

PACKAGE LEAFLET: INFORMATION FOR THE USER

COLOSPA

200mg Prolonged-release Capsules

MEBEVERINE HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

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1. WHAT COLOSPA IS AND WHAT IT IS USED FOR

Colospa is a capsule containing Mebeverine hydrochloride. This belongs to a group of medicines called antispasmodics.

This medicine is used to treat the symptoms of irritable bowel syndrome (IBS).

This 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 or pharmacist 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 to 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 doctor or 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 COLOSPA

Do not take Colospa if:

- You are allergic to mebeverine hydrochloride or any of the other capsule ingredients

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

Take special care with Colospa

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

Taking Colospa with food and drink

You can drink alcohol while you are taking Colospa.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

You should talk to your doctor or pharmacist before taking Colospa 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 Colospa before you become pregnant or as soon as you know you are pregnant. Colospa 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.

3. HOW TO TAKE COLOSPA

Always take Colospa as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Try to take the capsule 20 minutes before a meal - some people find their symptoms to be strongest after they have eaten.
- Swallow the capsule whole with a drink of water. Do not chew the capsule.

How much Colospa to take

Adults (including the elderly)

- The normal starting dose is one capsule twice a day.

Children

- This medicine is not recommended for use in children.

If you take more Colospa than you should

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

If you forget to take Colospa

If you miss a capsule, take it when you remember. However, if it is nearly time for the next dose, skip the missed dose and carry on as normal with the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Colospa

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

If you have any further questions on the use of this medicine, 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 capsules. 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 suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE COLOSPA

- Keep out of the reach and sight of children.
- Do not use the capsules after the expiry date which is stated on the carton and blister pack. The expiry date refers to the last day of that month.
- Store Colospa in the original package.
- Do not store above 30°C. Do not refrigerate or freeze.
- Return any unused capsules to a pharmacist.
- Medicines should not be disposed of via waste water or household waste. Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet was last revised in July 2015.