

PATIENT INFORMATION LEAFLET

MEBEVERINE HYDROCHLORIDE

50 MG/5 ML 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 50 mg/5ml Oral Suspension. It will be referred to as Mebeverine Oral Suspension hereafter for ease of reading.

In this leaflet:

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

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

The name of your medicine is Mebeverine hydrochloride 50mg/5ml Oral suspension (referred to as Mebeverine Oral Suspension throughout this leaflet). 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 bowels, such as:

- colicky abdominal pain and cramps
- persistent diarrhoea with no obvious cause (this may or may not occur between bouts of constipation)
- wind.

Mebeverine Oral Suspension can also be used to relieve spasms in the gut resulting from certain other diseases.

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

Do not take Mebeverine Oral Suspension if:

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

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

Children

This medicine is NOT suitable for children under 10 years of age.

Other medicines and Mebeverine Oral Suspension

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal preparations. Some medicines may be affected by Mebeverine oral suspension or they may affect how Mebeverine oral suspension works.

Taking Mebeverine Oral Suspension with food

Take the suspension preferably 20 minutes before meals to reduce symptoms after eating.

Pregnancy, breast feeding

If you are pregnant or breastfeeding, 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 drive or operate machinery.

Mebeverine Oral Suspension contains

- **Sodium:** This medicine contains 63.5 mg of sodium (main component of cooking/table salt) per 15 ml dose. This is equivalent to 3% of the recommended maximum daily dietary intake of 2g sodium for an adult.
- **Sodium benzoate:** This medicinal product contains 30 mg of sodium benzoate in each 15 ml dose which is equivalent to 2mg/ml.
- **Castor oil:** May cause stomach upset and diarrhoea.

3. How to take Mebeverine Oral Suspension

Always take Mebeverine Oral Suspension exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose to suit your condition.

The recommended dose is:

Adults and children over 10 years of age: 15 ml, three times a day.

The dose may be gradually reduced after a few weeks when your condition improves.

Children under 10 years of age

This medicine is NOT suitable for children under 10 years of age.

Method of administration

Shake the suspension before taking it.

Take the suspension preferably 20 minutes before meals to reduce symptoms after eating.

If you take more Mebeverine Oral Suspension than you should

Contact your doctor, pharmacist or nearest hospital casualty department immediately. Take the bottle and any remaining suspension with you so that medical staff can see what you have taken. Do this even if you feel well.

If you forget to take Mebeverine Oral Suspension

If you forget to take a dose, take it as soon as you remember. However, 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 medicine, 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 Mebeverine Oral Suspension and see the doctor or go to the nearest hospital IMMEDIATELY if you experience any of the following side effects:

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps.

These may be signs of a serious allergic reaction. You may require urgent medical treatment.

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 Oral 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 the carton. The expiry date refers to the last day of that month.

After opening the container, this medicine can be used for **30 days**.

Do not store above 30°C. Store the bottle in the original packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help to protect the environment.

6. Contents of the pack and other information

What Mebeverine Oral Suspension contain:

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

The other ingredients are disodium pamoate, microcrystalline cellulose and carmellose sodium, citric acid monohydrate, polysorbate 20, sodium benzoate (E211), trisodium citrate dihydrate, macrogol glycerol hydroxy stearate (castor oil), saccharin sodium, simethicone emulsion, banana flavour, purified water.

What Mebeverine Oral Suspension look like and contents of the pack:

300 ml of a yellow-coloured, easily dispersible sugar-free suspension in an amber glass bottle. A measuring cup is enclosed in each pack.

Marketing Authorisation Holder:

Somex Pharma
Ilford, Essex, IG3 8BS. UK.

Manufacturer:

Pernix Pharma Ltd
Kamilla u.3., Zalaegerszeg, 8900
Hungary

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