

COLOFAC 135mg TABLETS (mebeverine hydrochloride)

Your medicine is known by Colofac 135mg Tablets but will be referred to as Colofac Tablets throughout the following 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.

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 ARE 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.

2. BEFORE YOU TAKE COLOFAC TABLETS

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.

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

Like all medicines Colofac Tablets can cause side effects (unwanted effects or reaction) but not everyone gets them.

Allergic reactions such as:

- swelling of your face, lips or tongue
- a red skin rash, itching, inflamed skin.

If you notice any of the above, stop taking this medicine and see your doctor straight away.

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

5. HOW TO STORE COLOFAC TABLETS

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Colofac Tablets should not be stored above 25°C. Store in the original package.
- Do not use after the expiry date printed on the carton label or blister strip.
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. FURTHER INFORMATION

What Colofac Tablets contains

- Each tablet contains 135mg of the active ingredient mebeverine hydrochloride
- Colofac Tablets also contain the following inactive ingredients: lactose, starch, povidone, talc, magnesium stearate, sucrose, gelatin, acacia gum carnauba wax and beeswax.

What Colofac Tablets looks like and contents of the pack

- Colofac Tablets are round white sugar coated tablets.
- Colofac Tablets are available as blister packs of 60 or 100 tablets.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, Middlesex, HA0 1DX.

Manufacturer

This product is manufactured by either of the below manufacturers-

- Abbott Healthcare, S.A, Av Diagonal 507, 08029 Barcelona, Spain
- Solvay Pharma S.A, Av Diagonal 507, 08029 Barcelona, Spain
- Recipharm Parets, S.L. Ramon y Cajal, 2 08150 Parets del Valles, Barcelona, Spain

POM PL No. 19488/0544

Leaflet revision date: 12 July 2012

Colofac is a registered trade mark of Solvay Pharmaceuticals BV, The Netherlands.

S544 LEAFLET Colofac 20120712

PACKAGE LEAFLET: INFORMATION FOR THE USER

MEBEVERINE HYDROCHLORIDE 135mg TABLETS

Your medicine is known by Mebeverine hydrochloride 135mg Tablets but will be referred to as Mebeverine Tablets throughout the following 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.

In this leaflet

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

1. WHAT MEBEVERINE TABLETS ARE AND WHAT THEY ARE USED FOR

Mebeverine 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 TABLETS

Do not take Mebeverine 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 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 Tablets with food and drink

You can drink alcohol while you are taking Mebeverine 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 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 Mebeverine Tablets before you become pregnant or as soon as you know you are pregnant. Mebeverine 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 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 TABLETS

How to take Mebeverine 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 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 Tablets to children or adolescents younger than 18 years.

If you take more Mebeverine Tablets than you should

If you or someone else takes too many Mebeverine 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 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 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

Like all medicines Mebeverine Tablets can cause side effects (unwanted effects or reaction) but not everyone gets them.

Allergic reactions such as:

- swelling of your face, lips or tongue
- a red skin rash, itching, inflamed skin.

If you notice any of the above, stop taking this medicine and see your doctor straight away.

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

5. HOW TO STORE MEBEVERINE TABLETS

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Mebeverine Tablets should not be stored above 25°C. Store in the original package.
- Do not use after the expiry date printed on the carton label or blister strip.
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. FURTHER INFORMATION

What Mebeverine Tablets contains

- Each tablet contains 135mg of the active ingredient mebeverine hydrochloride
- Mebeverine Tablets also contain the following inactive ingredients: lactose, starch, povidone, talc, magnesium stearate, sucrose, gelatin, acacia gum carnauba wax and beeswax.

What Mebeverine Tablets looks like and contents of the pack

- Mebeverine Tablets are round white sugar coated tablets.
- Mebeverine Tablets are available as blister packs of 60 or 100 tablets.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, Middlesex, HA0 1DX.

Manufacturer

This product is manufactured by either of the below manufacturers-

- Abbott Healthcare, S.A, Av Diagonal 507, 08029 Barcelona, Spain
- Solvay Pharma S.A, Av Diagonal 507, 08029 Barcelona, Spain
- Recipharm Parets, S.L. Ramon y Cajal, 2 08150 Parets del Valles, Barcelona, Spain

POM PL No. 19488/0544

Leaflet revision date: 12 July 2012

S544 LEAFLET Mebeverine 20120712