

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.

- 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 hydrochloride 135 mg Film-coated Tablets are and what they are used for

Mebeverine hydrochloride 135 mg Film-coated Tablets contain 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) 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 by relaxing muscles of the gut.

The main symptoms of irritable bowel syndrome (IBS) include:

- Stomach pain and spasm
- Persistent diarrhoea, or alternating constipation and diarrhoea
- Flatulence (wind) and feeling bloated
- 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 hydrochloride 135 mg Film-coated Tablets

Do not take Mebeverine hydrochloride 135 mg Film-coated Tablets:

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

If any of 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 hydrochloride 135 mg Film-coated Tablets:

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

Do not use this medicine without talking to your doctor if you:

- are aged 40 years or over and your symptoms have changed or it has been some time since you last had IBS
- have passed blood in your stools or motions
- are feeling sick or being sick
- have lost your appetite or lost weight
- look pale and feel tired
- are suffering from severe constipation
- have a fever
- have recently travelled abroad
- are, or may be, pregnant or planning to become pregnant
- have abnormal vaginal bleeding or discharge
- have difficulty or pain passing urine.

Consult your doctor if you have developed new symptoms, or if the symptoms worsen, or if they do not improve after 2 weeks of treatment.

Other medicines and Mebeverine hydrochloride 135 mg Film-coated Tablets

Mebeverine hydrochloride 135 mg Film-coated Tablets are 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 and notice any strange side effects when you start taking Mebeverine hydrochloride 135 mg Film-coated Tablets.

Mebeverine hydrochloride 135 mg Film-coated Tablets with food and alcohol

You can drink alcohol while you are taking Mebeverine hydrochloride 135 mg Film-coated Tablets.

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 135 mg Film-coated Tablets before you become pregnant or as soon as you know you are pregnant. Mebeverine hydrochloride 135 mg Film-coated 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 hydrochloride 135 mg Film-coated Tablets 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 135 mg Film-coated Tablets 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 135 mg Film-coated Tablets

Always take Mebeverine hydrochloride 135 mg Film-coated Tablets 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 water. Do not chew the tablet.

Adults and 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 can be lowered if your symptoms improve.

Use in children and adolescents:

Mebeverine hydrochloride 135 mg Film-coated Tablets are not recommended for use in children and adolescents below 18 years of age.

If you take more Mebeverine hydrochloride 135 mg Film-coated Tablets than you should

If you or someone else takes too many Mebeverine hydrochloride 135 mg Film-coated 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 hydrochloride 135 mg Film-coated Tablets

If you miss a tablet, wait until the next tablet is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Mebeverine hydrochloride 135 mg Film-coated 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 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 suffer from difficulty in breathing, swelling of the face, neck, lips, tongue or throat (severe allergic reactions), stop taking the tablets and go to your doctor **immediately, or your nearest hospital**.

Other side effects (frequency unknown): allergic reactions may occur, such as skin reactions (inflamed or reddened skin, itching or skin rashes).

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

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: HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mebeverine hydrochloride 135 mg Film-coated 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 carton, blister, bottle or label after 'EXP'. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- HDPE bottle pack: Discard 90 days after first opening of the container.
- Do not use this medicine if you notice any visible signs of deterioration.
- 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 hydrochloride 135 mg Film-coated Tablets contain

- 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 135 mg Film-coated Tablets look like and contents of the pack

Mebeverine hydrochloride 135 mg Film-coated Tablets are white colored, circular biconvex shaped, film-coated tablets plain on both sides.

Alu/PVC/PVdC blister pack: 12, 15, 18, 20, 21, 28, 30, 56, 60, 84, 90 and 100 tablets.

HDPE Bottle: 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland.

Manufacturer

Meiji Pharma Spain S.A., Avda. De Madrid, 94., 28802, Alcalà de Henares, (Madrid), Spain.

This product is authorised in the Member States of the EEA under the following name(s):
Mebeverine hydrochloride 135 mg Film-coated Tablets (United Kingdom, Ireland)

This leaflet was last revised in August 2020.