

Colofac® 135mg Tablets

Variation 0008: To change the manufacturers name from `Abbott Healthcare SAS' to `Mylan Laboratories SAS', with consequential changes to the labels and leaflet.

Variation 0012: To change the storage conditions from `Store in the original package. Do not store above 30°C' to `Store in the original package to protect from light. Do not store above 30°C', with consequential changes to the labels and leaflet.

No other changes approved

How to take Colofac Tablets

- * If you have any further questions, ask your doctor or pharmacist.
- * This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- * If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Your medicine is called Colofac 135mg Tablets and will be referred to as Colofac Tablets throughout the leaflet.

In this leaflet:

- 1 What Colofac Tablets are and what they are used for
- 2 Before you take Colofac Tablets
- 3 How to take Colofac Tablets
- 4 Possible side effects
- 5 How to store Colofac Tablets
- 6 Further information

1 What Colofac Tablets and what they are used for

Colofac Tablets contain Mebeverine hydrochloride. This belongs to a group of medicines called antispasmodics.

This medicine is used to treat symptoms of irritable bowel syndrome (IBS) and similar problems such as chronic irritable colon, spastic constipation, mucous colitis and spastic colitis.

Irritable bowel syndrome (IBS) is a very common condition which causes spasm and pain in the 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. The way this medicine works is by relieving the spasm, pain and other symptoms of IBS.

The main symptoms of irritable bowel syndrome (IBS) include:

- * stomach pain and spasm
- * feeling bloated and having wind
- * having diarrhoea (with or without constipation)
- * small, hard, pellet-like or ribbon-like stools (faeces)

These symptoms may vary from person to person.

Talk to your doctor if these symptoms do not improve after a while, if you develop new symptoms or you are concerned about your symptoms.

Your diet and lifestyle can also help treat IBS:

How you restrict your diet depends on the way IBS affects you. If you find that certain foods bring on the symptoms, then it makes sense not to eat them. A high fibre diet may help, but ask your pharmacist for more information.

Some people find that learning to relax can help to lessen their symptoms of IBS. You may find it helpful to set aside a few moments each day to relax and gently unwind.

Do not take Colofac Tablets if:

- * You are allergic to any of the tablet ingredients (see section 6 for a list of ingredients).

If any of the above applies to you, do not take this medicine and talk to your doctor or pharmacist.

Take special care with Colofac Tablets

Check with your doctor or pharmacist before taking your medicine if:

- * You have developed new symptoms or your symptoms have become worse.
- * You have liver or kidney problems.

If the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

Taking Colofac Tablets with food and drink

You can drink alcohol while you are taking Colofac Tablets.

Taking other medicines

No interactions with other medicines are known.

Pregnancy and breast-feeding

You should talk to your doctor or pharmacist before taking Colofac Tablets if you are pregnant or might become pregnant. There is only limited information about the safety of Mebeverine for pregnant woman. Your doctor may advise you to stop taking Colofac Tablets before you become pregnant or as soon as you know you are pregnant. Colofac Tablets should not be used during breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Colofac Tablets

This medicine contains lactose and sucrose (types of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

Colofac[®] 135mg Tablets

(mebeverine hydrochloride)

Patient Information Leaflet (continued)

3 How to take Colofac Tablets

How to take Colofac Tablets

- * Try to take the tablet twenty minutes before a meal - some people find their symptoms to be strongest after they have eaten.
- * Swallow the tablet whole with water. Do not chew the tablet.

How many Colofac Tablets to take

Adults and the elderly:

- * Take 1 tablet 3 times a day
- * The number of tablets you take can be lowered if your symptoms improve
- * **Do not take** more than 3 tablets per day.

Do not give Colofac Tablets to children or adolescents younger than 18 years

If you take more Colofac Tablets than you should

If you or someone else takes too many Colofac Tablets (an overdose), talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Colofac Tablets

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.

How to stop taking Colofac Tablets

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 product, ask your doctor or pharmacist.

4 Possible side effects

Most people will not have problems, but some may get some effects (unwanted effects or reactions).

