

Package leaflet: Information for the patient

Mebeverine Hydrochloride 135 mg 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

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

1. What this medicine is and what it is used for

This medicine contains an active substance called Mebeverine hydrochloride, which 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 this medicine**Do not take this medicine:**

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking this 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 other medicines

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

Taking with food and drink

You can drink alcohol while you are taking this medicine.

Pregnancy and breast-feeding

You should talk to your doctor or pharmacist before taking this medicine 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 this medicine before you become pregnant or as soon as you know you are pregnant. This medicine 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.

This medicine contains lactose and sucrose

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

3. How to take this medicine

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

The recommended dose is**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.

Use in Children and adolescents

Do not give this medicine to children or adolescents younger than 18 years.

Route and method of administration

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

If you take more of this medicine than you should

If you or someone else takes too many 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 this medicine

If you forget to take a dose at the usual time, take it as soon as you remember, unless it is time to take your next dose.

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

If you stop taking this medicine

Do not stop taking your tablets unless your doctor tells you to, 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 get any of these serious side effects, stop taking the tablets. See a doctor at once if you have:

- 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

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

5. How to store this medicine

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the label 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.

6. Contents of the pack and other information

What this medicine contains

- The active substance is 135 mg of Mebeverine hydrochloride.
- The other ingredients are:

Tablet core: Lactose monohydrate, Maize starch, Povidone K 30, Purified talc, Isopropyl alcohol, Magnesium stearate (E470b).

Tablet coat: Sucrose, Gelatin, Purified talc, Ethanol, Shellac (E904), Carnauba wax yellow (E903), Beeswax white (E901).

What this medicine looks like and contents of the pack

- The tablets are round, white to off-white, sugar coated tablets, plain on both sides.
- This medicine is available in packs containing 10, 15, 84 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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