

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

**F-gel<sup>®</sup>**

***Qualitative and quantitative composition:***

*active substance:* ketoprofen;

1 g of gel contains 25 mg of ketoprofen;

*excipients:* ethanol (96 %), methylparaben (E 218), carbomer 980, trometamine, lavender oil, neroli oil, purified water.

**Pharmaceutical form.** Gel.

*Basic physical and chemical properties:* homogeneous, colorless, almost transparent gel with a specific odour.

**Pharmacotherapeutic group.** Nonsteroidal anti-inflammatory drugs for topical use. Ketoprofen. ATC code M02A A10.

***Pharmacological properties.***

*Pharmacodynamic properties.*

The active substance of the drug – ketoprofen – belongs to the group of nonsteroidal anti-inflammatory drugs derived from arylpropionic acid. Ketoprofen has analgesic and anti-inflammatory effects due to inhibition of cyclooxygenase 1 (COX-1), cyclooxygenase 2 (COX-2) and bradykinin, stabilization of lysosomal membranes and inhibition of macrophage migration. It has analgesic and anti-inflammatory activity both at the early stage (vascular phase) and at the late stage (cellular phase) of the inflammatory response. Also, F-gel<sup>®</sup> inhibits platelet aggregation.

*Pharmacokinetic properties.*

When applied topically, ketoprofen is absorbed from the skin, penetrates locally into inflamed tissues and maintains therapeutic concentration for a long time. Absorption into the systemic circulation is very insignificant (only 5 % of the applied dose) and is very slow. When applying a gel containing 50 to 150 mg of ketoprofen to the skin, the concentration of the active substance in the blood plasma after 5-8 hours is not more than 0.08-0.15 µg/mL that practically does not have a clinically significant effect on the body.

**Clinical particulars.**

***Therapeutic indications.***

- Muscle and joint pain caused by traumas and injuries.
- Tendovaginitis.

***Contraindications.***

- Known hypersensitivity reactions, such as symptoms of bronchial asthma, allergic rhinitis or urticaria, that have occurred during the use of ketoprofen, fenofibrate, thiaprofenic acid, acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs.
- Hypersensitivity to any of the ingredients of the drug.

- History of skin allergy manifestations with the use of ketoprofen, fenofibrate, thiaprofenic acid, ultraviolet (UV) light blockers or perfumes.
- History of photosensitization reactions.
- Exposure to sunlight, including indirect sunlight and ultraviolet radiation in the solarium during the entire treatment period and for another 2 weeks after discontinuation of treatment with the drug.
- Skin lesions (injuries, rashes, eczema, traumas, skin infections).
- Third trimester of pregnancy.

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

Since drug concentration in the blood plasma is extremely low, the manifestations of symptoms of interaction with other drugs (similar to those with systemic use) are possible only with frequent and prolonged use:

*with methotrexate, cardiac glycosides, lithium salts, cyclosporine* – increased toxicity due to a decrease in their excretion;

*with anticoagulants, antithrombotic agents, with acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs, glucocorticosteroids, oral hypoglycemic agents, phenytoin* – potentiation of the effect of above-mentioned drugs; concomitant use of the drug with other topical forms (ointments, gels) containing ketoprofen or other nonsteroidal anti-inflammatory drugs is not recommended;

*with antihypertensive agents, diuretics, mifepristone* – weakening of the effect of above-mentioned drugs. At least 8 days should elapse between the course of treatment with mifepristone and the start of ketoprofen therapy.

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

F-gel<sup>®</sup> should be used topically only.

If gel application time is missed, then the dose should not be doubled during the next use of the drug.

Hands should be washed immediately after each application of the drug.

It is necessary to stop using the drug in case of skin reactions, including skin reactions when used concomitantly with products containing octocrylene (octocrylene is part of some cosmetic and hygiene products, such as shampoos, aftershave gels, shower gels, creams, lipsticks, anti-aging creams, makeup removers, hair lacquers, to delay their photodegradation). Treatment should be discontinued immediately after the development of any skin reaction after the use of the drug.

F-gel<sup>®</sup> should not be used on areas with acne, open wound areas and on areas located next to them, on the mucous membranes, on areas around the eyes and in the eyes.

Do not apply the gel under occlusive dressings.

Exposure to sun (even on a foggy day) or exposure to UV rays on the skin in a tanning salon, during topical application of ketoprofen, it may cause potentially serious skin reactions (photosensitization). To avoid the risk of photosensitization, you should: protect the treated skin areas by wearing clothing during treatment and for 2 weeks after the end of the drug administration, wash your hands thoroughly after each application of the gel, when using the drug for a long time, use surgical gloves to avoid local irritation, do not visit solarium during treatment and for the next 2 weeks after the end of the drug use.

