

## Mebeverine 135 mg Tablets

Mebeverine hydrochloride

### Package leaflet: Information for the user

**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

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

#### 1 What Mebeverine is and what it is used for

Mebeverine is an anti-spasm drug.

Mebeverine is used to treat:

- spasms in the gut
- irritable bowel syndrome and other similar conditions.

#### 2 What you need to know before you take Mebeverine

**Do NOT take Mebeverine if you:**

- are allergic (hypersensitive) to mebeverine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- have paralytic ileus (paralysis of part of the gut).

#### Warnings and precautions

**Talk to your doctor before you start to take this medicine if you:**

- suffer from acute porphyria (an enzyme deficiency).

#### Other medicines and Mebeverine

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor for advice before taking this medicine.

#### Driving and using machines

Mebeverine is not known to affect your ability to drive or operate machinery.

#### Important information about some of the ingredients of Mebeverine

##### *Lactose and 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.

##### *Sodium*

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

##### *Methyl parahydroxybenzoate*

You should also note that Mebeverine contains the preservative methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).

#### 3 How to take Mebeverine

Always take Mebeverine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The tablets should be swallowed preferably with a drink of water.

The usual dose is:

##### **Adults (including the elderly):**

1 tablet three times a day preferably about 20 minutes before eating.

After several weeks, once the desired effect has been achieved, your doctor may gradually reduce your dose.

##### **Children and adolescents under 18 years of age:**

Mebeverine is not recommended.

##### **If you take more Mebeverine than you should**

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

### **If you forget to take Mebeverine**

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

### **If you stop taking Mebeverine**

Do not stop taking your medicine without talking to your doctor first 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, Mebeverine can cause side effects, although not everybody gets them.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

### **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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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**

**Keep this medicine out of the sight and reach of children.** Mebeverine Tablets should be stored at or below 25°C. Store in the original package or keep blisters in the outer carton (protect from light). Do not transfer them to another container. Do not use Mebeverine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

medicines no longer required. These measures will help to protect the environment.

## **6 Contents of the pack and other information**

### **What Mebeverine Tablets contain:**

- The active ingredient is mebeverine hydrochloride.
- The other ingredients are lactose monohydrate, potato starch, sodium starch glycolate, povidone K30, purified talc (E553), magnesium stearate (E572). The tablet coating contains: sucrose, purified talc (E553), calcium carbonate, macro glyceryl ricinoleate, titanium dioxide (E171), acacia, magnesium stearate, methyl parahydroxybenzoate (E218) and white beeswax (E901). The printing ink contains: shellac, black iron oxide (E172) and propylene glycol (E1520).

### **What Mebeverine Tablets look like and contents of the pack:**

- Mebeverine Tablets are white or almost white, biconvex, sugar coated tablets. They are plain on one side and printed 135/4301 on the reverse.
- Mebeverine Tablets are available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160 and 168 tablets.  
Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation holder**

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

#### **Manufacturer**

Teva Pharmaceutical Works Private Ltd Company, 13 Pallagi H-4042, Debrecen, Hungary

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