

Scheduling Status:**S1****LECROLYN 20 mg/mL eye drops, solution****LECROLYN 40 mg/mL eye drops, solution****LECROLYN 20 mg/mL SDU eye drops, solution****LECROLYN 40 mg/mL SDU eye drops, solution****Sodium cromoglicate**

Read all of this leaflet carefully because it contains important information for you.

LECROLYN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use LECROLYN carefully to get the best results from it. Keep this leaflet. You may need to read it again.

- Do not share LECROLYN with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet:

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

1. What LECROLYN is and what it is used for:

LECROLYN contains the active substance sodium cromoglicate.

This belongs to a group of medicines called anti-allergics. It works by stopping the release of the natural substances in your eyes that can lead to an allergic reaction of the eyes.

LECROLYN is used for the treatment of allergic conjunctivitis (an eye allergy where you experience red, sore, itchy and watery eyes).

2. What you need to know before you use LECROLYN:

Do not use LECROLYN:

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

Warnings and precautions

Take special care with LECROLYN:

- If you wear soft contact lenses (multi-dose container), you should remove them before using LECROLYN eye drops (the multi-dose container). After using LECROLYN eye drops, you should wait 15 minutes before putting your contact lenses back in.
- If you have dry eyes, problems with your cornea or with long-term use if you have any eye disease (multi-dose container).
- If you need to use LECROLYN for an extended period of time.
- If you are using LECROLYN with steroid treatment (used to treat mild to moderate non-infectious eye allergies and inflammation).

LECROLYN can be used prophylactically. Consult your health care provider before you stop using LECROLYN.

The LECROLYN eye drops (multidose units) should be discarded 1 month after first opening of the bottle, or if the solution stops looking clear.

Once opened, use LECROLYN SDU (the single-dose units) eye drops immediately. After use, throw away the pipettes and any medicine left in it – do not use again.

Children

If irritation of the eyes occurs, this may have an effect on the way children use the treatment.

Other medicines and LECROLYN

Always tell your health care provider if you are taking or using any other medicine. (This includes complementary or traditional medicines.)

There are no known interactions with other medicines.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using LECROLYN.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

LECROLYN may cause side effects such as stinging or blurring of vision when first used. If you experience blurred vision, wait until your vision clears before driving or using machinery.

It is not always possible to predict to what extent LECROLYN may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which LECROLYN affects you.

LECROLYN 20 mg/mL eye drops contains benzalkonium chloride

LECROLYN contains 0,00014 mg benzalkonium chloride in each drop (0,0035 mL) which is equivalent to 0,04 mg/mL.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using LECROLYN and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using LECROLYN, talk to your doctor.

LECROLYN 40 mg/mL eye drops contains benzalkonium chloride

LECROLYN contains 0,00024 mg benzalkonium chloride in each drop (0,0030 mL) which is equivalent to 0,08 mg/mL.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using LECROLYN and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using LECROLYN, talk to your doctor.

3. How to use LECROLYN:

Do not share any medicines prescribed for you with any other person.

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

The usual dose for adults and children over 4 years is: 1 – 2 drops into each eye 4 times daily.

You should use the eye drops regularly, as treatment with LECROLYN is essentially prophylactic (used to prevent eye allergies).

Apply your eye drops in the following way:

1. Before using your LECROLYN you should wash your hands.

2. You may find it helps to sit in front of a mirror, so that you can see what you are doing. Tilt your head backwards, gently pull down your lower eyelid and carefully place one or two LECROLYN in the space between the eyelid and the eye. Take care not to touch the dropper with your eye or fingers.
3. Release the eyelid and blink a few times to make sure the liquid covers the whole surface of the eye.
4. Repeat the procedure with the other eye and then replace the cap on the bottle.

If you are also on treatment with other eye drops, you should use and apply eye drops 15 minutes apart.

If you use more LECROLYN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use LECROLYN

Do not use a double dose to make up for a forgotten dose. Use the next dose as usual, when it is time to use it.

4. Possible side effects:

LECROLYN can have side effects.

Not all side effects reported for LECROLYN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LECROLYN, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using LECROLYN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LECROLYN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Local irritation.

Side effects with an unknown frequency:

- Transient burning or stinging and blurring may occur after instillation.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LECROLYN.

5. How to store LECROLYN:

LECROLYN eye drops and LECROLYN SDU eye drops

- Store at or below 25 °C, do not freeze.
- Protect from light.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

After first opening

LECROLYN eye drops: Throw the bottle away 1 month after first opening it or if the solution stops looking clear.

LECROLYN SDU eye drops: After opening the foil sachet, throw away any remaining contents after one month. Once the single dose units (pipettes) are opened, use the single-dose unit immediately and discard of the units and any remaining contents.

6. Contents of the pack and other information:

What LECROLYN contains

The active ingredient is sodium cromoglicate.

LECROLYN 20 mg/mL eye drops contains 20 mg sodium cromoglicate per 1,0 mL.

LECROLYN 40 mg/mL eye drops contains 40 mg sodium cromoglicate per 1,0 mL.

LECROLYN 20 mg/mL SDU contains 20 mg sodium cromoglicate per 1,0 mL.

LECROLYN 40 mg/mL SDU contains 40 mg sodium cromoglicate per 1,0 mL.

The other ingredients are:

LECROLYN eye drops

Boric acid, Disodium edetate, Water for injection.

LECROLYN SDU eye drops

Sodium chloride, Water for injection.

What LECROLYN looks like and contents of the pack

Colourless or slightly yellowish clear solution.

LECROLYN eye drops

The multi dose container is a 10 mL transparent, soft low density polyethylene (LDPE) eye drop bottle with a pigmented (white) hard high density polyethylene (HDPE) cap.

Pack size: 1 multi dose container.

LECROLYN SDU eye drops

The unit dose container is low density polyethylene (LDPE) resin pipettes packed into a carton.

Pack sizes:

LECROLYN 20 mg/mL: 40 pipettes of 0,25 mL, 100 pipettes of 0,25 mL. 4 or 10 blister strips in foils are packed into a carton.

LECROLYN 40 mg/mL: 60 pipettes of 0,25 mL. 6 blister strips in foils are packed into a carton.

Not all pack sizes may be marketed.

Holder of certificate of registration

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