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 signs of illness 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.

What is 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
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1. What SPASMOMEN is and what it is used for

SPASMOMEN tablets contain 40 mg of otilonium bromide which belongs to a group of medicines called "synthetic anticholinergics".
SPASMOMEN has a selective and intense antispasmodic action on the smooth muscle of the digestive tract and is therefore indicated in all hyperkinetic or spastic states which may exist in various locations and may also vary in cause and extent and are attributable to a pathological contraction of the fibrocells of the smooth muscle.
If used at the recommended therapeutic dose, the medicine causes no side effects whatsoever and, in particular, does not precipitate atropine-like effects.

SPASMOMEN is used to treat irritable bowel and painful, spastic states of the distal enteric tract in adults.

2. What you need to know before you take SPASMOMEN

Do not take SPASMOMEN:
- if you are allergic to Otilonium or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking SPASMOMEN.
The medicine must be used with caution in patients with glaucoma, prostatic hypertrophy, pyloric stenosis.
Keep out of the reach of children.

Children and adolescents
Do not give this medicine to children and adolescents younger than 18 years, as data on its use is limited in this population.

Other medicines and SPASMOMEN
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
No interactions with other drugs have been reported.

SPASMOMEN with food, drink and alcohol
No interactions with food, drink and alcohol have been reported.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Its use in pregnant women or during breast-feeding must be limited to cases of real need and must have strict medical supervision.

Driving and using machines
Spasmomen has no or negligible influence on the ability to drive and use machines.

SPASMOMEN contains lactose, which is a certain type of a 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 medicinal product.

SPASMOMEN contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take SPASMOMEN

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

The recommended dose is 1 film-coated tablet 2-3 times daily, according to doctor's advice.
Take your tablets with water, preferably 20 minutes before meals, without breaking, crushing or chewing them.

Use in children and adolescents
SPASMOMEN should not be used in patients under 18 years of age.

If you take more SPASMOMEN than you should
In the animal otilonium bromide has been found to be almost free of toxicity. Consequently, no particular problems related to overdose should arise in man, either. In the specific case of overdose, a supportive symptomatic therapy is advisable.

If you forget to use SPASMOMEN
If you forget to take a dose at the scheduled time, take it as soon as you remember. In any case, do not take a double dose to make up for a forgotten tablet"

4. Possible side effects

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

STOP taking SPASMOMEN **and seek urgent medical advice** if you develop any of the below mentioned signs of an **allergic reaction**:
Frequency not known (frequency cannot be estimated from the available data):
- difficult breathing or swallowing, swelling of face, lips, tongue or throat;
- intensive skin itching or pain of the skin with redness, rash and swelling.

Other side effects, that you may have with SPASMOMEN are:
Frequency not known (frequency cannot be estimated from the available data):
- dry mouth
- nausea

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. You can also report side effects directly via the Malta ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SPASMOMEN

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

This medicinal product does not require any special storage conditions.

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

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 protect the environment.

6. Contents of the pack and other information

What SPASMOMEN contains

The active substance is Otilonium bromide
Each tablet contains 40 mg of Otilonium
The other ingredient are:

Tablet core: starch rice, lactose monohydrate, sodium starch glycollate, magnesium stearate
Tablet coat: hypromellose, titianium dioxide E 171, macrogol 6000, talc.

What SPASMOMEN looks like and contents of the pack
SPASMOMEN 40 mg film-coated tablets are available in the form of white to almost-white round shaped, biconvex film-coated tablets of 5.4 mm diameter. Each pack contains 30 film-coated tablets (PVC/PVDC//Al blister)

Marketing Authorisation Holder and Manufacturer

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