

ALVERINE CITRATE
60mg & 120mg capsules

PATIENT INFORMATION LEAFLET

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

This medicine is available without prescription. However, you still need to take Alverine citrate Capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after a few days.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

THE LEAFLET CONTAINS INFORMATION ON:

1. What Alverine citrate Capsules are and what they are used for.
2. 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. Further Information

1. WHAT ALVERINE CITRATE CAPSULES ARE AND WHAT THEY ARE USED FOR

Alverine citrate belongs to a group of medicines called 'antispasmodic'. It works by relaxing the muscles in the intestine (gut) and uterus (womb). This helps to stop the pain you feel when these muscles tense up.

Alverine citrate Capsules are 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.

Alverine citrate Capsules are also used for a condition of the large intestine called painful diverticular disease of the colon. It is also used to relieve period pains.

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

2. BEFORE YOU TAKE ALVERINE CITRATE CAPSULES

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

Do not take Alverine citrate Capsules if you:

- are allergic (hypersensitive) to Alverine citrate or any other ingredients in the capsules.
- have been told by your doctor that you have paralytic ileus.
- are or may be pregnant
- are breast feeding
- your doctor has told you that you have obstruction of the gut or that your small bowel is not working properly.

Consult your doctor if any of the above applies to you as this may not be the right treatment for you.

Take special care with Alverine citrate Capsules and consult your doctor if you:

- have developed new symptoms, or if your symptoms worsen, or if they do not improve after 2 weeks of treatment.
- 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.

Taking other medicine

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

Pregnancy and breast-feeding

The safety of alverine citrate for use during pregnancy and breast-feeding has not been established. Hence, it should be taken only if your doctor advises to do so. Please ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you feel dizzy while taking Alverine citrate Capsules, you should avoid driving or operating machinery.

3. HOW TO TAKE ALVERINE CITRATE CAPSULES

Follow your doctor's directions about when and how to take your capsules and look at the label on the carton. Your pharmacist will also help if you are not sure.

Alverine citrate 60 mg Capsules:

1 or 2 capsules one to three times daily.

Alverine citrate 120 mg Capsules:

1 capsule one to three times daily.

Swallow your capsules without chewing them with a drink.

Children under 12 years old should not take Alverine citrate Capsules

If you take more Alverine citrate Capsules than you should

It is important to stick to the dose on the label of the medicine. If you or someone else swallows several of these capsules all together, contact your doctor or nearest hospital emergency department immediately. Always take any capsules left over with you and also the box, as this will allow easier identification of the capsules.

If you forget to take Alverine citrate Capsules

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose do not take a double dose to make up for a forgotten dose, just carry on as before.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Alverine citrate Capsules can have side effects although not everybody gets them.

Stop taking Alverine citrate Capsules and tell your doctor immediately if you experience:

- Yellowing of the whites of the eyes and skin. This could be an inflammation of the liver and may occur very rarely.
- 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.

Tell your doctor if you experience:

- A rash or feel unwell.

This may be an allergic reaction to Alverine citrate Capsules and may occur occasionally.

The following side effects have been reported rarely:

- feeling of sickness,
- dizziness,
- headache,
- allergy,
- rash or itching.

If any of the side effects gets serious, or if 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 ALVERINE CITRATE CAPSULES

- Keep out of the reach and sight of children.
- Do not use Alverine citrate Capsules after the expiry date, which is stated on the blister and carton. The expiry date refers to the last day of the month.
- Do not store above 25°C. Store in the original packaging.
- 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. FURTHER INFORMATION

What Alverine citrate Capsules contain

The name of your medicine is Alverine citrate 60 mg Capsules & Alverine citrate 120 mg Capsules. The active substance in your capsule is Alverine citrate. Each capsule contains 60mg or 120mg of alverine citrate. This is the ingredient that makes Alverine citrate Capsules work. Other ingredients are maize starch, pregelatinized starch (Starch 1500), magnesium stearate, gelatin, black iron oxide, brilliant blue and titanium dioxide.

What Alverine citrate Capsules look like and contents of the pack

Alverine citrate 60 mg Capsules are grey/blue, hard gelatin capsules printed with 'AV' on cap and '60' on body, containing a white to off white powder.

Alverine citrate 120 mg Capsules are grey/blue, hard gelatin capsules printed with 'AV' on cap and '120' on body, containing a white to off white powder.

Alverine citrate 60 mg and Alverine citrate 120 mg capsules are supplied in blisters containing 3, 10, 12, 20, 30, 60, 90 or 100 capsules, in strips of 10 capsules as appropriate. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder of these capsules is Auden Mckenzie (Pharma Division) Ltd., Whiddon Valley, Barnstaple, North Devon, EX32 8NS, United Kingdom.

Manufacturer of these capsules is

Auden Mckenzie (Pharma Division) Ltd., Mckenzie House, Bury Street, Ruislip, Middlesex, HA4 7TL, UK.

&

Tiofarma BV, Benjamin Franklinstraat 7-9, 3261 LW Oud-Beijerland, The Netherlands.

&

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This leaflet was prepared in October 2015.