

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

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

If you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colofac

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C. Store in the original package to protect from light.

- Do not use this medicine after the expiry date, which is stated on the carton and blister strips.

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

- 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 Colofac contains

- The active ingredient is mebeverine hydrochloride. Each tablet contains 135 mg of mebeverine hydrochloride.
- The other ingredients are:
 - ☞ Tablet core: lactose monohydrate, starch (potato or maize), povidone, talc and magnesium stearate
 - Coating: talc, sucrose, gelatin, acacia and carnauba wax

What Colofac looks like and contents of the pack

The tablets are round, white and sugar-coated.

They are provided in PVC/Aluminium blister strips containing 100 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Colofac is held by:

Viatrix Healthcare Limited,
Damastown Industrial Park,
Mulhuddart,
Dublin 15
DUBLIN,
Ireland

For information in large print, tape, CD or Braille, phone 01 4691500.

And the tablets are manufactured at:

Mylan Laboratories SAS
Route de Belleville
Lieu dit Maillard
01400 Châtillon-sur-Chalaronne
France

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