly. Because it can irritate your esophagus:
  - Always take the tablets during meal.
  - Swallow the tablets whole in a sitting position with a glass of water.
  - Do not crush, suck or chew the tablets.
  - Do not lie down for 30 minutes after taking it.
- If you have a problem with your esophagus or a part of your stomach has protruded into your rib cage (stomach hernia), you need to take PIVERTEL correctly as described above.

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

### **Using PIVERTEL with food and drink**

There is no data on the interaction of PIVERTEL with food and drink.

### **Pregnancy**

*Consult your doctor or pharmacist before using this medicine.*

If you are pregnant, think you may be pregnant, or are planning to have a baby, consult your doctor or pharmacist before taking this medicine.

PIVERTEL is not recommended for use during pregnancy.

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

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medicine.*

Do not use this medicine if you are breastfeeding.

### **Driving and using machines**

The effects of PIVERTEL on driving and using machines are unknown.

Before doing any of these activities, observe how PIVERTEL affects you.

### **Important information about some excipients contained in PIVERTEL**

PIVERTEL contains lactose. If you have been told by your doctor that you are intolerant to some sugars, consult your doctor before taking this medicinal product.

### **Use with other drugs**

Tell your doctor if you are taking other medicines (such as phenothiazine, antiparkinson drugs called anticholinergic drugs) to relieve spasm in your intestines or bile duct. PIVERTEL may increase the antispasmodic effect of these medicines.

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

### **3. How to use PIVERTEL?**

#### **Instructions for proper use and dosage/frequency of administration:**

##### **Adults**

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

##### **Administration route and method:**

It is important that you take PIVERTEL correctly. Because it can irritate your esophagus:

- Always take the tablets during meal.
- Swallow the tablets whole with a full glass of water. Do not crush, suck or chew the tablets.
- Do not take the tablets while lying down or just before going to bed.

It is recommended that you take the tablets at equal intervals throughout the day and at the same time each day.

Taking it at the same time every day will help you remember.

##### **Different age groups**

###### **Use in children:**

PIVERTEL is not recommended for use in children.

###### **Use in the elderly:**

The dose is the same as for adults.

## **Special use cases**

### **Kidney/Liver failure:**

The safety and effectiveness of PIVERTEL in patients with renal/liver impairment have not been studied.

Do not forget to take your medicine on time.

Unless your doctor recommends otherwise follow these instructions

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

### **If you use more PIVERTEL than you should:**

*If you have used more PIVERTEL than you should, talk to a doctor or pharmacist.*

### **If you forget to use PIVERTEL**

If you forget to take a dose, skip the missed dose and take the next dose at the normal time.

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

### **Effects that may occur when treatment with PIVERTEL is terminated**

No adverse effects are expected when treatment with PIVERTEL is terminated.

#### ***4. What are the possible side effects?***

Like all medicines, PIVERTEL may have side effects in people who are sensitive to the ingredients it contains.

### **If one of the following happens, stop using PIVERTEL and IMMEDIATELY inform your doctor or go to the emergency department of the nearest hospital:**

- Allergic (hypersensitivity) reactions to the drug, such as difficulty breathing, swelling of the face, lips, tongue or throat (angioedema).
- Skin problems such as redness, rash, itching or hives

These are all very serious side effects.

If you have one of these, it means you have a serious allergy to PIVERTEL. You may need emergency medical attention or hospitalization. All of these very serious side effects are very rare.

Side effects are classified as follows:

Very common (may occur in at least 1 in 10 patients)

Common (may affect less than 1 in 10 but more than 1 in 100 patients)

Uncommon (may affect less than 1 in 100 but more than 1 in 1000 patients)

Rare (may occur in less than 1 in 1000 patients but in more than 1 in 10000 patients)

Very rare (may occur in less than 1 in 10 000 patients)

Unknown (Cannot be estimated based on available data)

### **Unknown**

- Hypersensitivity reactions (e.g., a severe allergic reaction (anaphylaxis), urticaria, swelling of the lips and face, etc.),
- Stomach ache
- Diarrhea
- Nausea
- Esophagus, stomach or intestinal disorders such as vomiting
- Difficulty swallowing (dysphagia)
- Rash
- Itching
- Urticaria
- Redness (erythema) on the skin

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

### **5. Storage of PIVERTEL**

Keep PIVERTEL in its packaging and out of sight and reach of children.

Store at room temperature below 25°C.

**Use in accordance with expiration date.**

*Do not use PIVERTEL after the expiration date on the packaging.*

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

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

***Marketing Authorization Holder:***

Drogsan İlaçları San. ve Tic. A.Ş.  
Oğuzlar Mah. 1370. Sok. No:7/3  
06520 Balgat / ANKARA

***Manufacturer:***

Drogsan İlaçları San. ve Tic. A.Ş.  
Esenboğa Merkez Mah. Çubuk Cad.  
No:31 06760 Çubuk / Ankara

*This patient information leaflet was approved on 29/08/2022.*