

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sodium cromoglicate 100 mg/5 ml oral solution

Sodium cromoglicate

Read all of this leaflet carefully before you start using 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 sign 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. See section 4.

What is in this leaflet:

1. What sodium cromoglicate oral solution is and what it is used for
2. What you need to know before you use sodium cromoglicate oral solution
3. How to use sodium cromoglicate oral solution
4. Possible side effects
5. How to store sodium cromoglicate oral solution
6. Contents of the pack and other information

1. What sodium cromoglicate oral solution is and what it is used for

Sodium cromoglicate oral solution contains the active substance sodium cromoglicate, which belongs to a group of medicines called anti-inflammatory drug, antiallergic agents, excluding corticosteroids.

Eating certain foods may cause allergic reactions. Substances which can cause an inflammatory reaction in your stomach or intestine are released during this allergic reaction from mast cells. The release of these substances can lead to symptoms such as nausea, abdominal pain, diarrhoea, tightness, nose allergy, skin rashes, gall bumps or eczema.

Sodium cromoglicate is an agent that inhibits the release of these substances.

Sodium cromoglicate is prescribed by your doctor to prevent allergic symptoms caused by food ingredients that cannot always be avoided.

2. What you need to know before you use sodium cromoglicate oral solution

Do not use sodium cromoglicate oral solution

If you are allergic to sodium cromoglicate or any of the other ingredients of this medicine. (listed in section 6)

Warnings and Precautions

Talk to your doctor or pharmacist before using sodium cromoglicate oral solution.

Do not use sodium cromoglicate if you have a medical history of a sudden severe allergic reaction (anaphylactic shock) or other life-threatening reactions to food.

Children and adolescents

Do not use sodium cromoglicate oral solution in children under 2 years. It is not known whether sodium cromoglicate is harmful in children under 2 years.

Other medicines and sodium cromoglicate oral solution

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This also applies to medicines that you can get without a prescription.

Sodium cromoglicate oral solution with food, drink and alcohol

Take sodium cromoglicate oral solution 15 minutes before meals (see section 3 'How to use sodium cromoglicate').

Pregnancy, breast feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Use only during pregnancy after consultation with your doctor.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. An effect is unlikely.

3. How to use sodium cromoglicate oral solution

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take sodium cromoglicate oral solution 15 minutes before the meal. If you need to use sodium cromoglicate oral solution 4 x a day, then this means that you should take 3 x sodium cromoglicate oral solution before meals (3 meals a day) and 1 x before bedtime.

The recommended dose is

Adults:

Drink 4 times a day the content of 2 ampoules of 5 ml before the meal.

Use in Children:

Drink 4 times a day the content of 1 ampoule of 5 ml before the meal.

If the treatment does not produce enough results within 2-3 weeks, then your doctor may increase the dose. If the treatment results in adequate results, then your doctor will try to reduce the dose. The optimal dosage will be determined individually for each individual.

Nutrients, for which you are allergic, may occasionally cause an allergic reaction in the mouth. If this is the case, then you should rinse your mouth with the solution before swallowing it.

If you take more sodium cromoglicate oral solution than you should

In general, there are no adverse effects to be expected when too much sodium cromoglicate oral solution is taken.

If you forget to take sodium cromoglicate oral solution

Do not take a double dose to make up for a forgotten dose.

If you stop taking sodium cromoglicate oral solution

If you stop taking sodium cromoglicate oral solution, then the symptoms may return for which you received sodium cromoglicate oral solution.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In some cases, nausea, vomiting, abdominal pain, rash and joint pain have been reported. Very rarely, an allergic reaction has been reported.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via Yellow Card Scheme at Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store sodium cromoglicate oral solution

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other Information**What sodium cromoglicate oral solution contains**

- The active substance is sodium cromoglicate. Each ml of oral solution contains 20 mg sodium cromoglicate.
- The other ingredient is water for injections.

What sodium cromoglicate oral solution looks like and the contents of the pack

Sodium cromoglicate oral solution is clear colorless solution. Free from any visible particles.

Sodium cromoglicate oral solution is available in 5 ml ampoule of LDPE Blow fill seal (BFS) container with twist off cap.

Pack sizes: 8 ampoules, 96 ampoules
Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands: Natriumcromoglicaat BB 100mg, drank

United Kingdom: Sodium cromoglicate 100 mg/5 ml oral solution

This leaflet was last revised in 05/2018