

PACKAGE LEAFLET: INFORMATION FOR THE USER

Alverine Citrate 60 mg and 120 mg Hard Capsules

(Referred to as Alverine Citrate Capsules in the remainder of the leaflet)

Barcode

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, please ask your doctor or pharmacist.
- This medicine is prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness 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.

What is in this leaflet:

1. What Alverine Citrate Capsules are and what it is used for
2. What you need to know before you take Alverine Citrate Capsules
3. How to take Alverine Citrate Capsules
4. Possible side effects
5. How to store Alverine Citrate Capsules
6. Contents of the pack and other information

1. What Alverine Citrate Capsules are and what it is used for

The name of your medicine is Alverine Citrate Capsules. The capsules contain a medicine called alverine citrate. Alverine Citrate Capsules belong to a group of medicines called anti-spasmodics. 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 aged 12 and above 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.

Alverine Citrate Capsules 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 Alverine Citrate Capsules

Do not take Alverine Citrate Capsules if:

- you are **allergic (hypersensitive)** to alverine citrate or any other ingredient in this medicine (see section 6)
- your doctor has told you that you have **obstruction of the gut** or that your **small bowel is not working properly**
- you are pregnant and/or breast-feeding.

You should not take Alverine Citrate Capsules if any of the above applies to you. If you are unsure speak to your doctor or pharmacist.

Warnings and precautions

If this is the first time you have had these symptoms talk to your doctor or pharmacist before taking Alverine Citrate Capsules. If any of the following apply do not take Alverine Citrate Capsules until you have spoken to your doctor; it may not be the right treatment for you. See your doctor as soon as possible if you:

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

If any of the above applies to you speak to your doctor before taking Alverine Citrate Capsules.

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

Children and adolescents

Alverine Citrate Capsules should not be used in children under the age of 12.

Other medicines and Alverine Citrate Capsules

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

Pregnancy, Breast-feeding and Fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, do not take this medicine. Ask your doctor or pharmacist for advice before taking this medicine.

Alverine Citrate Capsules should not be taken by pregnant women, unless your doctor decides otherwise.

Breast-feeding is not recommended whilst taking Alverine Citrate Capsules.

Driving and using machines

If you experience dizziness while taking Alverine Citrate Capsules, avoid driving or operating machinery.

Alverine Citrate Capsules contain E122 and E102

The capsule shell contains; E122 carmoisine and E102 tartrazine which may cause allergic reactions.

3. How to take Alverine Citrate Capsules

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

Adults (including the elderly):

The usual dose is 60 mg or 120 mg taken up to three times a day.

Children (under the age of 12)

Alverine Citrate Capsules is not suitable for children under the age of 12.

If you take more Alverine Citrate Capsules than you should

If you or someone else takes too many Alverine Citrate Capsules, contact your doctor or nearest hospital emergency department immediately. Take the box and any capsules that are left over with you if you can.

The symptoms of an overdose may include low blood pressure (hypotension) and atropine-like toxic effects (such as fast heart rate, dizziness, dry mouth, nausea, blurred vision, dilated pupils, confusion and hallucinations).

The doctor will assess your condition and decide how to treat an overdose.

Continued overleaf...

If you forget to take Alverine Citrate Capsules

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 further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Alverine Citrate Capsules can cause side effects, although not everybody gets them.

Stop taking Alverine Citrate Capsules and tell your doctor straight away if you notice any of the following serious side effects:

- rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath.
- yellowing of the whites of the eyes and the skin, as inflammation of the liver (hepatitis) has been known to occur.

If you have any of the above side effects, you should tell your doctor immediately.

Other side effects of Alverine Citrate Capsules may include:

- feeling sick (nausea)
- dizziness
- headache.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on the leaflet. You can report side effects directly via:

The United Kingdom: The Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

Ireland: 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 Alverine Citrate Capsules

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

- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Store below 25°C, in the original container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Alverine Citrate Capsules contain

The active ingredient is alverine citrate.

Alverine 60 mg Hard Capsules: Each capsule contains Alverine Citrate equivalent to 60mg Alverine Citrate.

Alverine 120 mg Hard Capsules: Each capsule contains Alverine Citrate equivalent to 120mg Alverine Citrate.

The other ingredients are: maize starch and magnesium stearate. The capsule shell contains gelatin; the capsule cap and body contain brilliant blue (E133), carmoisine (E122), tartrazine (E102) and titanium dioxide (E171). The printing ink on the capsule contains; shellac, propylene glycol and black iron oxide (E172).

What Alverine Citrate capsules look like and the contents of the pack

Alverine Citrate capsules are available in aluminum foil, PVC/PVDC blister strips. Each carton contains 20, 30, 60, 100 or 120 hard capsules.

Alverine Citrate 60 mg hard capsules consist of gelatin capsule shell size #3, with blue cap (marked as (ALV) and blue body (marked as 60), filled with white to off-white granular powder.

Alverine Citrate 120 mg hard capsules consist of gelatin capsule shell size #1, with blue cap (marked as ALV) and white body (marked as 120), filled with white to off-white granular powder.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

Blackrock Pharmaceuticals Ltd
Abbey Place, 24-28 Easton Street
High Wycombe, HP11 1NT, UK

MA Number (60 mg): PL 33271/0002

MA Number (120 mg): PL 33271/0003

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