



Mebeverine 200mg modified-release capsules

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 is and what it is used for

This medicine is a capsule containing Mebeverine hydrochloride, which belongs to a group of medicines called antispasmodics.

This medicine is used to treat the symptoms of irritable bowel syndrome (IBS).

This 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 to 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 doctor or 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 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 Mebeverine:

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

Children and adolescents

This medicine is not recommended for use in children and adolescents below 18 years old.

Other medicines and Mebeverine

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.

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 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.

Breast-feeding

Mebeverine 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 contains Sucrose

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

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

Adults (including the elderly)

- The recommended starting dose is one capsule twice a day.

If you take more Mebeverine than you should

If you or someone else takes too much Mebeverine (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

If you miss a capsule, take it when you remember. However, if it is nearly time for the next dose, skip the missed dose and carry on as normal with the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Mebeverine

Do not stop taking Mebeverine 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 the capsules. 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). By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Mebeverine

Keep 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. The expiry date refers to the last day of that month.

Store Mebeverine in the original package.

Store below 30°C.

Return any unused capsules to a pharmacist. 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 capsule contains 200mg of mebeverine hydrochloride in a modified release formulation.

The other ingredients are:

Capsule core

Sugar spheres (sucrose, maize)

Povidone

Hypromellose

Capsule Coating

Ethyl cellulose N-45

Macrogol 6000

Magnesium stearate

Capsule Shell

Gelatin

Titanium dioxide (E171)

What Mebeverine looks like and the contents of the pack

Mebeverine comes as creamy white hard capsules, filled with white to off white coloured spherical pellets.

Packs may contain 10, 30 or 60 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Aspire Pharma Limited

Unit 4, Rotherbrook Court, Bedford Road, Petersfield Hampshire, GU32 3QG, United Kingdom

Alternative Manufacturer

Wave Pharma Limited

Ground Floor, Cavendish House, 369 Burnt Oak Broadway Edware, HA8 5AW, United Kingdom

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