Package leaflet: Information for the patient

Mebeverine hydrochloride 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.
Always take this medicine exactly as described in this leaflet or as your doctor, or pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

What is in this leaflet

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

1. What Mebeverine hydrochloride is and what it is used for

Mebeverine hydrochloride contains the active substance Mebeverine hydrochloride. This belongs to a group of medicines called antispasmodics.

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

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 you develop new symptoms or if these symptoms continue for more than 2 weeks.

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 hydrochloride

Do not take Mebeverine hydrochloride:

- If you are allergic to mebeverine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- If you are younger than 18 years of age.

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

Take special care with Mebeverine hydrochloride:
See your doctor before using any IBS treatment if you:

- have not suffered from IBS before or
- have developed new symptoms or your symptoms have become worse
- have liver or kidney problems.

Talk to your doctor or pharmacist if any of the following applies to you:

- You are 40 years of age or over and your symptoms have changed or it has been some time since you last had IBS
- You have blood in your stools (faeces)
- You are feeling sick (nauseous) or are sick (vomiting)
- You are looking pale and feeling tired
- You have constipation
- You have a fever
- You have recently travelled abroad
- You are pregnant, or planning to become pregnant
- You have unusual bleeding or discharge from your vagina
- You have difficulty or pain when passing water (urinating)

Your doctor will tell you whether it is safe for you to start taking Mebeverine hydrochloride.

Mebeverine hydrochloride with food and drink
You can drink alcohol while you are taking Mebeverine hydrochloride.

Other medicines and Mebeverine hydrochloride
No interactions with other medicines are known. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

There is only limited information about the safety of Mebeverine for pregnant women. Your doctor may advise you to stop taking Mebeverine hydrochloride before you become pregnant or as soon as you know you are pregnant. Mebeverine hydrochloride 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 hydrochloride 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 hydrochloride contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially sodium-free.

3. How to take Mebeverine hydrochloride

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

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

How much Mebeverine hydrochloride to take

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.

Do not give Mebeverine hydrochloride to children or adolescents younger than 18 years.

How to stop taking Mebeverine hydrochloride
You can lower the dose if your symptoms get better.

If you take more Mebeverine hydrochloride than you should
If you or someone else takes too much Mebeverine hydrochloride (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 hydrochloride
If you miss a tablet, wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.
If you have any further questions on the use of this product, 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:

- 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 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 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 hydrochloride

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, blister after 'EXP'. The expiry date refers to the last day of that month.
- You should lock this medicine in a cupboard or medicine cabinet
- This medicine does not require any special storage conditions.
- If your doctor stops your treatment, return any unused tablets 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 to protect the environment.

6. Contents of the pack and other information

What Mebeverine hydrochloride contains

- The active substance is mebeverine hydrochloride. Each tablet contains 135 mg mebeverine hydrochloride.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (type A), povidone, purified talc, magnesium stearate, hypromellose (HPMC E3), macrogols (PEG 400), titanium dioxide.

What Mebeverine hydrochloride looks like and contents of the pack

Mebeverine hydrochloride are white colored, circular biconvex shaped, film coated tablets plain on both sides.

Alu/PVC/PVdC blister pack: 12, 15, 18, 20, 21, 28, and 30 tablets.

Not all pack sizes may be marketed.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, 020 8831 1580 (UK only)
Please be ready to give the following information:
Product name: Mebeverine hydrochloride 135mg Film-coated Tablets
Reference number: PL 21880/0248

Marketing Authorisation Holder and Manufacturer
Medreich PLC
Warwick House
Plane Tree Crescent
Feltham TW13 7HF
United Kingdom

This product is authorized in the Member States of the EEA under the following name(s):
Mebeverine hydrochloride 135mg Film-coated Tablets (UK)

This leaflet was last revised in April 2019