

PACKAGE LEAFLET: INFORMATION FOR THE USER

RUDAKOL

135mg Film-coated tablets

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 •

What is in this leaflet?

1. What RUDAKOL is and what it is used for
2. Before you take RUDAKOL
3. How to take RUDAKOL
4. Possible side effects
5. How to store RUDAKOL

1. WHAT RUDAKOL IS AND WHAT IS IT USED FOR

RUDAKOL 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 RUDAKOL

Do not take RUDAKOL Tablets if:

- You are allergic to any of the tablet 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 RUDAKOL 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 RUDAKOL Tablets with food and drink

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

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

If you take more RUDAKOL Tablets than you should

If you or someone else takes too many RUDAKOL 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 RUDAKOL 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 RUDAKOL 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.

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

5. HOW TO STORE RUDAKOL

- **Keep out of the reach and sight of children.**
- You should lock this medicine in a cupboard or medicine cabinet.
- 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.
- Do not store your tablets above 30°C.
- Keep them in their original container.

If your doctor stops your treatment, return unused tablets to a 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.