

Package leaflet: Information for the user

Diclofenac Liderlens 40 mg/ml cutaneous spray, solution diclofenac sodium

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 have 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 you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

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

1. What Diclofenac Liderlens is and what it is used for

Diclofenac Liderlens contains the active substance diclofenac sodium, which belongs to the group of nonsteroidal anti-inflammatory drugs (NSAID) and should be applied on the skin of the affected surface area.

This medicinal product is used in adults and adolescents over 14 years for the short-term local symptomatic treatment of mild to moderate pain and inflammation following acute blunt trauma of small and medium-sized joints and surrounding structures.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you use Diclofenac Liderlens

Do not use Diclofenac Liderlens

- If you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to peanut or soya, as it contains soya lecithin
- If you have ever had an allergic reaction with difficulty in breathing (asthma), skin rash, runny nose, or swelling of the face or tongue to any medicine used in pain relief, fever or inflammation such as ibuprofen or acetylsalicylic acid (also used as a blood thinner).
- On open injuries, inflamed or infected skin as well as on eczema, or mucous membranes.
- In the last three months of pregnancy – please see section Pregnancy and breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Diclofenac Liderlens.

- If you have previously suffered from bronchial asthma or allergies.
- If you accidentally get some spray into your eyes rinse thoroughly with clear water and inform your doctor.
- Never swallow Diclofenac Liderlens.
- Discontinue use of Diclofenac Liderlens if any skin rash develops after application.
- Do not cover the treated area with occlusive (waterproof or non-breathable) bandages or plasters.
- Do not expose the treated areas to the sun or use sunlamps.

The possibility of systemic side effects from use of Diclofenac Liderlens cannot be excluded if the medicine is used on large areas of skin and over a prolonged period. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Danger: Flammable. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

Children and adolescents

Do not use this medicinal product in children and adolescents under 14 years.

Other medicines and Diclofenac Liderlens

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Talk to your doctor before you use Diclofenac Liderlens:

- If you are taking any medicinal products containing diclofenac, acetylsalicylic acid or any other NSAID, as for example ibuprofen.

The use of other NSAID (including acetylsalicylic acid or ibuprofen) at the same time as Diclofenac Liderlens may increase the risk of side effects.

Pregnancy and breastfeeding

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

Pregnancy

Diclofenac Liderlens must not be used during the last 3 months of pregnancy, as it could increase the risk of complications for the mother and new-born.

Diclofenac Liderlens should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Oral forms (e.g. tablets) of Diclofenac Liderlens can cause adverse effects in your unborn baby. It is not known if the same risk applies to Diclofenac Liderlens when it is used on the skin.

Breastfeeding

Do not use Diclofenac Liderlens during breastfeeding, unless otherwise indicated by your doctor. However, Diclofenac Liderlens should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period.

Driving and using machines

Cutaneous application of Diclofenac Liderlens does not affect the ability to drive and use machines.

Diclofenac Liderlens contains propylene glycol (E1520), ethanol and soybean lecithin:

This medicine contains 30 mg propylene glycol (E1520) in each pump stroke.

This medicine contains 6.65 mg alcohol (ethanol) in each pump stroke.

This medicine contains soya oil. If you are allergic to peanut or soya, do not use this medicine.

3. How to use Diclofenac Liderlens

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

The recommended dose is:

Adults and adolescents over 14 years:

Apply 4-5 pump strokes 3 times a day at regular intervals. The number of strokes depends on the size of the affected area. The maximum dose must not exceed 5 pump strokes each time. The maximum daily dose is 15 pump strokes.

Treatment can be stopped when the symptoms (pain and swelling) have receded.

Do not continue treatment for more than 7 days without seeking medical advice.

Tell your doctor if symptoms worsen or persist after 3 days of treatment.

Use in children and adolescents:

Do not use in children or adolescents under 14 years.

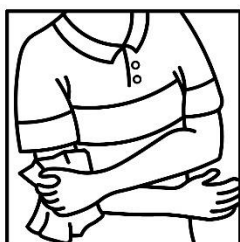
Method of use:

Diclofenac Liderlens is for cutaneous use only.

