

Package leaflet: Information for the user
SimAlvia 60 mg / 300 mg, soft capsules
Alverine citrate / 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 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 SimAlvia, soft capsules are and what they are used for
2. What you need to know before you take SimAlvia, soft capsules
3. How to take SimAlvia, soft capsules
4. Possible side effects
5. How to store SimAlvia, soft capsules
6. Contents of the pack and other information

1. What SimAlvia, soft capsules are and what they are used for

SimAlvia, soft capsules contain two active ingredients:

- alverine that belongs to a class of drugs called musculotropic antispasmodics,
- and simeticone that belongs to a class of medicines called antifatulents.

This medicine reduces the muscle contractions of the gut and flatulence (gas).

It is used to relieve pain associated with contractions (spasms) of the intestine and bloating. This medicine is for adults only.

2. What you need to know before you take SimAlvia, soft capsules

Do not take SimAlvia

- if you are allergic to alverine citrate or simeticone or any of the other ingredients of this medicine (listed in section 6).
- if you have had any unwanted effects after taking this medicine.
- if you are allergic to peanut or soya, because SimAlvia, soft capsules contains soya lecithin.
- if you have been told by your doctor that you have paralytic ileus.
- if you are suffering from severe constipation.
- if you are pregnant.
- if you are breastfeeding.

Consult your doctor if you have developed new symptoms, or if your symptoms worsen, or if they do not improve after 2-week treatment.

Other medicines and SimAlvia

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 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.

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.

SimAlvia contains soya lecithin

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take SimAlvia, 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

The recommended dose is 1 capsule 2 or 3 times a day.

Method of administration

This medicine is to be taken orally at the beginning of meals. Swallow the capsule with a glass of water.

If you take more SimAlvia than you should

Dizziness has been reported after taking more than the recommended dose. Consult your doctor or pharmacist immediately.

If you forget to take SimAlvia,

Do not take a double dose to make up for a forgotten capsule.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop taking the treatment and 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, paler stools, loss of appetite, unexplained and persistent nausea, unusual tiredness or vomiting (effect on the liver considered to be very rare, in other words affecting less than 1 person in 10,000).

The following other side effects have been reported with unknown frequency (the available information does not allow to evaluate the frequency):

- Skin rash,
- Urticaria (swollen pale or red skin wheals that may itch, burn or sting),

- Itching,
- Dizziness,
- Headaches,
- Nausea (feeling sick),
- Increased blood levels of liver enzymes (transaminases, alkaline phosphatase) and bilirubin (see section 2).

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. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store SimAlvia, soft 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 carton. The expiry date refers to the last day of that month.

Store below 25°C.

Keep in outer carton in order to protect from light.

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

6. Contents of the pack and other information

What SimAlvia contains

- The active substances for one soft capsule are: alverine citrate (60 mg) and simeticone (300 mg).
- The components of the capsule shell are: gelatin, glycerol and titanium dioxide and soya lecithin and fractionated coconut oil are used as external lubricants.

What SimAlvia looks like and contents of the pack

This medicine is in the form of whitish and oblong soft capsule.
Each box contains 10, 20, 30, 40, 60 or 90 soft capsules in blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Laboratoires GALENIQUES VERNIN
20, rue Louis-Charles Vernin
77190 Dammarie-les-Lys
FRANCE

Manufacturer

Catalent France Beinheim SA
74, rue Principale,
67930 Beinheim

FRANCE

or

Laboratoires MAYOLY SPINDLER
6, Avenue de l'Europe – BP 51
78401 CHATOU CEDEX
FRANCE

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium: Simalviane

Ireland: SimAlvia

United Kingdom (Northern Ireland) : SimAlvia

This leaflet was last revised in 07/2021