

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## COLOFAC®

*Mebeverine hydrochloride Tablets 135 mg*



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### What is in this leaflet

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Please read this leaflet carefully before you start taking Colofac.

This leaflet answers some common questions about Colofac.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Colofac against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### What Colofac is used for

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Colofac is used to relieve the symptoms of irritable bowel syndrome, which can include, abdominal pain and cramps, diarrhoea, constipation and flatulence.

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

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

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

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

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### Before you take Colofac

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#### ***When you must not take it***

**Do not take Colofac if you have an allergy to:**

- any medicine containing mebeverine hydrochloride
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not give this medicine to children.**

Safety and effectiveness in children have not been established.

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

If you use in the first trimester it may affect your developing baby. Your doctor can discuss with you the risks and benefits involved.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### ***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- angina, irregular heart-beat or other heart conditions/disease
- liver problems or liver disease
- kidney problems or kidney disease
- intolerance to lactose, fructose, or galactose
- glucose-galactose malabsorption
- sucrase-isomaltase or Lapp lactase insufficiency

**If you have not told your doctor about any of the above, tell him/her before you start taking Colofac.**

### ***Taking other medicines***

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Colofac.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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### **How to take Colofac**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### ***How much to take***

The usual dose is one tablet three times a day.

### ***How to take it***

Swallow the tablets whole with a full glass of water.

### ***When to take it***

Take Colofac preferably 20 minutes before a meal.

Take your medicine 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 long to take it***

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### ***If you forget to take it***

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 that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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## **While you are taking Colofac**

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### ***Things you must do***

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are taking Colofac.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor or pharmacist immediately.

Keep all of your doctor's appointments so that your progress can be checked.

### ***Things you must not do***

Do not take Colofac to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give your medicine 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.

If appropriate, your doctor will gradually reduce the amount you take each day.

### ***Things to be careful of***

Be careful driving or operating machinery until you know how Colofac affects you.

### ***If you take too much (overdose)***

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Colofac. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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## **Side effects**

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Tell your doctor or pharmacist as soon as possible if you do not

feel well while you are taking Colofac.

This medicine helps most people with irritable bowel syndrome, but it may have unwanted side effects in a few people.

All medicines can have some unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- indigestion or heartburn
- constipation
- dizziness
- headache
- tiredness or fatigue
- difficulty sleeping
- loss of appetite

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips or tongue or other parts of the body
- difficulty swallowing or breathing
- decrease or low heart rate
- hives or skin rash

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

Do not be alarmed by the following lists of possible side effects. You may not experience any of them.

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## After taking Colofac

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### **Storage**

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the box they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

Do not store Colofac or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

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

### **Disposal**

**If your doctor or pharmacist tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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### **What it looks like**

Colofac tablets are white, round sugar-coated tablets.

Colofac tablets are available in blisters of 30 and 90 tablets.

### **Ingredients**

#### Active ingredient(s):

Colofac contains 135 mg of mebeverine hydrochloride as the active ingredient.

#### Inactive ingredient(s):

Colofac also contains:

- lactose
- potato starch
- povidone
- purified talc
- magnesium stearate
- sucrose
- gelatin
- acacia

- carnauba wax

Gelatin raw material may contain sulfur dioxide residue. This medicine does not contain gluten.

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## If you want to know more

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

### **Who supplies this medicine**

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Telephone: (09) 579 2792

### **Date of Information**

12 November 2020 (Based on datasheet dated 06 November 2020)