

PACKAGE LEAFLET

Package Leaflet: Information for the user

Spasmonal Forte 120 mg Hard capsules alverine citrate

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

1. WHAT SPASMONAL FORTE IS AND WHAT IT IS USED FOR

SPASMONAL Forte is an ‘anti-spasmodic’ medicine. It relaxes the muscles in the intestine (gut) and uterus (womb). This helps stop pain you feel when the muscles become tense.

It is used to help people who have Irritable Bowel Syndrome (IBS), some of the symptoms of IBS are:

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

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

SPASMONAL Forte 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 FORTE

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

Do not take SPASMONAL Forte if:

- You are allergic (hypersensitive) to alverine citrate or any of the other ingredients of SPASMONAL Forte
- 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 Forte 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 other medicines

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

Taking SPASMONAL Forte with food and drink

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

Pregnancy and breast-feeding

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

Driving and using machines

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

3. HOW TO TAKE SPASMONAL FORTE

Always take SPASMONAL Forte 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 capsule at a time taken up to 3 times a day

SPASMONAL Forte is not suitable for children under 12 years old.

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

If you forget to take SPASMONAL Forte, 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 Forte can cause side effects, although not everybody 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;
- 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.

Stop taking SPASMONAL forte and see your doctor as soon **as possible**, if you notice any of the above side effects.

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 HPRA 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 FORTE

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 Forte after the expiry date 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 Forte contains

The active substance is alverine citrate. Each hard capsule contains 120 milligrams of alverine citrate.

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

What SPASMONAL Forte looks like and contents of the pack

Each carton contains 60 hard gelatine (size 1) capsules which are blue/grey in colour and marked 'SP120'.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is
Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
Ireland

It is made by

Famar Anonymous Industrial Single Member Company of Pharmaceuticals And Cosmetics
Anthoussa Avenue 7,
Anthoussa (attikis),
153 49,
Greece

Norgine Pharma
29 rue Ethé Virton
28100 Dreux
France

Product authorisation number: PA2010/043/002.

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 local representative of the Marketing Authorisation Holder.

This leaflet was last revised in January 2025.

SPASMONAL is a registered trademark.