

PACKAGE LEAFLET

Package leaflet: Information for the user **Lecrolyn sine 40 mg/ml eye drops, solution** Sodium cromoglicate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if your symptoms do not get better, or if they get worse after two days.

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 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. See section 4.

What is in this leaflet:

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

1. What Lecrolyn sine is and what it is used for

Lecrolyn sine contains the active substance called sodium cromoglicate. This belongs to a group of medicines called anti-allergics.

Lecrolyn sine is used to treat eye symptoms due to allergy. It works by stopping the release of the natural substances like histamine in your eyes that can lead to an allergic reaction. Signs of an allergic reaction include itchy, watery, red or inflamed eyes and puffy eyelids. Usually both eyes are affected. These symptoms occur usually in spring or summer when pollen from grasses or trees comes into contact with the eyes of people who are sensitive to them.

You must talk to a doctor if your symptoms do not get better, or if they get worse after two days.

2. What you need to know before you use Lecrolyn sine

Do not use Lecrolyn sine

if you are allergic to sodium cromoglicate, or any of the other ingredients of Lecrolyn sine (listed in section 6).

Warnings and precautions

Talk to your doctor before using Lecrolyn sine if you only have symptoms in one eye, as allergic reactions normally involve both eyes.

Other medicines and Lecrolyn sine

During concomitant use of other eye drops, there should be at least 15 minutes between the use of different drops.

Pregnancy and breast-feeding

No adverse effects on the fetus have been demonstrated. Lecrolyn sine can be used during pregnancy and breast feeding.

Driving and using machines

As other eye drops, Lecrolyn sine may cause short-term blurring of vision. If this happens to you, do not drive or use machines until your vision is fully restored.

Contact lenses

Lecrolyn sine does not contain any preservative. It can therefore be used together with contact lenses.

3. How to use Lecrolyn sine

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

The recommended dose for children and adults is **1–2 drops in each eye two times a day**.

If the intensity of symptoms necessitates more frequent dosing, then the frequency of dose administration should not exceed 4 times daily.

Before instillation of the eye drops:

- wash your hands before opening the bottle
- when opening the bottle for the very first time, drop one drop to waste
- choose the position that you find most comfortable for the instillation of the drops (you can sit down, lie on your back, or stand in front of a mirror)

Instillation:

1. Hold the bottle directly below the cap and turn the cap to open the bottle. Do not touch anything with the tip of the bottle to avoid contamination of the solution.



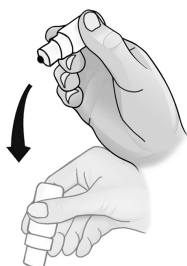
2. Tilt your head backwards and hold the bottle above your eye.



3. Pull the lower eyelid down and look up. Squeeze the bottle gently and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.



4. Blink a few times so that the drop spreads over the eye.
5. Follow the instructions 2. – 4. for dropping Lecrolyn sine also into the other eye.



6. Before recapping the bottle, shake it once downwards in order to get rid of any remaining solution from the tip of the bottle. This is necessary to ensure the usability of the bottle.

If your eyes do not get better, or if they get worse after two days of using Lecrolyn sine, see your doctor or pharmacist.

It is best to use your eye drops regularly every day while high pollen levels are expected, to keep your eye condition controlled.

[To be completed nationally, in CZ only: Do not use this product for more than 6 weeks without medical advice.]

If you use more Lecrolyn sine than you should

There are no known reactions of overdosing Lecrolyn sine.

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.

Allergic reactions (hypersensitivity) have been reported. However, it is not known how often this occurs.

If you get symptoms like rash, swallowing or breathing problems, swelling of your lips, face, throat, tongue and worsening of redness, you must immediately contact your doctor.

A common side effect (may affect up to 1 in 10 people) is local burning during application.

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 the national reporting system *{will be completed according to Annex 5}*.

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

5. How to store Lecrolyn sine

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

Store below 25°C. Do not freeze.

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

After first opening the bottle, the solution can be used for **8 weeks**. The bottle must be kept tightly closed.

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 Lecrolyn sine contains

- The active substance is sodium cromoglicate. 1 ml solution contains 40 mg sodium cromoglicate.
- The other ingredients are glycerol, disodium edetate, polyvinylalcohol, water for injections.

What Lecrolyn sine looks like and contents of the pack

Lecrolyn sine is a clear, colourless or slightly yellowish solution provided in a white plastic bottle with a white dropper applicator with a blue tip and a white plastic screw cap.

Pack sizes: 1 x 5 ml, 2 x 5 ml, 3 x 5 ml and 1 x 10 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in 2021-04-02