

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

SPASMEND Tablets

Each tablet contains:

Mephenesin 150 mg

Paracetamol 500 mg

Sugar free

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

SPASMEND is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SPASMEND carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SPASMEND with any other person.
- Ask your pharmacist or health care provider if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet:

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

1. What SPASMEND is and what it is used for

SPASMEND is used to treat generalised and symptomatic pain with paracetamol, combined with mephenesin which is a skeletal muscle relaxant. In combination these all treat pain associated with tension.

2. What you need to know before you take SPASMEND tablets

Do not take SPASMEND:

- if you are hypersensitive, allergic, to mephenesin, paracetamol or any of the ingredients listed in section 6.
- if you have impaired kidney and liver function.

Warnings and precautions

Take special care with SPASMEND:

- as this product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.
- as Paracetamol should be taken with care by patients with impaired renal or hepatic function.
- as mephenesin may cause drowsiness; patients that are affected should not drive or operate machinery.
- Do not use continuously for more than 10 days without consulting a doctor.

Children and adolescents

Do not give SPASMEND to children younger than 18 years old.

Other Medicines and SPASMEND

Always tell your health care professional if you are taking any other medicine, including complementary or traditional medicines.

SPASMEND should not be taken together with barbiturates and opioids. The combined effect can cause increased drowsiness and impaired, concentration, vision, speech and alertness.

SPASMEND with food and drinks

Not applicable.

Pregnancy, breastfeeding and fertility

Safety affecting fertility, pregnancy and lactation has not been established.

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

Driving and using machines

Patients should be warned against driving vehicles, using machinery or performing potentially hazardous tasks where loss of concentration and alertness caused by SPASMEND, may lead to accidents and injury.

It is not always possible to predict to what extent SPASMEND may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SPASMEND affects them.

3. How to take SPASMEND

Do not share medicines prescribed for you with any other person.

Always take SPASMEND exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Adults (18 years and older):

One or two tablets to be taken orally every four hours. The maximum dosage is eight tablets per day, for 10 days.

Consult a doctor if no relief is obtained with the recommended dosage.

DO NOT EXCEED THE RECOMMENDED DOSE

If you take more SPASMEND than you should

Symptoms of overdosage include nausea and vomiting. Liver damage, which may be fatal, may only appear after a few days. Kidney failure has been found in using SPASMEND during severe intoxication. In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center immediately.

If you forget to take SPASMEND

Do not take / receive a double dose to make up for forgotten individual doses. Take a single dose, of one or two tablets orally, as soon as you remember.

4. Possible side effects

SPASMEND can have side effects.

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

Tell your doctor immediately if you notice any of the following:

Frequency not known:

- Fatigue and lack of energy
- skin rashes with or without mucous
- itchy skin

- redness on the skin
- swelling
- nausea, vomiting
- fever
- anorexia
- increased heart rate
- low blood pressure
- anaemia

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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 or nurse. 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 SPASMEND.

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

5. How to store SPASMEND

Store all medicines out of reach of children.

Store in a cool, dry place at or below 30 °C.

Do not remove the blister pack from the outer carton until required for use.

Do not store in bathrooms.

Do not use after the expiry date stated on the packaging.

Do not use SPASMEND if you notice any visible signs of deterioration.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SPASMEND contains

The active substances are:

Mephenesin 150 mg

Paracetamol 500 mg

The other ingredients are:

Croscarmellose sodium, colloidal anhydrous silica, pregelatinised starch, Colour Green Apple Deep F1620®, magnesium stearate, maize starch.

What SPASMEND looks like and contents of the pack

SPASMEND tablets are light green, round, flat beveled edge tablets scored on one side.

They come in 3x8's (24's), 6x8's (48's) and 5x20's (100's) blister packs using PVC film & printed aluminium foil. 100 tablets packed in a white cylindrical HDPE screw type container with induction sealing, screw cap and silica gel.

Not all pack sizes indicated are necessarily marketed.

Holder of Certificate of Registration

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