

Verine®

135mg as Film-Coated tablets
200mg as Sustained Release Capsules
Mebeverine hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- Keep the leaflet in a safe place because you may want to read it again.
- If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be 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.

In this leaflet:

1. WHAT VERINE IS AND WHAT IT IS USED FOR
2. BEFORE YOU TAKE VERINE
3. HOW TO TAKE VERINE
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE VERINE
6. FURTHER INFORMATION

1. WHAT VERINE IS AND WHAT IT IS USED FOR

Verine contains Mebeverine hydrochloride. This belongs to a group of medicines called antispasmodics.

This medicine is used to treat symptoms of irritable bowel syndrome (IBS) and similar problems such as chronic irritable colon, spastic constipation, mucous colitis and spastic colitis.

Irritable bowel syndrome (IBS) is a very common condition which causes spasms and pain in the gut or intestine.

The intestine is a long muscular tube which food passes down so it can be digested. If the intestine goes into spasm and squeezes too tightly, you get pain. The way this medicine works is by relieving the spasm, pain and other symptoms of IBS.

The main symptoms of irritable bowel syndrome (IBS) include:

- Stomach pain and spasms
- Feeling bloated and having wind
- Having diarrhoea (with or without constipation)
- Small, hard, pellet-like or ribbon-like stools (faeces)

These symptoms may vary from person to person.

Talk to your doctor if these symptoms do not improve after a while, if you develop new symptoms or you are concerned about your symptoms.

Your diet and lifestyle can also help treat IBS:

How you restrict your diet depends on the way IBS affects you. If you find that certain foods bring on the symptoms, then it makes sense not to eat them. A high fiber diet may help, but ask your pharmacist for more information.

Some people find that learning to relax can help to lessen their symptoms of IBS. You may find it helpful to set aside a few moments each day to relax and gently unwind.

2. BEFORE YOU TAKE VERINE

Do not take Verine if:

- You are allergic to mebeverine hydrochloride or any of the other ingredients (see section 6 for a list of ingredients).

If any of the above applies to you, do not take this medicine and talk to your doctor or pharmacist.

Take special care with Verine

Check with your doctor or pharmacist before taking your medicine if:

- You have developed new symptoms or your symptoms have become worse.
- You have liver or kidney problems.

If the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

Taking Verine with food and drink

You can drink alcohol while you are taking Verine.

Taking other medicines

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

You should talk to your doctor or pharmacist before taking Verine if you are pregnant or might become pregnant. There is only limited information about the safety of Mebeverine for pregnant women. Your doctor may advise you to stop taking Verine before you become pregnant or as soon as you know you are pregnant. Verine should not be used during breast-feeding.

Driving and using machines

This medicine is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Verine 135mg film-coated tablets

Verine 135mg Film-Coated tablets contain lactose. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. HOW TO TAKE VERINE

Always take Verine as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Try to take Verine twenty minutes before a meal - some people find their symptoms to be strongest after they have eaten.
- Swallow Verine tablet or capsule whole with water. Do not chew the tablet or the capsule.

How many Verine to take

Verine 135mg film-coated tablets

Adults and the elderly:

- Take 1 tablet 3 times a day
- The number of tablets you take can be lowered if your symptoms improve
- Do not take more than 3 tablets per day.

Verine 200mg sustained release capsules

Adults and the elderly:

- The normal starting dose is one capsule twice a day.
- Do not give Verine to children or adolescents younger than 18 years.

If you take more Verine than you should

If you or someone else takes too many Verine (an overdose), talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Verine

If you miss a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

How to stop taking Verine

Do not stop taking Verine without talking to your doctor, even if you feel better.

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

4. POSSIBLE SIDE EFFECTS

Most people will not have problems, but some may get some side effects (unwanted effects or reactions).

If you get any of these serious side effects, stop taking Verine. See a doctor at once:

- Difficulty in breathing, swelling of face, neck, tongue or throat (severe allergic reactions)

These other effects are less serious. If they bother you talk to a pharmacist:

- Skin rash, red itchy skin.

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

5. HOW TO STORE VERINE

- Keep out of the reach and sight of children.
- Do not use Verine after the expiry date which is printed on the carton and blister pack.
- The expiry date refers to the last day of that month.
- Do not store Verine above 30°C.
- Keep them in their original container.

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 Verine contains

Verine 135mg film-coated tablets:

Each tablet contains 135mg Mebeverine hydrochloride as an active ingredient.

Verine 200mg sustained release capsules:

Each Sustained release capsule contains 200mg Mebeverine hydrochloride as an active ingredient.

And other ingredients include:

Verine 135mg film-coated tablets:

Excipients:

Lactose BP 200, Maize Starch, Povidone 30, Purified Talc and Magnesium Stearate

Coating Material:

Polysorbate 80, Purified Talc, Titanium Dioxide Pharma Grade, Polyethylene Glycol MW 6000, and Hydroxypropyl methylcellulose

Verine 200mg sustained release capsules:

Excipients

Gelatin Caps-Verine 200 mg

What Verine looks like and contents of the pack

Verine 135mg film-coated tablets:

A white to off-white, round, biconvex film-coated tablet, engraved with "179" on one side and plain on other.

Each pack contains 30 film-coated tablets.

Verine 200mg sustained release capsules:

Size No. 0, hard gelatin capsule with opaque medium orange body and opaque scarlet cap containing pale yellow pellets. The capsule is printed with "VERINE 200 mg" on both parts.

Each pack contains 30 sustained release capsules

Marketing Authorisation Holder and Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant
Saudi Pharmaceutical Industries &
Medical Appliances Corporation
Saudi Arabia

This leaflet was approved in June 2014.

"Verine" is a trade mark
34VE951

To report any side effect(s):

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfdia.gov.sa
- Website: www.sfdia.gov.sa/npc

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists