

Spasmonal® 60mg Hard Capsules

(alverine citrate)

Patient Information Leaflet

Please read all of this leaflet carefully before taking your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

- * 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 any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1 What Spasmonal is and what it is used for
- 2 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 Before you take Spasmonal

If this is the first time you have 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)

Do not take Spasmonal 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.

Taking with other medicines

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

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 should not affect your ability to drive or use machines.

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 including anaphylaxis, which is a serious allergic reaction of rapid onset.

Spasmonal[®] 60mg Hard Capsules

(Alverine citrate)

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

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

5 How to store this medicine

Do not store above 25°C. Store in the original container in order to protect from light. Store in a dry place. Keep all medicines out of the reach and sight of children.

Do not use Spasmonal after the "expiry" which is stated on the carton and blister packaging after Exp.: 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 in Spasmonal is alverine citrate. Each hard capsule contains 60 milligrams of alverine citrate.

Spasmonal also contains maize starch, magnesium stearate, gelatin, indigo carmine (E132), titanium dioxide (E171) and Iron oxide (E172).

What Spasmonal looks like and contents of the pack

Each pack contains 100 hard gelatin (size 3) capsules which are blue / grey in colour and are marked 'SP' on one half and '60' on the other.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Norgine Ltd, Hengoed, Mid Glamorgan CF82 8SJ, United Kingdom.

Spasmonal is a registered trademark of Meda AB.

POM

Revision date: 05/04/13

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0) 1527 505414 for help.

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 food
- * Do not eat food which seem to make your IBS worse

For any information about this medicine, please contact the Authorisation Holder.