

**PACKAGE LEAFLET**  
**for medical use of a medicinal product**

**Darfen<sup>®</sup> gel**

***Qualitative and quantitative composition:***

*active substance:* ibuprofen, levomenthol;

1 g of gel contains: 50 mg of ibuprofen, 30 mg of levomenthol;

*list of excipients:* ethanol 96%, propylene glycol, carbomer, diisopropanolamine, purified water.

**Pharmaceutical form.** Gel.

*Main physical and chemical properties:* transparent homogeneous gel with menthol scent.

**Pharmacotherapeutic group.**

Topical products for joint and muscular pain.

ATC code M02A X10.

***Pharmacological properties.***

*Pharmacodynamic properties.*

Darfen<sup>®</sup> gel – is a combined medicinal product for external use, containing ibuprofen with menthol of natural origin. Ibuprofen, a propionic acid derivative, is a member of the group of non-steroidal anti-inflammatory drugs (NSAIDs), has analgesic, anti-inflammatory effects due to inhibition of prostaglandin synthetase. The effect of levomenthol, the optical isomer of menthol, is due to reflex reactions associated with irritation of sensitive nerve endings in the skin. Menthol stimulates skin nociceptors. As a result, peptides are released and have a vasodilator effect. The medicinal product has a distracting and irritating effect, as well as relieves pain.

*Pharmacokinetic properties.*

When applied topically, ibuprofen is rapidly absorbed through the skin. A very small amount enters the systemic circulation. The maximum blood concentration of ibuprofen is reached in 2 hours after administration of the medicinal product and is 0,6 µg/ml. The topical absorption of ibuprofen is approximately 5% of the oral absorption.

Levomenthol, which is absorbed through the skin, is transported to the liver. Some phase I metabolism may occur in the skin, but most occurs in the liver. Menthol is hydroxylated and then conjugated to glucuronide before circulating to the kidneys for urinary excretion.

**Clinical particulars.**

***Therapeutic indications.***

Darfen<sup>®</sup> Gel is recommended to relieve pain and reduce inflammation in rheumatic, muscle and joint pain, back pain, pain and swelling due to injury, sprains and sports injuries.

***Contraindications.***

The medicinal product is contraindicated:

- in case of hypersensitivity to ibuprofen, levomenthol, acetylsalicylic acid or to any component of the medicinal product or other NSAIDs (including oral administration);
- in case of asthma and a history of bronchial asthma attacks, urticaria, Quincke's edema, or acute rhinitis caused by administration of acetylsalicylic acid or other NSAIDs;
- for use on damaged or exposed (without epithelium) skin;
- for use on open wounds, for inflammatory and infectious skin diseases, such as wet eczema, as well as for use on mucous membranes;
- with dermatosis;
- in the presence of a local infection;
- for simultaneous use in the same area with other medicinal products for topical use;
- with ulcerative lesions of the gastrointestinal tract.

### ***Interaction with other medicinal products and other forms of interaction.***

In case of co-administration with acetylsalicylic acid or other medicinal products of the NSAID group, the risk of side effects increases. NSAIDs may interact with medicinal products used to lower blood pressure, may decrease the diuretic effect of furosemide, and may increase the effect of anticoagulants, although this is very unlikely for topical medicinal products.

### ***Special warnings and precautions for use.***

This medicinal product contains propylene glycol, which can cause skin irritation, therefore, before the first use, it is necessary to check the patient's sensitivity to Darfen<sup>®</sup> Gel on a small area of the skin.

Oral ibuprofen is known to exacerbate kidney failure or exacerbate active peptic ulcer disease. Patients with a history of renal impairment, asthma and a history of active gastric ulcer and duodenal ulcer and patients who are being treated with oral NSAIDs should consult a doctor before using this medicinal product. Do not apply the gel to mucous membranes, near the mucous membranes, on the lips, nostrils, areas around the eyes, genitals and anus, as well as on damaged, inflamed or irritated skin. In case of contact of the gel on the indicated areas, it is necessary to immediately wash off the preparation with plenty of clean water.

After using Darfen<sup>®</sup> Gel, you should always wash your hands unless they are being treated.

If a medicinal product is swallowed, the patient should immediately consult a doctor or the nearest emergency room.

An airtight bandage should not be applied to the gel application site.

Discontinue use if rash or irritation occurs and consult a physician.

Adverse reactions can be reduced by using the lowest effective dose for a short period of time.

If any adverse reactions occur, or if there is no improvement or if the condition worsens, the patient should consult a doctor.

The use of Darfen<sup>®</sup> Gel, as well as other medicinal product that inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility, although this is less likely for topical NSAIDs compared to oral medicinal products. For women who find it difficult to become pregnant or who are undergoing fertility tests, it may be advisable to discontinue Darfen<sup>®</sup> Gel.

