Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diclofenac Liderlens 40 mg/ml cutaneous spray solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml (5 pump strokes) of solution contains 40 mg of diclofenac sodium.
Each pump stroke (0.2 ml of solution) contains 8 mg of diclofenac sodium.

Excipients with known effect:
Each ml of solution contains:
Propylene glycol (E1520) ..... 150 mg
Soybean lecithin ..... 97.98 mg
Ethanol 96% ..... 33.26 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution.
A yellowish solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Diclofenac Liderlens is indicated in adults and adolescents aged 14 years and over. 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 periarticular structures.

4.2 Posology and method of administration

Posology
Adults and adolescents aged 14 years and over
Sufficient solution of Diclofenac Liderlens should be sprayed onto the skin on the affected site. Depending on the size of area to be treated, 4–5 pump strokes (32 – 40 mg of diclofenac sodium) should be applied 3 times a day at regular intervals. The maximum single dose of 1.0 ml (equivalent to 5 pump strokes) of the product should not be exceeded. The maximum daily dose is 15 pump strokes (3.0 ml of spray containing 120 mg of diclofenac sodium).
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.
The medicinal product is intended only for the short-term treatment.
The treatment may be discontinued when the symptoms (pain and swelling) have subsided. Treatment should not be continued beyond 7 days without medical review. The patient is advised to consult their doctor if the symptoms worsen or if no improvement is seen after 3 days.

Paediatric population
There are insufficient data on the efficacy and safety of this medicinal product in children and adolescents aged under 14 years.

Elderly
No special dose adjustment is required.
Due to the profile of possible adverse effects, elderly patients should receive particularly careful monitoring.

Patients with hepatic or renal insufficiency
No special dose adjustments are required.

Method of administration
For cutaneous use only.
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.
Before the first use, the pump must be pressed four times to be activated, discarding the contents. Failure to prime the pump can lead to application of a lower dose when used for the first time.

4.3 Contraindications

- Hypersensitivity to the active substance to any of the excipients listed in section 6.1.
- Diclofenac Liderlens contains soya lecithin. Patients with hypersensitivity to peanut or soya, must not use this medicinal product.
- Patients with a history of hypersensitivity reactions (e.g., bronchospasm, asthma, rhinitis, urticaria or angioedema) associated with the use of acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Open injuries, inflammation or infections of the skin, as well as on eczema or mucous membranes.
- During the third trimester of pregnancy (see section 4.6).

4.4 Special warnings and precautions for use

- The medicinal product should not be used on extensive areas. It should not be allowed to come into contact with the eyes and should not be ingested.
- Patients should be warned against exposure to sunlight or solarium radiaton in order to reduce the incidence of photosensitivity.
- This medicinal product can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.
- The concomitant use of this medicinal product with oral NSAIDs should be cautioned as the incidence of systemic undesirable effects may increase (see section 4.5).
- Discontinue the treatment if a skin rash develops after applying the product.

The possibility of systemic undesirable effects cannot be excluded if this medicinal product is used on large area of skin and over a prolonged period (see the product information on systemic forms of diclofenac).

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Bronchospasm may be precipitated in patients suffering from or with previous history of bronchial asthma or allergenic disease.

Danger: Flammable. Instruct patients to keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

This medicinal product 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.

Patients with hypersensitivity to peanut or soya must not use this medicinal product (see section 4.3).

4.5 Interaction with other medicinal products and other forms of interaction

As systemic absorption of diclofenac from topical application is very low, such interactions are very unlikely.

Concurrent use of acetylsalicylic acid or other NSAIDs may result in an increased incidence of adverse reactions (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy
There are insufficient data on the use of topical diclofenac during pregnancy.

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. Further to experience with NSAID treatments and systemic absorption, the following is recommended:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5%. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

This medicinal product should not be given during the first and second trimester of pregnancy, unless clearly necessary. If it is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

At the end of pregnancy, prostaglandin synthesis inhibitor exposes mother and neonate to the following risks:

- possible prolonged bleeding, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Therefore, diclofenac is contraindicated during the third trimester of pregnancy (see section 4.3).

Breastfeeding
Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of this medicinal product no effects on the nursing infant are anticipated. Because of a lack of controlled studies in breastfeeding women, the product should only be used during breastfeeding under advice from a healthcare professional. Under this circumstance, this medicinal product should not be applied on the breasts of nursing mothers, nor to elsewhere on large areas of skin for a prolonged period (see section 4.4).

4.7 Effects on ability to drive and use machines

Diclofenac Liderlens cutaneous spray, solution has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Skin disorders are commonly reported.

