

Package Leaflet: Information for the user

colofac[®]

MR Capsules

Mebeverine hydrochloride**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Colofac MR is and what it is used for

Colofac MR is a capsule containing Mebeverine hydrochloride. This belongs to a group of medicines called antispasmodics. This medicine is used to treat the symptoms of irritable bowel syndrome (IBS).

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 passes 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.

Some people find that learning to relax can help to lessen their symptoms of IBS. You may find it helpful to set aside a few moments each day to relax and gently unwind.

2. Before you take Colofac MR**Do not take Colofac MR if:**

- You are allergic to mebeverine hydrochloride or any of the other capsule ingredients (see section 6 for a list of ingredients)

If the above applies to you, do not take this medicine and talk to your doctor or pharmacist.

Take special care with Colofac MR

Check with your doctor or pharmacist before taking your medicine if:

- You have developed new symptoms or your symptoms have become worse
- You have liver or kidney problems.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

**Taking Colofac MR with food and drink**

You can drink alcohol while you are taking Colofac MR.

Taking other medicines

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

You should talk to your doctor or pharmacist before taking Colofac MR if you are pregnant or might become pregnant. There is only limited information about the safety of Mebeverine for pregnant women. Your doctor may advise you to stop taking Colofac MR before you become pregnant or as soon as you know you are pregnant. Colofac MR should not be used during breast-feeding.

Driving and using machines

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

3. How to take Colofac MR

Always take Colofac MR as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Try to take the capsule 20 minutes before a meal - some people find their symptoms to be strongest after they have eaten.
- Swallow the capsule whole with a drink of water. Do not chew the capsule.

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**How much Colofac MR to take****Adults (including the elderly)**

- The normal starting dose is one capsule twice a day.

Children

- This medicine is not recommended for use in children.

If you take more Colofac MR than you should

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

If you forget to take Colofac 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 Colofac MR

Do not stop taking Colofac MR 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

Most people will not have problems, but some may get some side effects (unwanted effects or reactions).

If you get any of these serious side effects, stop taking the capsules. See a doctor at once:

- Difficulty in breathing, swelling of face, neck, tongue or throat (severe allergic reactions)

These other effects are less serious. If they bother you talk to a pharmacist:

- Skin rash, red itchy skin

Reporting of suspected adverse reactions

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 United Kingdom national reporting system The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colofac MR

- **Keep out of the reach and sight of children.**
- Do not use the capsules after the expiry date which is stated on the carton and blister pack. The expiry date refers to the last day of that month.
- Store Colofac MR in the original package.
- Do not store above 30°C. Do not refrigerate or freeze.
- Return any unused capsules to a pharmacist.
- Medicines should not be disposed of via waste water or household waste. Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information**What Colofac MR contains**

Each capsule contains 200 mg of mebeverine hydrochloride in a modified release formulation.

The capsules also contain magnesium stearate, polyacrylate dispersion 30% , talc, hypromellose, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30% and glycerol triacetate. The capsule shell contains gelatine and titanium dioxide (E171). The printing inks contain shellac (E904), black iron oxide (E172), propylene glycol, concentrated ammonia solution and potassium hydroxide.

What Colofac MR looks like and the contents of the pack

Colofac MR Capsules are white, opaque and marked with the number 245.

Packs may contain 10 or 60 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is:
Mylan Products Ltd.,
20 Station Close, Potters Bar,
Herts, EN6 1TL, UK

The Manufacturer is:
Mylan Laboratories SAS
01400 Chatillon-sur-Chalaronne, France.

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