If you get any of these serious side effects, stop taking the tablets. See a doctor at once:

- * Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)

These other effects are less serious. If they bother you talk to a pharmacist:

- * Skin rash, red itchy skin

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App** Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Colofac Tablets

- * Store in the original package to protect from light.
- * Do not store above 30°C.
- * **Keep out of the sight and reach of children.**
- * Do not take the tablets after their expiry date which is printed on the outside of the pack.
- * Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- * If your medicine becomes discoloured or shows any other signs of deterioration consult your pharmacist who will tell you what to do.

6 Further information

What this medicine contains:

Each tablet contains 135 mg mebeverine hydrochloride.

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

What this medicine looks like and contents of the pack

Colofac Tablets are white, round and sugar coated with no superficial markings.

Each blister pack contains 100 tablets.

Manufacturer and Licence Holder

This medicine is manufactured by Mylan Laboratories SAS, 01400 Chatillon-sur-Chalaronne, France and is procured from within the EU. Product licence holder: LTT Pharma Limited, Unit 18 Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE and repackaged by Lexon (UK) Limited, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 33723/0145 Colofac 135mg Tablets

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Revision date: 03/01/19

**Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet
in a format suitable for you.**

Mebeverine Hydrochloride 135mg Tablets

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine.

- * 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- * If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Your medicine is called Mebeverine Hydrochloride 135mg Tablets and will be referred to as Mebeverine Hydrochloride Tablets throughout the leaflet.

In this leaflet:

- 1** What Mebeverine Hydrochloride Tablets are and what they are used for
- 2** Before you take Mebeverine Hydrochloride Tablets
- 3** How to take Mebeverine Hydrochloride Tablets
- 4** Possible side effects
- 5** How to store Mebeverine Hydrochloride Tablets
- 6** Further information

1 What Mebeverine Hydrochloride Tablets are and what they are used for

Mebeverine Hydrochloride Tablets contain Mebeverine Hydrochloride. This belongs to a group of medicines called antispasmodics.

This medicine is used to treat symptoms of irritable bowel syndrome (IBS) and similar problems such as chronic irritable colon, spastic constipation, mucous colitis and spastic colitis.

Irritable bowel syndrome (IBS) is a very common condition which causes spasm and pain in the 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. The way this medicine works is by relieving the spasm, pain and other symptoms of IBS.

The main symptoms of irritable bowel syndrome (IBS) include:

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Your diet and lifestyle can also help treat IBS:

How you restrict your diet depends on the way IBS affects you. If you find that certain foods bring on the symptoms, then it makes sense not to eat them. A high fibre diet may help, but ask your pharmacist for more information.

Some people find that learning to relax can help to lessen their symptoms of IBS. You may find it helpful to set aside a few moments each day to relax and gently unwind.

2 Before you take Mebeverine Hydrochloride Tablets

Do not take Mebeverine Hydrochloride Tablets if:

- * You are allergic to any of the tablet ingredients (see section 6 for a list of ingredients).

If any of the above applies to you, do not take this medicine and talk to your doctor or pharmacist.

Take special care with Mebeverine Hydrochloride Tablets

Check with your doctor or pharmacist before taking your medicine if:

- * You have developed new symptoms or your symptoms have become worse.
- * You have liver or kidney problems.

If the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

Taking Mebeverine Hydrochloride Tablets with food and drink

You can drink alcohol while you are taking Mebeverine Hydrochloride Tablets.

Taking other medicines

No interactions with other medicines are known.

Pregnancy and breast-feeding

You should talk to your doctor or pharmacist before taking Mebeverine Hydrochloride Tablets if you are pregnant or might become pregnant. There is only limited information about the safety of Mebeverine Hydrochloride for pregnant woman. Your doctor may advise you to stop taking Colofac Tablets before you become pregnant or as soon as you know you are pregnant. Mebeverine Hydrochloride Tablets should not be used during breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Mebeverine Hydrochloride Tablets

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Mebeverine Hydrochloride 135mg Tablets

Patient Information Leaflet (continued)

3 How to take Mebeverine Hydrochloride Tablets

How to take Mebeverine Hydrochloride Tablets

- * Try to take the tablet twenty minutes before a meal - some people find their symptoms to be strongest after they have eaten.
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How to stop taking Mebeverine Hydrochloride Tablets

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5 How to store Mebeverine Hydrochloride Tablets

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- * **Keep out of the sight and reach of children.**
- * Do not take the tablets after their expiry date which is printed on the outside of the pack.
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