



Package Leaflet: Information for the patient

Mebeverine 135 mg film-coated tablets

Mebeverine hydrochloride

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

1. What Mebeverine is and what it is used for

Mebeverine 135 mg film-coated tablets contain the active ingredient mebeverine hydrochloride. This belongs to a group of medicines called antispasmodics.

Mebeverine helps to relax the muscles of the gastro-intestinal tract (gut). It is used in conditions such as irritable bowel syndrome 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 spasm 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 spasm
- persistent diarrhoea, or alternating constipation and diarrhoea
- flatulence (wind) and feeling bloated
- 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 fibre 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. What you need to know before you take Mebeverine

Do not take Mebeverine:

If you are allergic to mebeverine or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Mebeverine 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.

Other medicines and Mebeverine

Mebeverine is not known to interact with other medicines but you should tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Mebeverine with alcohol

You can drink alcohol while you are taking Mebeverine 135 mg film-coated tablets.

Pregnancy, breastfeeding and fertility

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

There is only limited information about the safety of Mebeverine for pregnant women. Your doctor may advise you to stop taking Mebeverine before you become pregnant or as soon as you know you are pregnant. Mebeverine should not be used during breastfeeding.

Driving and using machines

Mebeverine are not likely to affect your ability to drive or use machines.

Mebeverine contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Mebeverine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per each film coated tablet, that is to say essentially 'sodium-free'.



3. How to take Mebeverine

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

Try to take the tablet 20 minutes before a meal - some people find their symptoms to be strongest after they have eaten. Swallow the tablet whole with water. Do not chew the tablet.

Adults (including the elderly):

- The recommended dose is one tablet three times a day. **Do not take** more than three tablets per day.
- The number of tablets you take may be lowered if your symptoms improve.

Children and adolescents: Mebeverine is **not** recommended for use in children and adolescents below 18 years of age.

If you take more Mebeverine than you should

If you or someone else take more Mebeverine Tablets than you should (overdose), contact your doctor or hospital emergency department **immediately**. Take this leaflet and any remaining tablets with you

If you forget to take Mebeverine

If you forget to take a dose of Mebeverine film-coated tablets at the right time, take it as soon as you remember, unless it is nearly time for your next dose. **Do not** take a double dose to make up for the forgotten tablet.

If you stop taking Mebeverine

Do not stop taking the tablets 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

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

If you notice the following **stop taking** the tablets and go to your doctor **immediately, or your nearest hospital**.

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

Other side effects: allergic reactions may occur, such as skin reactions, inflamed or reddened skin, swelling, hives, itching or skin rashes.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mebeverine

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 or label after EXP. The expiry date refers to the last day of that month.

Store this medicine in a dry place below 30°C and 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 protect the environment.

6. Contents of the pack and other information

What Mebeverine contains

The active substance is mebeverine hydrochloride. Each film-coated tablet contains 135 mg mebeverine hydrochloride
The other ingredients are:
microcrystalline cellulose
lactose monohydrate
povidone
talc
magnesium stearate
sodium starch glycollate.

The tablet coating includes hydroxypropyl methylcellulose (E464), titanium dioxide (E171) and polyethylene glycol.

What Mebeverine look like and contents of the pack

Mebeverine tablets are white-coated tablets marked "MV135" on one side.

The medicine is available in either plastic bottles or blister packs of 12, 15, 18, 20, 21, 28, 30, 56, 60, 84, 90 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer:

APL Swift Services (Malta) Ltd,
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000,
Malta.

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This leaflet was last revised in 10/2020

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Dublin 13
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