



Mebeverine hydrochloride 135mg 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

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1 What this medicine is and what it is used for

This medicine contains 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 or pharmacist 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 mebeverine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

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

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.
- if 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.

Children and adolescents

Mebeverine hydrochloride 135mg film-coated tablets are not recommended for use in children and adolescents below the age of 18, due to insufficient data on safety and efficacy.

Other medicines and Mebeverine hydrochloride

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

Mebeverine hydrochloride with food, drink and alcohol

You can drink alcohol while you are taking this medicine.

Pregnancy and breast-feeding

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.

Pregnancy

There is only limited information about the safety of mebeverine hydrochloride 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.

Breast-feeding

This medicine should not be used during breast-feeding.

Driving and using machines

This medicine is not likely to affect your ability to drive or use any tools or machines.

This medicine contains lactose

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 number of tablets you take can be lowered if your symptoms improve.
- **Do not take more than 3 tablets per day.**
- Try to take the tablet twenty minutes before a meal; some people find their symptoms are strongest after they have eaten.
- Swallow the tablet whole with water. Do not chew the tablet.

Adults (including the elderly)

- Take 1 tablet 3 times a day.

If you take more of this medicine than you should

If you or someone else takes too much of this medicine (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 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.

If you stop taking this medicine

Do not stop taking this medicine 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 get any of these serious side effects, stop taking this medicine. 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.

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 (website: 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 this medicine

- **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 and blister pack after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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 mebeverine hydrochloride.

Each tablet contains 135mg of mebeverine hydrochloride.

The other ingredients are:

Core tablet

Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate type A, povidone, magnesium stearate, talc.

Film coating

Opadry white (ingredients: hypromellose (E464), titanium dioxide (E171), polyethylene glycol/macrogol and talc).

What this medicine looks like and contents of the pack

Mebeverine hydrochloride 135mg film-coated tablets are white coloured, round shaped, biconvex film-coated tablets and plain on both sides.

Packs may contain 10, 15, 84 or 100 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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