Patients with bronchial asthma, hay fever, chronic lung disease, and patients with hypersensitivity to analgesics and antirheumatic medicinal products have a higher risk of developing asthma attacks, mucosal edema (Quincke's edema), or urticaria than in other patients. Systemic absorption of ibuprofen with topical application is less than with oral administration, so these complications may rarely occur. The use of the medicinal product in such patients should be carried out under the supervision of a physician.

Care should be taken to ensure that children do not touch the skin areas where the drug is applied. The areas of the skin to which the medicinal product is applied should not be exposed to prolonged exposure to sunlight to avoid skin photosensitivity

### ***Fertility, pregnancy and lactation.***

The safety of ibuprofen administration during pregnancy in humans has not been adequately described. No teratogenic effects were observed in animal studies with the oral medicinal product.

Ibuprofen and its metabolites pass into breast milk; therefore, it is not recommended to use this medicinal product during breastfeeding.

The medicinal product is not recommended for use in the first and second trimesters of pregnancy or during breastfeeding. The medicinal product is contraindicated in the third trimester, because in the case of sufficient systemic concentration, the risk of delayed labor, premature closure of the ductus arteriosus, bleeding in the mother and newborn and edema in the mother increases.

*Effects on ability to drive and use machines.*

Not established.

### ***Posology and method of administration.***

For external use only.

The sealed tube hole must be pierced with a thorn located in the upper outer part of the cap.

For each use, apply 1-7 cm of gel from a tube containing 50 g or 100 g of gel and 4-10 cm from a tube containing 15 g of gel.

Apply the gel to the painful area, followed by light rubbing until completely absorbed. If necessary, apply up to 3 times a day, but not more often than every 4 hours. If after two weeks there is no improvement, you should see a doctor. A bandage should not be applied to the gel application site.

*Children.*

The medicinal product is contraindicated for use in children under 12 years.

### ***Overdose.***

The probability of an overdose when using ibuprofen in the form of a gel for external use is negligible. However, in case of overdose, adverse reactions are possible, which are observed with the systemic use of ibuprofen (dyspeptic symptoms: nausea, heartburn, vomiting, flatulence; allergic skin reactions; headache, drowsiness, dizziness; arterial hypotension). If symptoms of overdose occur, the medicinal product should be discontinued and a doctor should be consulted. If the recommended dose is exceeded, wash off the gel with water. The specific antidote is unknown. Electrolyte balance correction is required.

### ***Undesirable effects.***

*Skin and subcutaneous tissue disorders:* hypersensitivity reactions that may occur in the form of skin purpura, Quincke's edema, bullous dermatoses (including epidermal necrolysis and erythema multiform); redness of the skin, skin irritation. The most common skin disorders are: rash, urticaria, itching, dry skin, burning sensation, contact dermatitis.

*Respiratory, thoracic and mediastinal disorders:* hypersensitivity reactions in the form of asthma attacks or worsening of its course, shortness of breath, dyspnea and bronchospasm may occur in patients with a history of asthma attacks or allergic diseases.

*Gastrointestinal disorders:* depending on the amount of applied gel, application site, skin integrity, duration of treatment, the presence of an occlusive dressing are possible, although unlikely: abdominal pain, dyspepsia.

*Renal and urinary disorders:* impaired renal function in patients with a history of kidney disease.

*Immune system disorders:* hypersensitivity reactions, including anaphylactic shock, angioneurotic edema and nonspecific allergic reactions.

Other systemic adverse reactions to NSAIDs depend on the amount of gel applied, the area applied, the integrity of the skin, the duration of treatment, and the use of an airtight dressing.

### ***Reported suspected adverse reactions.***

Reporting suspected adverse reactions after registration of a medicinal product is an important procedure. This allows for continued monitoring of the benefit/risk ratio for the respective drug. Healthcare providers should be informed of any suspected adverse reactions through the national alert system. Healthcare providers should be informed of any suspected adverse reactions through the national alert system.

***Shelf life*** 2 years.

**Special precautions for storage.**

Store in the original package at a temperature not exceeding 25 ° C. Keep out of the reach of children.

***Incompatibilities.***

Do not use with other topical medicinal products.

**Nature and contents of container.**

15 g or 50 g, or 100 g in a tube; 1 tube in a carton.

**Category of release.**

Non-prescription medicine.

**Manufacturer**

PrJSC "Pharmaceutical firm "Darnitsa".

**The manufacturer's location and address of the place of business.**

13, Boryspilska Street, Kyiv, 02093, Ukraine.

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