

Package Leaflet: Information for the user

Colofac 135 mg tablets (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.

What is in this leaflet

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2. What you need to know before you take Colofac
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1. What Colofac is and what it is used for

What Colofac is

The name of your medicine is Colofac 135 mg tablets (called Colofac in this leaflet). Colofac contains a medicine called mebeverine hydrochloride. This belongs to a group of medicines called antispasmodics, which act on your 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. This medicine works by relieving the spasm and pain.

What Colofac is used for

Colofac is used to relieve the symptoms of irritable bowel syndrome (IBS). These symptoms vary from person to person but can include:

- stomach pain and cramps
- feeling bloated and having wind
- diarrhoea, constipation or a combination of both
- small, hard, pellet-like or ribbon-like stools (faeces).

Colofac is also used to relieve cramps and pain in your stomach or gut caused by other medical conditions.

2. What you need to know before you take Colofac

Do not take Colofac

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

Do not take Colofac if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Colofac if:

- you have had any diseases of the bowel, apart from irritable bowel syndrome (IBS).
- you have developed new symptoms or your symptoms have become worse.

Other medicines and Colofac

Colofac is not expected to affect any other medicines that you take. Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes herbal medicines.

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Colofac is not recommended during pregnancy. Your doctor may advise you to stop taking Colofac or take another medicine instead.
- Colofac is not recommended for mothers who are breast-feeding. Your doctor may ask you to stop breast-feeding or advise you to take another medicine if you want to breast-feed.

Driving and using machines

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

Colofac contains lactose and sucrose (types of sugar).

This product contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Colofac

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

Taking this medicine

- Colofac can be taken by adults and children over 10 years.
- Swallow the tablets whole with a full glass of water. Do not crush or chew them.
- Try to take your tablets around the same time each day. This will help you remember to take them.

How much to take

Adults and children over 10 years

- The recommended dose is one 135 mg tablet three times each day.
- The tablets work best if you take them 20 minutes before a meal and space them evenly across your day.
- The number of tablets you take can be lowered if your symptoms improve.

Do not give Colofac 135 mg tablets to children under 10 years.

If you take more Colofac than you should

If you take more Colofac than you should talk to a doctor or go to a hospital straight away. Take the medicine pack and this package leaflet with you.

If you forget to take Colofac

- If you forget to take a dose, skip the missed dose. Then take the next dose at the normal time.
- 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.

If you stop taking Colofac

Do not stop taking the tablets 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine:

Stop taking Colofac and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

- Difficulty breathing, swelling of your face, neck, lips, tongue or throat. You may be having a severe allergic (hypersensitive) reaction to the medicine

If you get any of the side effects above, stop taking Colofac and see a doctor straight away.

Other side effects include:

- You may have a more minor allergic (hypersensitive) reaction to the medicine: e.g. skin rash, red itchy skin.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Colofac

Do not store above 30°C. Store in original container.

Do not take Colofac 135mg tablets after the expiry date shown on the carton (Expiry Date) and blister (EXP).

Keep this medicine out of the sight and reach of children.

Return any unused tablets to a pharmacist.

If your medicine appears to be discoloured, damaged or show any other signs of deterioration, please return them to your pharmacist who will advise you.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help protect the environment.

If you have any left-over/unused tablets, please return these to your pharmacist for safe disposal.

6. Contents of the pack and other information

What Colofac contains

Each tablet contains 135mg mebeverine hydrochloride.

The tablets also contain lactose, starch (potato or maize), povidone, talc, magnesium stearate. The sugar coating contains talc, sucrose, gelatin, acacia, carnauba wax.

What Colofac looks like and contents of the pack

The tablets are white, round, sugar coated with no markings.

Your medicine is available in packs containing 100 tablets.

Your tablets are manufactured by: Abbott Healthcare SAS, 01400 Chatillon-sur-Chalaronne, France.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

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