

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.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

What is 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 other 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 the 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:

- Abdominal pains like cramps 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 Forte can also be used for a condition of the large intestine called painful diverticular disease of the colon and to relieve period pains.

2. What you need to know before you take SPASMONAL Forte

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 obstruction of the gut or that your small bowel is not working properly.

Warnings and precautions

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

Do not take SPASMONAL Forte if any of the following apply to you, it may not be the right treatment for you.

See your doctor as soon as possible 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.

Children

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

Other medicines and SPASMONAL Forte

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

If you feel dizzy while taking SPASMONAL Forte you should avoid driving or operating machinery.

SPASMONAL Forte contains:

The colours Indigo Carmine (E132), Black Iron Oxide (E172), and Titanium Dioxide (E171).

3. How to take SPASMONAL Forte

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

– The usual dose is 1 capsule taken up to 3 times a day.

You should check with your doctor or pharmacist if you are not sure.

Use in children

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

If you take more SPASMONAL Forte than you should

If you take more SPASMONAL Forte than you should, contact a doctor immediately. Symptoms of an overdose may be low blood pressure, dizziness, increased heartbeat, dilated pupils, blurred vision, dry mouth and throat, difficulty breathing, or difficulty passing urine.

If you forget to take SPASMONAL Forte

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.

Stop taking SPASMONAL Forte and seek urgent medical advice immediately if you notice:

- Difficulties in breathing, shortness of breath, wheezing, swelling of your face or other parts of your body, as serious allergic reactions have been known to occur.
- Yellowing of the whites of the eyes or skin, as inflammation of the liver has been known to occur.

Tell your doctor or pharmacist if any of the following side effects occur or worsen.

Not known (frequency cannot be estimated from the available data):

- a feeling of sickness or dizziness,
- headache,
- allergic reactions, which may include itching or skin rash

– increased levels of some liver enzymes (which would be detected by your doctor during a blood test).

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SPASMONAL Forte

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

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.

Store in the original package in order to protect from moisture. Do not store above 25°C.

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 to protect the environment.

6. Contents of the pack and other information

What SPASMONAL Forte contains

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

The other ingredients are maize starch, magnesium stearate, gelatin and colours (E132, E171 and E172).

The printing ink contains: Shellac, Black Iron Oxide (E172), Propylene Glycol.

What SPASMONAL Forte looks like and contents of the pack

Each carton contains 2, 10, 20, 30, 60 or 90 blue/grey hard capsules marked “SP 120” in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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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

The leaflet was last revised in May 2024

SPASMONAL is a registered trademark.

If this leaflet is difficult to see or read and you would like it in a different format, please contact Mylan Products Ltd. Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.