Adverse reactions (See table below) are ranked according to their frequency: *very common* (≥ 1/10); *common* (≥ 1/100 to < 1/10); *uncommon* (≥ 1/1,000 to < 1/100); *rare* (≥ 1/10,000 to < 1/1,000); *very rare* (< 1/10,000), or *not known* (cannot to be estimated from available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Infections and infestations	
Very rare	Pustular rash
Immune system disorders	
Very rare	Hypersensitivity (including urticaria), angioneurotic oedema
Respiratory, thoracic and mediastinal disorders	

Very rare	Asthma
Gastrointestinal disorders	
Very rare	Gastroinstestinal complaints
Skin and subcutaneous tissue disorders	
Common	Rash, eczema, erythema, dermatitis (including contact dermatitis), pruritus*****
Uncommon	Dandruff, drying out of the skin, edema
Rare	Bullous dermatitis
Very rare	Photosensitivity reaction

* Pruritus has been reported at a frequency of 0.9% in a clinical trial, 236 patients with sprained ankles were treated with 4–5 pump strokes of a similar formulation of topical diclofenac three times a day (120 patients) or placebo (116 patients) for 14 days.

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. The unit dose of product should not exceed 1.0 g (equivalent to 5 pump strokes) of solution.

During long term treatment and/or when treating large areas there is a possibility of systemic adverse reactions. Reactions for example abdominal pain, dyspepsia, gastric and renal disorders may occur.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

The low systemic absorption of topical diclofenac renders overdose highly unlikely.

If the recommended dosage is significantly exceeded when applied to the skin, the solution should be removed again and washed off with water.

Accidental ingestion of Diclofenac Liderlens (1 bottle of 30 ml corresponds to an equivalent of 1200 mg of diclofenac sodium) may cause undesirable effects similar to those of an overdose of systemic diclofenac.

In the event of accidental ingestion resulting in significant systemic adverse effects, general therapeutic measures normally adopted to treat poisoning with non-steroidal anti-inflammatory medicines should be used. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion.

There is no specific antidote to manage diclofenac overdose.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical products for joint and muscular pain; Anti-inflammatory preparations, non-steroids for topical use, ATC code: M02AA15

Diclofenac is a non-steroidal anti-inflammatory/analgesic active substance which, via inhibition of prostaglandin synthesis, has been shown to be effective in standard animal models of inflammation. In humans, diclofenac reduces inflammation-related pain and swelling.

5.2 Pharmacokinetic properties

After cutaneous application of the solution containing 60 mg diclofenac sodium a rapid onset of diclofenac absorption can be observed leading to measurable plasma levels of about 1 ng/ml as early as 30 minutes and to maximum levels of about 3 ng/ml at about 24 hours after application.

Systemic concentrations achieved by diclofenac are approximately 50 times lower than those achieved following oral administration of equivalent amounts of diclofenac. Systemic plasma levels are not supposed to contribute to the efficacy of this medicinal product.

Diclofenac is extensively bound to plasma proteins (about 99 %).

Pharmacokinetics in special patient populations
Accumulation of diclofenac or its metabolites is not expected in patients with kidney failure.

5.3 Preclinical safety data

In rabbit skin tests, diclofenac cutaneous spray is classified as non-irritating.

Based on the conventional studies on safety pharmacology, genotoxicity and carcinogenic potential of diclofenac, the preclinical data do not indicate any particular hazards for humans beyond those already described in other sections of this SmPC. In animal studies, chronic toxicity after systemic administration of diclofenac was mainly shown in the form of gastrointestinal lesions and ulcers. In a 2-year toxicity study, a dose-dependent increase in heart thrombotic vascular occlusions was observed in rats treated with diclofenac.

In rats and rabbits, oral doses of diclofenac were not teratogenic, but embryotoxic at doses in the maternal-toxic range.

Diclofenac showed no effect on fertility in rats, but had an anti-ovulation effect on rabbits and reduced implantation in rats.

In rats, diclofenac led to dose-dependent narrowing of the fetal ductus arteriosus, disturbances of the course of birth (dystocia) and prolongation of the birth process (see section 4.3). Doses below the maternal-toxic limit had no effect on the postnatal development of the offspring.

Diclofenac poses a risk to the aquatic environment (see section 6.6).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol
Phospholipon 90G (containing phosphatidylcholine (derived from soybean lecithin), lysophosphatidylcholine, non-polar lipids and tocopherol)
96% Ethanol
Disodium phosphate
Sodium dihydrogen phosphate dihydrate
Disodium edetate
Propylene glycol (E1520)
Ascorbyl palmitate
Peppermint oil
Hydrochloric acid, dilute for pH adjustment
Sodium hydroxide 10% (w/w) for pH adjustment
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
After first opening: 6 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

30 ml type III amber glass bottle containing 25 g of cutaneous spray, solution, which are equivalent to 125 pump strokes in total respectively (each pump stroke delivers 0.2 ml of solution) equipped with a polypropylene pump and polyethylene imersion tube.

6.6 Special precautions for disposal and other handling

This medicinal product poses a risk to the environment (see section 5.3).

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Farmalider S.A.
Calle De La Granja 1 Planta 3
Alcobendas
Madrid
28108
Spain

8 MARKETING AUTHORISATION NUMBER

PA2090/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd December 2022

10 DATE OF REVISION OF THE TEXT

June 2025