

APPROVED

By Nabeela Farooq at 3:19 pm, May 16, 2016

Patient Information Leaflet
Colofac® 135mg tablets
(mebeverine hydrochloride)

Add/Amend: To correct the manufacturer address in the reason box and annotations on the label and leaflet to 'Route de Belleville, Lieu dit Maillard, 01400 Chatillon-sur-Chalaronne, France'. No other changes approved.

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.

In this leaflet:

- 1) What Colofac 135mg tablets are and what they are used for
- 2) Before you take Colofac 135mg tablets
- 3) How to take Colofac 135mg tablets
- 4) Possible side effects
- 5) How to store Colofac 135mg tablets
- 6) Further information

1) WHAT COLOFAC 135MG TABLETS ARE AND WHAT THEY ARE USED FOR

Colofac 135mg 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.

2) BEFORE YOU TAKE COLOFAC 135MG TABLETS

Do not take Colofac 135mg 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 135mg 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 135mg tablets

You can drink alcohol while taking Colofac 135mg 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 135mg tablets if you are pregnant or might become pregnant. There is only limited information about the safety of mebeverine for pregnant women. 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 135mg 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.

3) HOW TO TAKE COLOFAC 135MG TABLETS

How to take Colofac 135mg 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 135mg 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 135mg tablets to children or adolescents younger than 18 years.

If you take more Colofac 135mg tablets than you should

If you or someone else takes too many Colofac 135mg 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 135mg 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 135mg 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 side 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 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, pharmacist or nurse. 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5) HOW TO STORE COLOFAC 135MG TABLETS

- **Keep 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 the tablets after the expiry date which is printed on the carton and blister pack.
- The expiry date refers to the last day of that month.
- If the tablets become discoloured or show any sign of deterioration, return them to your pharmacist.
- 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.

6) FURTHER INFORMATION

What Colofac 135mg tablets contain

Each tablet contains 135mg mebeverine hydrochloride.

The other ingredients are: lactose monohydrate, starch (potato or maize), povidone, talc, magnesium stearate, sucrose, gelatin, acacia and carnauba wax.

What Colofac 135mg tablets look like and contents of the pack

Colofac 135mg tablets are white, round, unmarked, sugar-coated tablets.

Colofac 135mg tablets are available in printed cartons of 100 tablets in blister packs.

Manufactured by Mylan Laboratories SAS, Route de Belleville, Lieu dit Maillard, 01400 Châtillon-sur-Chalaronne, France.

Procured from within the EU by Product Licence Holder:
MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER.

Repackaged by MPT Pharma Ltd.

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Patient Information Leaflet

Mebeverine hydrochloride 135mg tablets

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.

In this leaflet:

- 1) What Mebeverine hydrochloride 135mg tablets are and what they are used for
- 2) Before you take Mebeverine hydrochloride 135mg tablets
- 3) How to take Mebeverine hydrochloride 135mg tablets
- 4) Possible side effects
- 5) How to store Mebeverine hydrochloride 135mg tablets
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1) WHAT MEBEVERINE HYDROCHLORIDE 135MG TABLETS ARE AND WHAT THEY ARE USED FOR

Mebeverine hydrochloride 135mg 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.

2) BEFORE YOU TAKE MEBEVERINE HYDROCHLORIDE 135MG TABLETS

Do not take Mebeverine hydrochloride 135mg 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 135mg 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 135mg tablets with food and drink

You can drink alcohol while you are taking Mebeverine hydrochloride 135mg 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 135mg tablets if you are pregnant or might become pregnant. There is only limited information about the safety of mebeverine for pregnant women. Your doctor may advise you to stop taking Mebeverine hydrochloride 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 135mg 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.

3) HOW TO TAKE MEBEVERINE HYDROCHLORIDE 135MG TABLETS

How to take Mebeverine hydrochloride 135mg 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 Mebeverine hydrochloride 135mg 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 Mebeverine hydrochloride 135mg tablets to children or adolescents younger than 18 years.

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If you or someone else takes too many Mebeverine hydrochloride 135mg 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 Mebeverine hydrochloride 135mg 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 Mebeverine hydrochloride 135mg 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 side 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 face, neck, tongue or throat (severe allergic reactions).

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5) HOW TO STORE MEBEVERINE HYDROCHLORIDE 135MG TABLETS

- **Keep 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 the tablets after the expiry date which is printed on the carton and blister pack.
- The expiry date refers to the last day of that month.
- If the tablets become discoloured or show any sign of deterioration, return them to your pharmacist.
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Mebeverine hydrochloride 135mg tablets are available in printed cartons of 100 tablets in blister packs.

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Procured from within the EU by Product Licence Holder:
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