

## Package leaflet: information for the user

### SPASMOMEN 40 mg film-coated tablets

*otilonium bromide*

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **In this leaflet:**

1. What SPASMOMEN is and what it is used for?
2. What you need to know before you take SPASMOMEN?
3. How to take SPASMOMEN?
4. Possible side effects
5. How to store SPASMOMEN?
6. Contents of the pack and other and other information

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

SPASMOMEN tablets contain a medicine called otilonium bromide. This belongs to a group of medicines called “spasmolytics”.

SPASMOMEN acts on the muscles of the large intestine by reducing their excessive and too frequent contractions. In that way the product relieves bowel spasms and regulates their excessive motility.

SPASMOMEN is used in patients older than 18 years old for the treatment of **irritable bowel syndrome** characterised by painful bowel spasms, distension and motility problems.

#### **2. What you need to know before you take SPASMOMEN?**

##### **Do not take SPASMOMEN:**

- if you are allergic to otilonium bromide or any of the ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking SPASMOMEN:

- if you have increased eye pressure (glaucoma)
- if you have an enlarged prostate gland (also known as prostatic hypertrophy),
- if you suffer from narrowing of the passage from the stomach into the intestine (pyloric stenosis).

##### **Other medicines and SPASMOMEN**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even if obtained without prescription.

Effect of SPASMOMEN on activity of other medicines is not known.

##### **SPASMOMEN with food and drink**

Take SPASMOMEN preferably 20 minutes before meals.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have, ask your doctor or pharmacist for advice before taking any medicine.

SPASMOMEN is not right for you if you are pregnant or breast-feeding, unless you have been told by your doctor that it is necessary and that you take it under his/her supervision.

### **Driving and using machines**

SPASMOMEN is not expected to affect your ability to drive or use machines.

**SPASMOMEN contains lactose** which is a type of sugar (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

## **3. How to take SPASMOMEN?**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### **Adults and elderly**

Take 1 tablet 2 to 3 times daily, according to your doctor's advice. Swallow your tablet whole, with water, preferably 20 minutes before meals. You should not break, crush or chew the tablet.

### **Use in children and adolescents**

These tablets are not suitable for children and adolescents younger than 18 years old.

### **If you take more SPASMOMEN than you should**

Adverse effects are not expected if you take more SPASMOMEN than you should. However, if you overdose and notice that you are not feeling well, talk to your doctor or to the emergency department, taking this leaflet and/or the medicine pack with you.

### **If you forget to take SPASMOMEN**

If you forget to take a dose of SPASMOMEN at the prescribed time, take it as soon as you remember. In any case, **DO NOT** take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**DISCONTINUE the intake** of the medicines **and seek medical advice without delay** if you develop any of the below mentioned signs of an **allergic reaction**:

- difficult breathing or swallowing, swelling of face, lips, tongue or throat;
- intensive skin itching or pain of the skin with redness, rash and swelling.

**Uncommon side effects** (side effects that may affect up to 1 in 100 people), that you may undergo with SPASMOMEN are:

- gastrointestinal disorders like dry mouth, nausea and abdominal pain upper;
- pruritus and skin redness;
- fatigue and asthenia;
- headache and vertigo.

In patients who were taking this medicine, isolated cases of allergic skin reactions in the form of rash (urticaria) and swelling of the deeper layers of the skin, especially around the lips, eyes, genitals, hands, feet and throat or tongue have been observed. In some cases sudden difficult breathing (angioedema) is possible.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store SPASMOMEN?**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and the blister after “Exp. date”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Store below 30°C.

### **6. Contents of the pack and other information**

#### **What SPASMOMEN contains?**

- The **active ingredient** is otilonium bromide (40 mg per film-coated tablet).
- **Other ingredients** are: lactose hydrate, rice starch, sodium starch glycolate, type A, magnesium stearate, hypromellose, titanium dioxide (E 171), macrogol 4000 and 6000, talc (for additional information on **lactose** see section 2).

#### **What SPASMOMEN looks like and contents of package?**

SPASMOMEN are white to almost-white round shaped, biconvex film-coated tablets  
10 or 30 film coated tablets in PVC/PVDC/Al blister, in a box.

#### **Marketing Authorisation Holder**

A.Menarini Industrie Farmaceutiche Riunite S.r.l  
Via Sette Santi 3, 50131 Florence, Italy

#### **Manufacturer**

Berlin-Chemie AG  
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#### **Classification for supply**

Medicinal product subject to medical prescription.

**This leaflet was last revised in MM/YYYY.**