

## PATIENT INFORMATION LEAFLET

### PIVERTEL 50 mg Film Coated Tablet

It is taken orally.

- **Active ingredient:** Each tablet contains 50 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, 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 consult 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 offered in blister packs consisting of 40 and 80 film-coated tablets. Tablets are round, biconvex, white or slightly yellowish in colour.

- PIVERTEL contains pinaverium bromide. It belongs to a group of medicines called antispasmodics and acts on your bowel and bile duct.
- The intestine is a channel consisting of long muscles through which food passes to be digested. The bile duct is the channel through which bile flows from your liver to the post-stomach section. If the intestine or bile duct goes into spasm and contracts forcefully, you will have pain. This medicine provides relief of spasm and pain.
- PIVERTEL is used to relieve stomach or intestinal complaints caused by medical conditions in the intestine or bile duct. Although these complaints vary from person to person, they may be as follows;
  - Stomach pain and cramps
  - Diarrhea, constipation or both
  - Bloating and windiness
- PIVERTEL is also used to clear the intestine of feces before a barium enema - this is a type of X-ray.

## ***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.
- 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 medication.*

Do not use this medicine if you are pregnant.

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

Side effects such as feeling sleepy may be observed. In this case, the ability to react may decrease.

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

PIVERTEL contains lactose (a type of sugar). 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 medications (called anticholinergic drugs) to relieve spasm in your intestines or bile ducts. PIVERTEL may increase the antispasmodic effect of these drugs.

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

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

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

#### **Adults**

- The usual dose is 1 tablet 3 times a day.

- Your doctor may increase the dose as needed to 2 tablets twice a day or up to a maximum of 6 tablets a day.
- Before barium enema, take tablets only for 3 days until your doctor's visit. The usual dose is 2 tablets twice a day.

**Administration route and method:**

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

- Always take the tablets in the middle of a meal.
- Swallow the tablets whole with a full glass of water. Do not crush, suck or chew the tablets.

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 PIVARTEL is too strong or weak, talk to your doctor or pharmacist.*

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

In case of overdose, complaints such as nausea, gas and diarrhea may occur. *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.

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 1,000 patients) Rare (may affect less than 1 in 1,000 but more than 1 in 10,000 patients)

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

Unknown (Cannot be estimated based on available data)

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

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

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. The frequency of these very serious side effects is unknown.

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

- Esophagus, stomach or intestinal disorders such as difficulty swallowing, feeling or being sick, abdominal-stomach pain, diarrhea.

All these are serious side effects. Immediate medical attention may be required. The frequency is unknown.

### **Side effects specifically associated with PIVERTEL**

#### **Common**

- Headache
- Stomach ache
- Constipation
- Dry mouth
- Indigestion
- Nausea

#### **Uncommon**

- Feeling sleepy
- Diarrhea
- Vomiting
- Asthenia (weakness)

#### **Frequency unknown**

- Hypersensitivity
- Gastrointestinal disorders, Dysphagia (difficulty in swallowing)
- Skin disorders, rash, itching, urticaria and redness 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 dates.**

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

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

***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.  
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*This patient information leaflet was approved on 06/09/2022.*