

Abbott Laboratories South Africa (Pty) Ltd	Submission date: 25 November 2022	Type: Post-registration variations (format update, editorial changes and clinical safety update)
Colofac 135 mg tablets	Approval Date: 26 January 2023	Category: IAIN, IB
135 mg mebeverine hydrochloride	Implemented: 26 January 2023	Code: C.I.0.1, C.I.0.2a, C.I.0.3, C.I.13
Country code: ZA	Reg no.: Q/11.2/165	Sequence no.: 0000 (eSub)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

COLOFAC 135 mg coated tablets

Mebeverine hydrochloride

COLOFAC 135 mg contains sugar (79 mg sucrose and 97 mg lactose monohydrate per tablet)

Read all of this leaflet carefully because it contains important information for you

COLOFAC 135 mg is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use COLOFAC 135 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share COLOFAC 135 mg with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What COLOFAC 135 mg is and what it is used for
2. What you need to know before you take COLOFAC 135 mg
3. How to take COLOFAC 135 mg
4. Possible side effects
5. How to store COLOFAC 135 mg
6. Contents of the pack and other information

1. What COLOFAC 135 mg is and what it is used for

COLOFAC 135 mg contains mebeverine hydrochloride. This belongs to a group of medicines

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called antispasmodics.

COLOFAC 135 mg is used to treat symptoms of irritable colon or irritable bowel syndrome including persistent diarrhoea, alternating constipation and diarrhoea, abdominal pain (stomach pain) and abnormal bloating after eating.

COLOFAC 135 mg is also used to treat symptoms of irritable colon due to certain conditions such as inflammation of the small intestine, inflammation in the large intestine or other conditions that may cause inflammation in the gastro-intestinal tract.

2. What you need to know before you take COLOFAC 135 mg

Do not take COLOFAC 135 mg:

- if you are hypersensitive (allergic) to mebeverine hydrochloride or any of the other ingredients of COLOFAC 135 mg (listed in section 6).

Warnings and precautions

Take special care with COLOFAC 135 mg if you are pregnant (see **Pregnancy and breastfeeding**).

Children and adolescents

Do not give COLOFAC 135 mg to children or adolescents younger than 18 years of age.

Other medicines and COLOFAC 135 mg

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

COLOFAC 135 mg with food, drink and alcohol

You can drink alcohol while you are taking COLOFAC 135 mg.

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Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

COLOFAC 135 mg should not be used if you are pregnant or breastfeeding.

Driving and using machines

COLOFAC 135 mg may make you feel dizzy. Do not drive a vehicle or operate machines until you know how COLOFAC 135 mg affects you.

COLOFAC 135 mg contains sucrose and lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before giving COLOFAC 135 mg.

3. How to take COLOFAC 135 mg

Do not share your medicines with any other person.

Always take COLOFAC 135 mg exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of COLOFAC 135 mg is too strong or too weak, tell your doctor or pharmacist.

Take one (1) tablet three (3) times daily, preferably before meals.

The number of tablets can be lowered if your symptoms improve.

Take the tablets with enough water to swallow them. The tablets should not be chewed because they have an unpleasant taste.

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If you take more COLOFAC 135 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the medicine pack with you.

If you forget to take COLOFAC 135 mg

If you miss a tablet, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking COLOFAC 135 mg

Do not stop taking the tablets without talking to your doctor, even if you feel better.

4. Possible side effects

COLOFAC 135 mg can have side-effects.

Not all side-effects reported for COLOFAC 135 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COLOFAC 135 mg, please consult your health care provider for advice.

If any of the following happens, stop taking COLOFAC 135 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to COLOFAC 135 mg. You may need urgent medical attention or hospitalisation.

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Tell your doctor if you notice any of the following:

Side effects with unknown frequency:

- Feeling depressed.
- Headache.
- Dizziness.
- Diarrhoea or constipation.
- Skin rash.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of COLOFAC 135 mg.

5. How to store COLOFAC 135 mg

- Store in a dry, dark place, at temperatures not exceeding 30 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COLOFAC 135 mg contains

Each tablet contains 135 mg mebeverine hydrochloride as the active ingredient.

The other ingredients are acacia, carnauba wax, gelatin, lactose monohydrate, magnesium

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stearate, povidone, starch (potato), sucrose and talc.

What COLOFAC 135 mg looks like and contents of the pack

COLOFAC 135 mg tablets are white, round sugar-coated tablets.

COLOFAC 135 mg tablets are packed in PVC/aluminium blister strips in an outer carton.

Pack sizes: 10, 20, 100 and 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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