

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Colofac® IBS

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 becomes 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 IBS is and what it is used for

Colofac IBS is a tablet 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 and pain.

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 if you develop new symptoms or if these symptoms continue for more than 2 weeks.

Your diet and lifestyle can also help treat IBS:

How you restrict your diet depends on the way IBS affects you. If you find that certain things bring on the symptoms, then it makes sense not to eat them. A high fibre diet may help, but ask your 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 IBS

Do not take Colofac IBS if:

- You are allergic to any of the tablet ingredients (see section 6 for a list of ingredients)
 - You are younger than 18 years of age
- If any of the above applies to you, do not take this medicine and talk to your doctor or pharmacist.

Take special care with Colofac IBS

See your doctor before using any IBS treatment if you:

- have not suffered from IBS before or
- have developed new symptoms or your symptoms have become worse
- have liver or kidney problems.

Talk to your doctor or pharmacist if any of the following applies to you:

- You are 40 years of age or over and your symptoms have changed or it has been some time since you last had IBS
- You have blood in your stools (faeces)
- You are feeling sick (nauseous) or are sick (vomiting)
- You are looking pale and feeling tired
- You have constipation
- You have a fever
- You have recently travelled abroad
- You are pregnant, or planning to become pregnant
- You are a woman and you have unusual bleeding or discharge from your vagina
- You have difficulty or pain when passing water (urinating)

Your doctor will tell you whether it is safe for you to start taking Colofac IBS.



Taking Colofac IBS with food and drink

You can drink alcohol while you are taking Colofac IBS.

Taking other medicine

No interactions with other medicines are known.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking Colofac IBS 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 IBS before you become pregnant or as soon as you know you are pregnant. Colofac IBS 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.

Important information about some of the ingredients of Colofac IBS

This medicine contains lactose and sucrose (types of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Colofac IBS

How to take Colofac IBS

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

How much Colofac IBS to take

Adults and the elderly:

- Take 1 tablet 3 times a day
- The number of tablets you take can be lowered if your symptoms improve

- Do not take more than 3 tablets per day.
- Do not give Colofac IBS to children or adolescents younger than 18 years.

How to stop taking Colofac IBS

You can lower the dose if your symptoms get better.

If you take more Colofac IBS than you should

If you or someone else takes too much Colofac IBS (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 IBS

If you miss a tablet, wait until the next dose is due. Do not try to make up for the dose you have missed. Do not 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

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 tablets. 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 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 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 IBS

- **Keep out of the reach and sight of children.**
- You should lock this medicine in a cupboard or medicine cabinet.
- Do not use the tablets after the expiry date which is printed on the carton and blister pack.
- Do not store your tablets above 30°C and keep them in the original container.

If your doctor stops your treatment, return any unused tablets to a pharmacist.

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. Further information

What Colofac IBS contains

Each tablet contains 135 mg mebeverine hydrochloride

The tablets also contain lactose, starch (potato), povidone, talc, magnesium stearate, sucrose, gelatin, acacia and carnauba wax.

What Colofac IBS looks like and contents of the pack

Colofac IBS tablets are white, round and sugar coated with no markings.

Colofac IBS is available in packs containing 10, 15, 84 or 100 tablets in blister strips.

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 Châtillon-sur-Chalaronne, France

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