

Package Leaflet: Information for the user

Mebeverine 50 mg/5 ml Sugar Free Oral Suspension

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

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

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

Mebeverine oral suspension 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.

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

Do not take Mebeverine Suspension

- 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 Suspension

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 Suspension or they may affect how well Mebeverine Suspension 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 Suspension is unlikely to affect your ability to operate machinery or to drive.

Mebeverine Suspension contains sodium, castor oil and sodium benzoate.

- **sodium**
This medicinal product contains 61.5 mg of sodium (main component of cooking/table salt) in each 15 ml spoonful of oral suspension. This is equivalent to 3% of the WHO recommended daily intake of 2 g sodium for an adult.
- **castor oil**
This may cause stomach upset and diarrhoea.
- **sodium benzoate**
This medicine contains 30 mg sodium benzoate in each 15 ml spoonful of oral suspension which is equivalent to 2 mg/ml.

3. How to take Mebeverine Suspension

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

Recommended doses

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.

Method of administration

- Shake the suspension before taking.
- Take the suspension preferably 20 minutes **before meals** to reduce symptoms after eating.

If you take more Mebeverine Suspension 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 Suspension

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, 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 Suspension

- 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 bottle label and on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Keep container in the outer carton.
- 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 5 ml spoonful of oral suspension contains 50 mg mebeverine hydrochloride (as pamoate).
- The other ingredients are:
microcrystalline cellulose, carmellose sodium, citric acid monohydrate, sodium citrate, polysorbate 20, polyoxyl 40 hydrogenated castor oil, disodium pamoate monohydrate, sodium benzoate (E 211), saccharin sodium, banana flavour, simethicone emulsion and purified water.

(See end of Section 2 for further information on sodium, castor oil and sodium benzoate).

What Mebeverine Suspension looks like and contents of the pack

Mebeverine Suspension is a yellow, banana flavoured suspension.
It is available in amber glass bottles of 300 ml.

Marketing Authorisation Holder

Chemidex Pharma Ltd., trading as Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB.

Manufacturer

Delpharm Bladel BV, Industrieweg 1, 5531 AD Bladel, The Netherlands.

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