

Ralicrom™

Sodium cromoglicate

100 mg capsules

What is in this leaflet

Please read this leaflet carefully before you start taking Ralicrom.

This leaflet answers some common questions about Ralicrom. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ralicrom against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Ralicrom is used for

Ralicrom 100 mg capsules contain a medicine called sodium cromoglicate. It belongs to a group of medicines called anti-allergics. It works by preventing the release of the natural substances in your body that can cause an allergic reaction. It also lowers your response when you are exposed to substances to which you are allergic.

Ralicrom is used to treat allergic reactions to certain foods and to treat chronic inflammatory conditions such as proctitis, ulcerative colitis or proctocolitis (an inflammatory disease of the large bowel (colon) and/or back passage (rectum)).

Ask your doctor if you have any questions about why Ralicrom has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take Ralicrom

When you must not take it

Do not take Ralicrom if you have an allergy to:

- any medicine containing sodium cromoglicate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

Do not take this medicine if you are pregnant.

Check with your doctor first if you are pregnant or intend to become pregnant before taking Ralicrom.

Do not breastfeed if you are taking this medicine.

Talk to your doctor first if you are breastfeeding or intend to breastfeed before taking Ralicrom.

Do not give this medicine to a child under the age of 2 years of age.

Safety and effectiveness in children younger than 2 years have not been established.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Ralicrom, talk to your doctor.

Before you start to take it

Tell your doctor if:

- **you have allergies to:**
Any other medicines including sodium cromoglycate or any other substances, such as foods, preservatives or dyes.

- **you are pregnant or intend to become pregnant.** Your doctor can discuss with you the risks and benefits involved.
- **you are breastfeeding planning to breastfeed.** Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Ralicrom.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Ralicrom.

How to take Ralicrom

How much to take

Adults

Two capsules, four times a day. When your symptoms improve, your doctor may lower your dose.

Children (aged between 2 and 14 years)

One capsule, four times a day. When your child's symptoms improve, your doctor may lower the dose.

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How to take it

The best way to take Ralicrom is to open the capsule(s) and put the powder in a cup, add a small quantity of very hot water e.g., 1 teaspoonful and dilute it with cold water to drink.

Alternatively, you can take the capsules by swallowing them whole with a drink of water.

When to take it

Take Ralicrom before a meal.

Take Ralicrom at about the same time each day. Taking your capsules at the same time each day will have the best effect. It will also help you remember when to take the capsules.

How long to take it

Continue taking your medicine for as long as your doctor tells you. Do not stop taking Ralicrom capsules just because you feel better.

If you forget to take it

If you forget a dose, take it as soon as you remember it. 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. This may increase the chance of unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking Ralicrom

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Ralicrom.

Things you must not do

Do not give Ralicrom to anyone else, even if they have the same condition as you.

Things to be careful of

If you have life-threatening reactions to food, DO NOT RELY ON Ralicrom, as it does not protect you from these serious conditions.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital if you think that you or anyone else may have taken too much Ralicrom.

Do this even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ralicrom.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin rashes
- pain in your joints
- feeling sick (nausea)

If any of the following happen, stop taking Ralicrom and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

Swelling of the face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, hives, fainting. These are very serious side effects. If you have them, you may have had a serious allergic reaction to Ralicrom. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

After taking Ralicrom

Storage

Keep your capsules in the bottle until it is time to take them. Reclose the container tightly after use. If you take the capsules out of the pack, they may not keep well.

Keep your capsules in a cool dry place where the temperature stays at or below 30°C.

Do not store Ralicrom in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

The capsule is a clear/clear hard gelatin, overprinted with SODIUM CROMOGLICATE 100 mg in black and containing a white powder.

Ingredients

Active ingredient(s): Sodium cromoglicate

Inactive ingredients: Gelatin capsule, black ink

Sponsor details

Ralicrom is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

Date of preparation

26 January 2022

(Based on Data Sheet dated 26 January 2022)