PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

SPASMOMEN 40 mg film-coated tablets

Otilonium bromide

Contains sugar (lactose monohydrate)

Each SPASMOMEN film-coated tablet contains 28 mg lactose monohydrate.

Read all of this leaflet carefully because it contains important information for you.

SPASMOMEN is available without a doctor's prescription for you to treat a mild illness.

Nevertheless, you still need to use SPASMOMEN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SPASMOMEN with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

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
4. Possible side effects
5. How to store SPASMOMEN
6. Contents of the pack and other information.

1. What SPASMOMEN is and what it is used for

SPASMOMEN contains a medicine called otilonium bromide. This belongs to a group of medicines called antispasmodic medicines.

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

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

2. What you need to know before you take SPASMOMEN

Do not take SPASMOMEN:

- If you are hypersensitive (allergic) to otilonium bromide or any of the other ingredients of SPASMOMEN (listed in section 6 of this leaflet).

Warnings and precautions:

Tell your doctor or health care provider 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).

Children and adolescents:

SPASMOMEN is not suitable for children and adolescents younger than 18 years old.

Other medicines and SPASMOMEN:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

The effect of SPASMOMEN on activity of other medicines is negligible.

SPASMOMEN with food and drink:

There are no known interactions between SPASMOMEN, food and drink.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking SPASMOMEN.

Driving and using machines:

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

SPASMOMEN contains lactose:

SPASMOMEN contains lactose monohydrate which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SPASMOMEN.

3. How to take SPASMOMEN

Do not share any medicines presribed for you with any other person.
Always take SPASMOMEN exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 1 SPASMOMEN tablet 2 – 3 times a day.
Swallow your SPASMOMEN tablet whole, with a glass of water, preferably 20 minutes before meals. You should not break, crush or chew the tablet.

If you have the impression that the effect of SPASMOMEN is too strong or too weak, tell your doctor or pharmacist.

If you take more SPASMOMEN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining SPASMOMEN tablets with you so that the doctor will know what you have taken.

If you forget to take SPASMOMEN:

If you have missed a dose of SPASMOMEN, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

SPASMOMEN can have side effects.

Not all side effects reported for SPASMOMEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SPASMOMEN, please consult your health care provider for advice.

If any of the following happens, stop taking SPASMOMEN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SPASMOMEN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Dry mouth, nausea and upper abdominal (stomach) pain.
- Itching of the skin and skin redness.
- Fatigue and a feeling of weakness.
- Headache.
- Vertigo (a feeling of dizziness or spinning).

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SPASMOMEN.

5. How to store SPASMOMEN

- Store at or below 30 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SPASMOMEN contains:

The active ingredient is otilonium bromide.

Each film-coated tablet contains 40 mg otilonium bromide.

The other ingredients are: Hypromellose, lactose monohydrate, macrogol, magnesium stearate, rice starch, sodium starch glycolate, talc and titanium dioxide (E171).

What SPASMOMEN looks like and contents of the pack:

White to almost-white, round, biconvex, film-coated tablet.

White opaque PVC/PVDC/silver aluminium blister strips of 10 or 15 tablets.

Pack sizes: 10 or 30 tablets.

Holder of certificate of registration:

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