Follow the instructions carefully:

- Remove the transparent protective cap from the pump.
- Before the first use, the pump must be pressed four times to activate it, discarding the contents. Failure to prime the pump can lead to application of a lower dose when used for the first time.
- Wash and dry the painful area. The spray is applied to the affected parts of the body and gently rubbed into the skin. Afterwards, the hands should be wiped with a paper towel and then washed, unless the hands are the area to be treated.
- If too much spray is accidentally applied, the excess spray should be wiped with a paper towel.
- The paper towel should be disposed in the household waste to prevent unused product reaching the aquatic environment.

Before applying a bandage, the spray should be left to dry for a few minutes on the skin.



Wash and dry the painful area



Apply on the area to be treated



Gently massage to promote absorption.

If you use more Diclofenac Liderlens than you should

If you apply more of your medicine than you should wipe the surplus off with a tissue.

If you swallow some of the spray inform your doctor immediately or go to the nearest hospital casualty.

Take the bottle and the leaflet with you.

If you forget to use Diclofenac Liderlens

If you forget to apply this medicinal product when necessary, apply the solution as soon as possible and continue treatment as before. Do not use a double dose to make up for a forgotten dose.

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 medicinal product can cause side effects, although not everybody gets them.

Discontinue use of Diclofenac Liderlens if any skin rash develops. Reactions at the site of application have been reported commonly after topical use (applied to the skin) of diclofenac preparations. These include rashes, itching, reddening, burning sensations or scaling of the skin.

Some rare and very rare adverse effects can be serious:

If you experience any of the following signs of allergy, **stop using Diclofenac Liderlens and seek medical advice immediately.**

- Rare (may affect up to 1 in 1,000 people): Skin rash with blisters.
- Very rare (may affect up to 1 in 10,000 people): Wheezing, shortness of breath or feeling of tightness in the chest (asthma). Hypersensitivity reactions, including urticaria or hives (red welts, raised and often with itching and burning). Swelling of the face, lips, tongue or throat. Other side effects may occur, however, these are often mild and temporary. If you notice any of them, tell your doctor or pharmacist as soon as possible.
- Common (may affect up to 1 in 10 people): Skin rash, itching, reddening or stinging of the skin after using the medicinal product.
- Uncommon (may affect up to 1 in 100 people): Dandruff, drying out of the skin, edema

- Very rare (may affect up to 1 in 10,000 people): The skin may be more sensitive to the sun (photosensitivity). Possible signs are sunburn with itching, swelling and blistering. Pustular rash. Gastrointestinal complaints.
- Systemic side effects such as stomach pain and disorders, heartburn, liver or kidney problems and hypersensitivity reactions may occur if the medicine is used for a prolonged period and/or it is used on large areas of the 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. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Diclofenac Liderlens

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

Store in the original package in order to protect from light.

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.

Do not use this medicine after 6 months of first opening.

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. Content of the pack and other information

What Diclofenac Liderlens contains:

- The active substance is diclofenac sodium. Each ml of cutaneous spray, solution (equivalent to 5 pump strokes) contains 40 mg of diclofenac sodium. Each pump stroke (0.2 ml of solution) contains 8 mg of diclofenac sodium.
- The other ingredients are: propylene glycol (E1520), isopropyl alcohol, phospholipon 90G (contains phosphatidylcholine derived from soybean lecithin and lysophosphatidylcholine, non-polar lipids and tocopherol), ethanol 96%, disodium phosphate, sodium dihydrogen phosphate dihydrate, disodium edetate, ascorbyl palmitate, peppermint oil, hydrochloric acid, dilute, sodium hydroxide 10% and purified water.

What Diclofenac Liderlens looks like and contents of the pack:

Diclofenac Liderlens is a yellowish solution.

30 ml amber glass bottle with 25 g cutaneous spray solution containing 125 pump strokes equipped with a polypropylene pump and polyethylene immersion tube.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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