

Package leaflet: Information For the User

ALVERSIME SOFT CAPSULES

Alverine citrate and Simeticone

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, ask your doctor or pharmacist.
- This medicine has been 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 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.

What is in this leaflet

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

1. What ALVERSIME soft capsules is and what it is used for

This medicine is used for the symptomatic treatment of digestive pain and bloating.

2. What you need to know before you take ALVERSIME soft capsules

Do not take ALVERSIME soft capsules in the following cases:

- Allergic to the active substances or to any of the excipients.
- If you have already experience an adverse drug reaction after taking this medicine.

Special warnings and precautions for use

Talk to your doctor if symptoms persist or become worse or in case of prolonged constipation. ALVERSIME can increase liver enzyme levels in the blood (see section 4). Your doctor may decide to prescribe blood tests during the treatment to check the condition of your liver. Elevated liver enzymes levels may cause your doctor to stop treatment.

Ask your doctor or pharmacist if you have any doubts.

Taking or using other medicines

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you find out that you are pregnant during the treatment, inform your doctor. You should not take this medicine when you are breastfeeding.

Effects on ability to drive and use machines: It is unlikely that ALVERSIME will have an effect on your ability to drive vehicles or use machines. However, it is possible that ALVERSIME can cause dizziness and this can have an effect on your ability to drive vehicles or use machines.

3. How to take ALVERSIME soft capsules

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

Dosage:

ADULT: 1 soft capsule 2-3 times daily at the beginning of meals or when in pain.

Method of administration:

This medicine is to be taken orally at the beginning of meals or when in pain.

Swallow the capsule with a glass of water.

If you take more ALVERSIME soft capsules than you should:

Cases of dizziness have been reported when doses higher than recommended have been taken. Consult your doctor or pharmacist immediately.

If you forget to take ALVERSIME soft capsules

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time. Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

If you experience any of the adverse reactions below, contact a doctor immediately:

- Signs of a severe allergic reaction, particularly swelling of the face, lips, mouth, tongue and/or throat, that can cause difficulties in breathing or swallowing, skin rash, itching, severe dizziness with increased heart rate and copious sweating (severe allergic reaction considered to be very rare, in other words affecting less than 1 person in 10,000).
- Signs suggestive of a liver dysfunction. Symptoms may include yellowing of the skin or the white of the eyes, dark colour of urine, loss of appetite, nausea or vomiting (effect on the liver considered to be very rare in other words affecting less than 1 person in 10,000).

Other adverse reactions listed below have been reported with an unknown frequency (available information is too sparse to be able to evaluate a frequency):

- Skin rash;
- Hives;
- Itching;
- Dizziness;
- Headaches;
- Nausea;
- Elevated liver enzymes in the blood (transaminases, alkaline, phosphatases) and bilirubin.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ALVERSIME soft capsules

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

Expiry date

Do not use ALVERSIME soft capsules after the expiry date which is stated on the outer carton.

Storage conditions

In hermetic container, dry and cool place, below 30°C, protect from light.

6. Contents of the pack and other information

What ALVERSIME soft capsules contain:

The active substances are:

Alverine citrate.....60 mg

Simeticone.....300 mg

For one capsule.

The other ingredients are:

Composition of the gelatin soft capsule: Gelatin, Glycerol, Titanium dioxide

Pharmaceutical form and contents

What ALVERSIME soft capsules looks like and contents of the pack

ALVERSIME is a pale-yellow opaque oblong shaped soft capsule containing a white paste

Packed as 10 capsules are PVC/PVDC blister packed. 2 Blisters are packed in a printed carton.

Manufacturer

PHIL INTER PHARMA CO., LTD.

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Date of approval Leaflet

This leaflet was last revised in January 2023