MEGA LIFESCIENCES Public Company Limited AVARIN Capsules



Package leaflet: Information for the user

AVARIN (Simethicone 300 mg & Alverine Citrate 60 mg)

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

- a) What AVARIN is and what it is used for
- b) What you need to know before you take AVARIN
- c) How to take AVARIN
- d) Possible side effects
- e) How to store AVARIN
- f) Further information

a) What AVARIN is and what it is used for

AVARIN medicine contains Alverine Citrate and Simethicone which belongs to a group of medicines known as Antispasmodic/Antiflatulent.

This drug is indicated in the symptomatic treatment of gastrointestinal disorders such as irritable bowel syndrome or peptic ulcer (bloating, distension, fullness, pressure, pain and/or cramps).

It is also used in the treatment of dysmenorrhea.

b) What you need to know before you take AVARIN

Do not take AVARIN:

- If you are allergic (hypersensitive) to active substances or any of the other ingredients contained in this medicine.
- If you have had an adverse reaction after taking this medicine.

Take special care with AVARIN

Please see your doctor or pharmacist before taking this medicine:

— If symptoms persist or worsen, please consult your doctor.

Children and adolescents

Not recommended in children.

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Taking AVARIN with Other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Interaction with other medicinal products and other forms of interaction

None known.

Taking AVARIN with food and alcohol

AVARIN Soft Gelatin Capsules could be used together with meals.

Pregnancy, breast-feeding and fertility

Should not be administered to pregnant & lactating women.

Fertility

There are no data on the effects of alverine citrate or simeticone on human fertility.

Driving and using machines

None reported.

c) How to take AVARIN

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: One capsule 1-3 times daily after meals or as directed by a physician.

Method of administration:

The capsules are for oral use.

Swallow the capsules whole with sufficient liquid. They should not be broken or chewed.

If you take more AVARIN than you should

In such cases please contact your doctor or pharmacist immediately even if you feel well.

If you forget to take AVARIN

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

If you stop taking AVARIN

You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise

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you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms).

Generally, there will be no after- effects when treatment with AVARIN is stopped.

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

d) Possible side effects

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

- Nausea, headache, pruritus, rash, dizziness and hypotension or temporary lowering of blood pressure have been reported.
- Allergic reactions, including anaphylaxis, have also occurred.

e) How to store AVARIN

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C
- Do not use this medicine after the expiry date which is stated on the label, carton, and blister after EXP. The expiry date refers to the last day of that month.
- 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 protect the environment.

f) Further information

What AVARIN contains

EACH SOFT GEL CAPSULE OF AVARIN CONTAINS

- The other ingredients are
 - Aerosil 200,
 - Gelatin lime bovine 160 bloom (DGF),
 - Glycerin,
 - Purified water,
 - Iron Oxide Yellow (E172),
 - Iron Oxide Black (E172),
 - Brilliant Blue (E 133),
 - Titanium dioxide

What AVARIN looks like and contents of the pack

White colour, oily Suspension, filled in 10 minim, oblong, green, opaque, soft gelatin shell capsules

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Marketing Authorisation Holder

MEGA LIFESCIENCES Public Company Limited 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280, THAILAND

This leaflet was last revised in 06/11/2023