Package leaflet: Information for the patient

# Aurobeverine 200 mg modified-release capsules, hard

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

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

## 1. What Aurobeverine MR is and what it is used for

Aurobeverine MR contains the active ingredient mebeverine, which belongs to a group of medicines called antispasmodics.

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

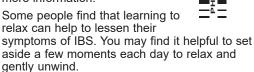
- stomach pain and spasm
- · feeling bloated and having wind
- having diarrhoea (with or without constipation)
- small, hard, pellet-like or ribbon-like stools (faeces)

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.



## 2. What you need to know before you take Aurobeverine MR

#### Do not take Aurobeverine MR:

 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.

#### Other medicines and Aurobeverine MR

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 before you become pregnant or as soon as you know you are pregnant and prescribe a different medicine instead.

Mebeverine should not be used during breastfeeding.

#### **Driving and using machines**

This medicine is not likely to affect you being able to drive or use any tools or machines.

#### Aurobeverine MR contains sucrose

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

#### 3. How to take Aurobeverine MR

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

- Aurobeverine MR may be used by adults.
- The capsules should be swallowed whole with a glass of water. Do not chew or crush the capsules. If you do, the medicine will be absorbed into your body too quickly and may not work properly.

The recommended dose is one 200 mg capsule twice a day. Take one capsule in the morning and one capsule in the evening.



### If you take more Aurobeverine MR than you should

If you or someone else takes too much medicine (an overdose), talk to a doctor or go to the hospital straight away. Take the medicine pack with you.

If you forget to take Aurobeverine MR

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 Aurobeverine MR

Do not stop taking your 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 the capsules. See a doctor at once or go to your nearest hospital if needed:

Frequency not known (cannot be estimated from the available data):

 Signs of a serious allergic reaction such as a raised itchy skin rash (hives), swelling of the face, neck, tongue or throat causing difficulty breathing or swallowing

#### Other possible side effects

Frequency not known (cannot be estimated from the available data):

Skin rash, red and/or 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 national reporting system 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. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Aurobeverine MR

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

#### Blister Pack:

Do not store above 30°C. Do not refrigerate or freeze. Store in the original package in order to protect from moisture.

#### **HDPE** container pack:

Store below 25°C. Store in the original container in order to protect from light and moisture. Use within 3 months after first opening the HDPE container.

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 Aurobeverine MR contains

The active substance is mebeverine hydrochloride. Each capsule contains 200 mg mebeverine hydrochloride.

The other ingredients are:

Capsule core: Sugar spheres (sucrose, maize starch), povidone, hypromellose Capsule shell: Gelatin, titanium dioxide (E 171) Capsule coating: Ethylcellulose, macrogol, magnesium stearate

## What Aurobeverine MR looks like and contents of the pack

Your medicine comes as hard gelatin capsules with creamy white bodies and caps, filled with white to off-white spherical pellets.

The modified-release capsules are available in blister packs and HDPE packs. Pack sizes of blister: 20, 30, 50, 60, 90 and 100 capsules.

Pack sizes of HDPE container: 250 capsules.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

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