

Package Leaflet: Information for the user

Spasmonal 60mg Hard capsules Alverine citrate

Read all of this leaflet carefully before you take 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. 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 SPASMONAL is and what it is used for
2. What you need to know before you take SPASMONAL
3. How to take SPASMONAL
4. Possible side effects
5. How to store SPASMONAL
6. Contents of the pack and further information

1. WHAT SPASMONAL IS AND WHAT IT IS USED FOR

SPASMONAL is an ‘antispasmodic’ medicine. It relaxes the muscles in the intestine (gut) and uterus (womb). This helps to stop the pain you feel when these muscles become tense. It is used to help people who have Irritable Bowel Syndrome (IBS). These are some of the symptoms of IBS:

- Tummy pains like cramp, which come and go
- Diarrhoea
- Constipation
- Feeling full and bloated
- Wanting to go to the toilet urgently

Sometimes these symptoms are worse if you are worried or under stress.

SPASMONAL is also used for a condition of the large intestine called painful diverticular disease of the colon.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SPASMONAL

If this is the first time you have had these symptoms, consult your doctor before using any treatment.

Do not take SPASMONAL if:

- You are allergic (hypersensitive) to alverine citrate or any of the other ingredients of SPASMONAL (please refer to Section 6).
- Your doctor has told you that you have paralytic ileus (obstruction of the gut).

Warnings and Precautions

Talk to your doctor or pharmacist before taking Spasmonal if:

- You are aged 40 years or over
- You have passed blood from the bowel
- You are feeling sick or vomiting
- You have lost your appetite or lost weight
- You are looking pale and feeling tired
- You are suffering from severe constipation
- You have a fever
- You have recently travelled abroad
- You are or may be pregnant
- You are breast-feeding
- You have abnormal vaginal bleeding or discharge
- You have difficulty or pain passing urine.

Consult your doctor if you have developed new symptoms, or if your symptoms worsen, or if they do not improve after 2 weeks treatment.

Taking with other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking SPASMONAL with food and drink

It does not matter if you take SPASMONAL with or without food.

Pregnancy and breast-feeding

Do not take SPASMONAL during pregnancy or whilst breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Spasmonal may cause dizziness. Do not drive and/or use machines if affected.

3. HOW TO TAKE SPASMONAL

Always take SPASMONAL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

*The usual dose is 1 or 2 capsules one to three times daily.

SPASMONAL is not suitable for children under 12 years old.

If you take more SPASMONAL than you should, contact a doctor immediately.

If you forget to take SPASMONAL, take it when you remember. If you forget for more than 4 hours, just take the next dose when you remember it is due.

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, SPASMONAL can cause side effects, although not everyone gets them. Allergic reactions can occasionally happen when you are taking SPASMONAL. This includes anaphylaxis, which is a serious allergic reaction of rapid onset.

Anaphylaxis can cause:

- rash,
- breathing difficulties,
- wheezing and swelling of the mouth or throat

Yellowing of the whites of the eyes and the skin, as inflammation of the liver has been known to occur very rarely.

Stop taking SPASMONAL and see your doctor as soon as possible.

Other side-effects may include:

- A feeling of sickness or dizziness,
- Headache,
- Itching or skin rash
- Shortness of breath and/or wheezing
- Jaundice due to hepatitis
- Abnormal liver function test

If any of the above become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SPASMONAL

Keep all medicines out of the reach and sight of children.

Do not store above 25°C. Store in the original container, in order to protect from light.

Do not use SPASMONAL after the expiry date (EXP), which is printed or embossed on the carton and blister as month/year. The expiry date refers to the last day of the month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION

What SPASMONAL contains:

The active substance is alverine citrate. Each hard capsule contains 60 milligrams of alverine citrate.

The other ingredients are maize starch, magnesium stearate, gelatine and colour indigo carmine (E132), titanium dioxide (E171), and black iron oxide (E172).

What SPASMONAL looks like and contents of the pack

Each carton contains 100 hard gelatine (size 3) capsules which are blue/grey in colour and are marked 'SP60'.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder of SPASMONAL is
Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
Ireland

It is made by
Norgine Pharma
29 rue Ethé Virton
28100 Dreux
France

Product authorisation number: PA2010/043/001.

HEALTH TIPS FOR YOU

Try to make your everyday life a bit healthier:

- Allow plenty of time to do things, and avoid stress
- Do not rush meals
- Try to eat a balanced diet with high fibre foods
- Do not eat foods which seem to make your IBS worse

For any information about this medicine, please contact the marketing authorisation holder.
This leaflet was last revised on April 2019.