

5. How to store SPASMONAL

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

Do not store above 25°C and store in a dry place.

Do not use SPASMONAL 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.

6. Further information

What SPASMONAL contains

The active substance is alverine citrate. Each capsule contains 60 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 looks like and contents of the pack
Each carton contains 3, 10, 12, 20, 90 or 100 blue/grey capsules marked "SP 60" in blisters.

The Marketing Authorisation Holder in the UK is Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, CM22 6PU, United Kingdom.

Manufacturer:
Norgine Ltd, Hengoed, Mid Glamorgan CF82 8SJ, UK.

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 approved in November 2013

MEDA

Spasmonal[®] -60 mg

alverine citrate

Read all of this leaflet carefully before you start taking this medicine.

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

If you need the information on this leaflet in an alternative format, such as large text, or Braille please ring from the UK: 0800 198 5000.

In this leaflet:

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1. What SPASMONAL is and what it is used for

SPASMONAL 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 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 can also be used for a condition of the large intestine called painful diverticular disease of the colon and to relieve period pains.

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2. 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.
- * Your doctor has told you that you have obstruction of the gut or that your small bowel is not working properly.

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 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

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

3. How to take SPASMONAL

Always take SPASMONAL exactly as your doctor has told you.

- * The usual dose is 1 or 2 capsules taken up to 3 times a day. You should check with your doctor or pharmacist if you are not sure.

SPASMONAL is not suitable for children under 12 years old.

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

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 everybody gets them.

Stop taking SPASMONAL and see your doctor as soon as possible if you notice:

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

Other side effects may include:

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

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

By reporting side effects you can help provide more information on the safety of this medicine.

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SPECIFICATION BOX: Leaflet		MEDA	
MANUFACTURER: Meda Pharma GmbH & Co. KG		COLOURS USED:	
PRODUCT: Spasmonal		 Pantone 300	
60 mg		 Black	
MEDA-NO.: 56UK2060120-02			
MFS-NO.: 78616104			
LAETUS-CODE: 593			
		COUNTRY: United Kingdom UK	
		LANGUAGE: english	
PACK SIZE: 198 x 159 mm		CORRECTION: 2.	
FONT SIZE: 7,0 x 8,25 pt		DATE: 18. 11. 2013	



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