Topical application of a large amount of gel may cause systemic effects, including hypersensitivity and asthma. Do not exceed the recommended dose and duration of treatment, as the risk of contact dermatitis and photosensitization reactions increases over time.

Isolated cases of systemic adverse reactions associated with kidney damage have been reported.

F-gel<sup>®</sup> should be used with caution in patients with impaired renal or hepatic function, in the presence of concomitant heart failure.

F-gel<sup>®</sup> should be used with caution and under physician's supervision in patients who take anticoagulants, diuretics and lithium salts.

Do not apply the gel near an open flame, as it contains ethanol.

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

*First and second trimester of pregnancy.* No teratogenic or embryotoxic effect was observed in studies in mice and rats. During studies in rabbits, a little embryotoxic effect was observed, probably associated

with toxicity regarding the mother. Since no safety studies of ketoprofen have been conducted in pregnant women, the use of the drug in the first and second trimesters of pregnancy should be avoided.

*Third trimester of pregnancy.* All prostaglandin synthesis inhibitors, including ketoprofen, cause toxic damage to the fetal cardiopulmonary system and kidneys. At the end of pregnancy, both the mother and baby may have an extended bleeding time.

Therefore, the use of the drug during the third trimester of pregnancy is contraindicated.

*Lactation* After systemic administration (orally, rectally, parenterally), traces of ketoprofen are found in breast milk. F-gel® should not be used during breastfeeding.

*Effects on ability to drive and use machines.*

There is no data on the negative impact of the drug on the reaction rate when driving or operating other machines.

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

Apply a thin layer of F-gel® to the skin of the affected area – 3-5 cm or more of gel 1-2 times a day and gently rub until completely absorbed. The amount of gel depends on the size of the affected area: 5 cm of gel correspond to 100 mg of ketoprofen, 10 cm – 200 mg of ketoprofen. Hands should be washed immediately after each application of the drug.

F-gel® may be co-administered with other ketoprofen dosage forms (capsules, tablets, rectal suppositories). The total maximum daily dose of ketoprofen should not exceed 200 mg, regardless of the dosage form used.

The duration of the course of treatment is determined individually, but not more than 10 days.

*Children.*

The safety and efficacy of the drug for this age group has not been established.

### ***Overdose.***

Since the level of ketoprofen that penetrates through the skin, in the blood plasma is low, an overdose is unlikely.

*Main symptoms:* irritation, erythema, itching.

*Treatment:* rinse the skin thoroughly under running water, stop using the gel and consult a physician.

The development of systemic undesirable effects is possible when using the drug for a long time, in high doses or on large areas of the skin.

Accidental oral administration of the gel may cause drowsiness, dizziness, nausea, vomiting, epigastric pain, and administration of high doses of ketoprofen may cause bradypnea, coma, convulsions, gastrointestinal bleeding, acute renal failure, and increased or decreased blood pressure.

*Treatment:* symptomatic therapy with the support of vital body functions. Gastric lavage and administration of activated charcoal (the first dose should be administered together with sorbitol) may be useful, especially in the first 4 hours after an overdose or when taking a dose that is 5-10 times higher than recommended.

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

*Gastrointestinal disorders:* heartburn, nausea, vomiting, diarrhea, constipation, peptic ulcer, gastrointestinal bleeding.

*Renal and urinary disorders:* worsening of renal dysfunction or renal failure, especially in patients with chronic renal failure, in rare cases – interstitial nephritis.

*Immune system disorders:* hypersensitivity reactions, including angioedema, bronchospasm, asthma attacks, anaphylactic reactions.

*Skin and subcutaneous tissue disorders:* hyperemia, pruritus, burning sensation, edema, urticaria, photosensitization reactions, dermatitis (contact, bullous), eczema, including bullous and flictenulous which may spread out and become generalized, Stevens-Johnson syndrome.

Depending on the permeability of the active substance, the amount of gel applied, the area of the treated area, integrity of the skin, duration of use of the drug, other gastrointestinal tract and urinary disorders are possible.

Elderly patients are more likely to experience undesirable effects when using non-steroidal anti-inflammatory drugs.

***Shelf life.***

2 years.

**Special precautions for storage.**

Keep in the original package at temperature 15°C to 25°C out of reach of children.

**Nature and contents of container.**

30 g in a tube; 1 tube in a pack.

**Category of release.**

Prescription only medicine.

**Manufacturer.**

PrJSC "Pharmaceutical firm "Darnitsa".

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

13, Boryspilska Street, Kyiv, 02093, Ukraine.

**Date of last revision.**

06.07.2018