

COLOFAC®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking COLOFAC?

COLOFAC contains the active ingredient mebeverine hydrochloride. COLOFAC is taken to relieve the symptoms of irritable bowel syndrome, which can include, abdominal pain and cramps, bowel spasm, diarrhoea and flatulence.

For more information, see Section [1. Why am I taking COLOFAC?](#) in the full CMI.

2. What should I know before I take COLOFAC?

Do not take if you have ever had an allergic reaction to COLOFAC or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take COLOFAC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COLOFAC and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take COLOFAC?

- Take COLOFAC at about the same time each day. The usual dose is one tablet three times a day.
- Take COLOFAC immediately before or during a meal. Swallow the tablets with a glass of water.

More instructions can be found in Section [4. How do I take COLOFAC?](#) in the full CMI.

5. What should I know while taking COLOFAC?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are taking COLOFAC.</p> <ul style="list-style-type: none"> ● If you become pregnant while you are taking COLOFAC, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none"> ● Do not take COLOFAC to treat any other complaints unless your doctor or pharmacist tells you to. ● Do not give COLOFAC to anyone else, even if they have the same condition as you. ● Do not stop taking COLOFAC, or lower the dosage, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> ● Be careful before you drive or use any machines or tools until you know how COLOFAC affects you.
Looking after your medicine	<ul style="list-style-type: none"> ● Keep your tablets in the pack until it is time to take them. ● Keep COLOFAC in a cool, dry place where

the temperature stays below 25°C.

- Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while taking COLOFAC?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor if you have any of these less serious side effects and they worry you: indigestion or heartburn, constipation, dizziness, headache, tiredness, difficulty sleeping, loss of appetite. **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects:** swelling of the face, lips or tongue, difficulty swallowing or breathing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

COLOFAC®

Active ingredient: *mebeverine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking COLOFAC. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking COLOFAC.**

Where to find information in this leaflet:

- [1. Why am I taking COLOFAC?](#)
- [2. What should I know before I take COLOFAC?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take COLOFAC?](#)
- [5. What should I know while taking COLOFAC?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking COLOFAC?

COLOFAC contains the active ingredient mebeverine hydrochloride. COLOFAC belongs to a group of medicines called known as antispasmodic agents.

COLOFAC works by relaxing the muscles in the gut, thereby relieving the symptoms of irritable bowel syndrome.

COLOFAC is taken to relieve the symptoms of irritable bowel syndrome, which can include, abdominal pain and cramps, bowel spasm, diarrhoea and flatulence.

2. What should I know before I take COLOFAC?

Warnings

Do not take COLOFAC if:

- you are allergic to mebeverine hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Check with your doctor if you:

- have any of the following medical conditions:
 - angina or other heart conditions
 - liver problems
 - kidney problems
 - lactose intolerance
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COLOFAC.

4. How do I take COLOFAC?

How much to take

- The usual dose is one tablet three times a day.
- Follow the instructions provided and continue taking COLOFAC until your doctor tells you to stop.
- It is important to keep taking your medicine even if you feel well.

When to take COLOFAC

- Take COLOFAC immediately before or during a meal.
- Take COLOFAC at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take COLOFAC

- Swallow the tablets with a glass of water.

If you forget to take COLOFAC

COLOFAC should be taken at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- This may increase the chance of getting an unwanted side effect.
- If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

If you take too much COLOFAC

If you think that you have taken too much COLOFAC, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking COLOFAC?

Things you should do

Call your doctor straight away if you:

- become pregnant while you are taking COLOFAC

If you are going to have surgery, tell the surgeon that you are taking COLOFAC.

Remind any doctor, dentist or pharmacist you visit that you are taking COLOFAC.

Things you should not do

- Do not take COLOFAC to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not give COLOFAC to anyone else, even if they have the same condition as you.
- Do not stop taking COLOFAC, or lower the dosage, without checking with your doctor

Driving or using machines

Be careful before you drive or use any machines or tools until you know how COLOFAC affects you.

Looking after your medicine

- **Keep your tablets in the pack until it is time to take them.**
- If you take the tablets out of the box or the blister pack they may not keep well.
- **Keep the medicine in a cool, dry place where the temperature stays below 25°C.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>The below list includes the more common side effects of your medicine. They are usually mild and short-lived.</p> <ul style="list-style-type: none">● indigestion or heartburn● constipation● dizziness● headache● tiredness● difficulty sleeping● loss of appetite	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• These side effects are rare.• swelling of the face, lips or tongue• difficulty swallowing or breathing	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What COLOFAC contains

Active ingredient (main ingredient)	mebeverine hydrochloride 135 mg per tablet
Other ingredients (inactive ingredients)	lactose monohydrate potato starch povidone purified talc magnesium stearate sucrose gelatin acacia carnauba wax
Potential allergens	lactose, sugars and traces of sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What COLOFAC looks like

COLOFAC tablets are white, round sugar-coated tablets. (AUST R 79335).

COLOFAC tablets are available in boxes of 30 and 90 tablets.

Who distributes COLOFAC

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

COLOFAC is made in France.

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COLOFAC® is a Viatrix company trade mark

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