**Package leaflet: Information for the user**

**Mebeverine hydrochloride 50mg/5ml Oral Suspension**

**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.

The name of your medicine is Mebeverine hydrochloride 50mg/5ml Oral Suspension but it will be referred to as 'Mebeverine' throughout this leaflet.

**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

This medicinal product contains mebeverine which is an antispasmodic.

It is used to treat the symptoms of a variety of bowel problems and works by relaxing the muscles in the gut, thereby relieving the symptoms of irritable bowel:
- colicky abdominal pain and cramps
- persistent diarrhoea where there is no obvious cause (this may or may not occur between bouts of constipation)
- wind.

Mebeverine can also be used for spasm in the gut resulting from certain other diseases.

You must talk to a doctor if you do not feel better or if you feel worse.

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

**Do not take Mebeverine**
- if you are allergic to mebeverine or to any of the other ingredients of this medicine (listed in section 6).

If this applies to you, speak to your doctor or pharmacist.

**Other medicines and Mebeverine**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may be affected by Mebeverine or they may affect how well Mebeverine will work.

**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 for advice before taking this medicine.

**Driving and using machines**
Mebeverine is unlikely to affect your ability to operate machinery or to drive.

**Mebeverine contains**
**Sodium benzoate (E 211):** This medicine contains 10.00mg sodium benzoate (E 211) in each 5ml which is equivalent to 2.00mg/ml of oral suspension.
**Macrogolglycerol 40 Hydroxystearate:** This may cause stomach upset and diarrhea.
**Propylene glycol (E 1520):** This medicinal product contains 6.5mg propylene glycol in each 5ml dose which is equivalent to 1.3mg/ml.
**Sodium:** This medicine contains 51.75mg sodium (main component of cooking/table salt) in each 15 ml dose, equivalent to 2.59% of the WHO recommended maximum daily intake of 2g sodium for an adult.

**3. How to take Mebeverine**

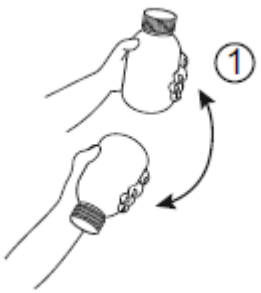
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**The recommended dose is**
**Adults and children over 10 years of age**
The usual dose is 15 ml three times a day.
The dose may be gradually reduced after a few weeks when your condition improves.

**Use in children under 10 years**
This medicine is NOT suitable for children under 10 years.

**Route and Method of administration:**
- This medicinal product must be taken orally.
- Shake the suspension before taking.
- Take the suspension preferably 20 minutes before meals to reduce symptoms after eating.
- Your doctor may also advise you to start or stop taking other medicines, depending on what condition you're being treated for and the way you respond to treatment.
- **Always take the full dose** that your doctor has prescribed. Never take only part of a dose.
- Your doctor or pharmacist may advise you to take a required dose using 20ml cup provided with 300ml pack.

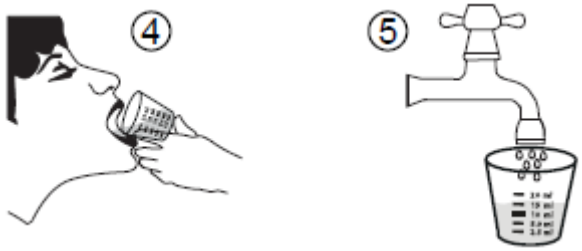
**Instructions for the use of cup:**
a) Shake bottle well before use (figure 1).



b) Open the bottle: press the cap and turn it anticlockwise (figure 2).
c) Fill the cup with a small amount of suspension by tilting the bottle horizontally to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 3).




d) Empty the contents of the cup into the patient's mouth slowly to avoid a choking hazard (figure 4).
e) Close the bottle with the plastic screw cap. Wash the cup with water (figure 5).




**If you take more Mebeverine than you should**
1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the bottle and any remaining suspension with you so that people can see what you have taken.
3. Do this even if you feel well.

**If you forget to take Mebeverine**
If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.
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.

**STOP taking** the suspension and **seek medical help immediately** if you have any of the following **allergic reactions:**
- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps.

**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 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.

**5. How to store Mebeverine**

- 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 and bottle label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25ºC.
- Do not refrigerate or freeze.
- Do not use this medicine if you notice that the suspension becomes discoloured or shows any signs of deterioration. Seek the advice of your 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 Suspension contains**
The active substance is mebeverine hydrochloride.

Each 5ml of oral suspension contains 50mg mebeverine hydrochloride (as pamoate).

The other ingredients are:
sodium benzoate (E 211), simeticone emulsion, microcrystalline cellulose and carmellose sodium, sodium citrate, citric acid monohydrate, polysorbate 20, macrogolglycerol 40 hydroxystearate, saccharin sodium, pamoic acid disodium salt monohydrate, banana flavour [contains propylene glycol (E1520)] and purified water.

**What Mebeverine looks like and contents of the pack**
Mebeverine is a yellow coloured suspension with banana flavour supplied in 300ml amber glass bottle with tamper-evident child-resistant white (polyethylene/polypropylene) plastic cap with EPE liner.

The pack also contains 20ml measuring cup with 5ml graduation marks and having additional graduation of 2.5ml for measuring and administering the dose.

**Marketing Authorisation Holder and Manufacturer:**
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**If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.**

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