

Mebeverine Hydrochloride

135mg Film-coated Tablets

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

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1. What Mebeverine Tablets are and what they are used for

Mebeverine Hydrochloride 135 mg Film-coated Tablets contain the active ingredient 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 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
- 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 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 Tablets

Do not take Mebeverine Tablets

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Mebeverine Tablets if:

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

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

Mebeverine Tablets with food and drink

You can drink alcohol while you are taking Mebeverine Tablets.

Other medicines and Mebeverine Tablets

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.

Pregnancy, breast-feeding and fertility

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. There is only limited information about the safety of Mebeverine Tablets for pregnant women. Your doctor may advise you to stop taking Mebeverine Tablets before you become pregnant or as soon as you know you are pregnant. Mebeverine Tablets 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.

Mebeverine Tablets contain lactose and sodium

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.

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

3. How to take Mebeverine Tablets

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 twenty minutes before a meal - some people find their symptoms to be strongest after they have eaten.

Swallow the tablet whole with a glass of 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 Tablets are **not** recommended for use in children and adolescents below 18 years of age.

If you take more Mebeverine Tablets than you should

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

If you forget to take Mebeverine Tablets

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

If you stop taking Mebeverine Tablets

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, 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.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Mebeverine Tablets

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 blister and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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 Tablets contain

The active substance is mebeverine hydrochloride. Each film-coated tablet contains 135 mg mebeverine hydrochloride.

The other ingredients are:

Tablet core: lactose monohydrate, silicified microcrystalline cellulose, sodium starch glycolate (Type A), povidone, talc (E553b), and magnesium stearate.

Tablet coating: poly (vinyl alcohol) - part hydrolyzed (E1203), talc (E553b), titanium dioxide (E171), glycerol monocaprylocaprate (type I), and sodium laurilsulfate.

What Mebeverine Tablets look like and contents of the pack

Mebeverine Hydrochloride 135mg Film-coated Tablets are white to off-white, round film-coated tablets, 10 mm diameter, debossed with M135 on one side and plain on other side.

The tablets are packaged in PVC/PVdC-Alu blister packs.

Pack sizes: 7, 10, 12, 14, 15, 18, 20, 21, 28, 30, 56, 60, 84, 90 and 100 tablets.

Not all pack sizes may be marketed.

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