APPROVED
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INSTRUCTION
for medical use of pharmaceutical product

FANIGAN® FAST

Composition:
active substances: diclofenac, menthol, methyl salicylate, linseed oil;
1 g of gel contains diclofenac diethylamine equivalent to diclofenac sodium 10 mg, menthol 50 mg, methyl salicylate 100 mg, linseed oil 30 mg;
excipients: propylene glycol, carbomer 940, disodium EDTA, polysorbate 80, benzyl alcohol, ammonia solution, purified water.

Pharmaceutical form. Gel.
Basic physical and chemical properties: homogeneous white gel with characteristic odour.

Pharmacotherapeutic group. Topical products for joint and muscular pain. Anti-inflammatory preparations, non-steroids for topical use.
ATC code M02A A.

***Pharmacological properties*.**
Pharmacodynamics.
The effect of Fanigan® Fast gel is due to its components.
Diclofenac is a nonsteroidal anti-inflammatory drug with a pronounced anti-rheumatic, analgesic and antipyretic effect. The major mechanism of action is inhibition of the prostaglandin biosynthesis.
When inflammation caused by injuries or rheumatic diseases, the use of diclofenac results in reducing pain, tissue swelling and reduction of function recovery time for the damaged joints, ligaments, tendons and muscles.
Menthol stimulates cold receptors. This is accompanied by constriction and reduction of capillary permeability at the site of its application, a sense of coolness. Menthol causes local distracting and moderate analgesic effect.
Methyl salicylate is a derivative of salicylic acid and causes local irritating effect. By stimulating the skin receptors, methyl salicylate causes production of a large quantity of biologically active substances that regulate pain sensitivity and their penetration into the blood stream. The substance P is released from the neurons. Reduction of accumulation of the substance P in the nerve terminals reduces pain. Besides, methyl salicylate, which belongs to the group of nonsteroidal anti-inflammatory drugs (NSAIDs), inhibits the synthesis of prostaglandins because of cyclooxygenase inhibition, which reduces swelling and infiltration of inflamed tissues.
Linseed oil, the main component of which is α-linolenic acid (ethyl ester of unsaturated fatty acid) has anti-inflammatory effect, antioxidant properties, improves blood circulation at the site of application.

Pharmacokinetics.

The effect of Fanigan® Fast gel starts several minutes after its application to the skin. After 20-30 minutes the effect reaches maximum. When topical application of the gel, only 5% of the dose is absorbed, thus systemic effect of the drug is minimal.

Clinical particulars.

Indications.

Topical treatment of myositis, fibrositis, ischias, sprain of muscles and tendons, traumatic injuries of the musculoskeletal system, myalgia and arthralgia in acute exercise, inflammatory and degenerative diseases of the joints (osteoarthritis of peripheral joints and spine), rheumatic damage of the musculoskeletal system (bursitis, arthritis, tendosynovitis, tendinitis).

Contraindications.

- Hypersensitivity to diclofenac or other components of the drug.
- A history of bronchial asthma attacks, urticaria or acute rhinitis caused by acetylsalicylic acid or other NSAIDs administration.
- Epidermis injury, open wounds at the site of application.
- Last trimester of pregnancy.

Interaction with other medicinal products and other forms of interaction.

As systemic absorption after topical application of the drug is very low, the likelihood of interactions is insignificant. However, possible interactions that differ from the oral forms of diclofenac should be taken into account.

Although there have been no sufficiently controlled studies of interactions, it is possible that excessive use of salicylates for topical application may increase the effect of coumarin anticoagulants and antiplatelet drugs. In this regard, the patients taking coumarin anticoagulants and antiplatelet drugs, including aspirin, should be cautious.

Administration details.

Caution should be exercised when using concomitantly with oral nonsteroidal anti-inflammatory drugs.

The possibility of the development of systemic side effects when topical application of diclofenac is insignificant compared to its oral dosage forms, but it is not excluded when applying the drug on relatively large areas of the skin for a long time.

It is not recommended to use Fanigan® Fast gel with other drugs containing diclofenac.

Caution should be exercised when using the drug in case of active peptic ulcer disease os the stomach and duodenum or history of peptic ulcer disease, impaired hepatic/renal function, hemodyscrasia, polyposis of the nasal mucosa.

It is recommended to apply Fanigan® Fast gel only to intact skin surfaces, preventing its contact with inflamed, wounded or infected skin. Avoid contact with eyes and other mucous tunics. Do not swallow the drug.

The drug contains salicylates are aspirin-like substances so the same precautions as the ones recommended for aspirin should be taken.

Fanigan® Fast gel contains propylene glycol which may cause skin irritation.

In case of any skin rash, the drug should be discontinued. Do not apply Fanigan® Fast gel under airtight occlusive dressing. In case of strain of ligaments, the affected area can be bandaged.

Administration during pregnancy or breast-feeding.

The clinical experience of use in pregnant women is limited, therefore it is not recommended to use this drug during pregnancy or breast-feeding. Fanigan® Fast gel is contraindicated during the III trimester of pregnancy because of the possibility of development of weakness of labour activity and/or premature closure of the arterial duct.

If there is good reason for the use of Fanigan® Fast gel during the breast-feeding period, when the expected benefit of the drug according to the doctor overweighs the potential risk, the drug should

not be applied to the breasts or large skin areas, and should not be used for a long time (more than 1 week).

Ability to affect the reaction rate when driving motor transport or other mechanisms.
Does not affect.

Dosage and administration.
In adults and children over 14 years of age, apply a thin layer of 2-4 g of gel (4-8cm) on the skin and slightly rub in 2-3 times per day. The average daily dose is 10 g of gel, which corresponds to 100 mg of diclofenac sodium. The drug should be applied on intact skin, avoiding contact with eyes and mucous tunics. Do not apply the gel on open wounds.
After application of the drug, wash your hands thoroughly, unless this area was subject to treatment.
The duration of treatment is determined by the physician depending on the character and course of the disease and efficacy of treatment.
The gel should not be applied longer than 14 days in case of damage or rheumatism of soft tissues, or 21 day in case of arthritis, unless otherwise recommended by the physician.
Elderly patients do not require dosage adjustment.

Children.
It is contraindicated in children aged less than 14 years. When using the drug in children aged from 14 years longer than 7 days or if the symptoms of the disease increase, it is necessary to consult a doctor.

Overdose.
The overdose is unlikely due to insignificant systemic absorption of diclofenac in case of topical application. In case of accidental ingestion, it should be taken into account that one 100 g tube of the drug contains equivalent of 1 g diclofenac sodium; along with this the development of systemic reactions is possible.
In case of accidental ingestion, it is recommended to empty the stomach and take absorbent. Symptomatic treatment is indicated with therapeutic measures used for treatment of poisoning with nonsteroidal anti-inflammatory drugs.

Adverse reactions.
Immune system: hypersensitivity reactions (including urticaria), angioedema.
Respiratory system: bronchial asthma, bronchospasm, dyspnoea.
Skin and connective tissue: irritation, desquamation, swelling of the skin, rash (including pustulous), eczema, erythema, dermatitis (including contact, bullous), itching, photosensitivity reactions, burning or tingling sensation, dry skin may occur at the site of application.

Shelf-life. 2 years.

Storage conditions.
Store at the temperature below 25 °C in the original package.
Do not freeze.
Keep out of reach of children.

Package.
30 g or 100 g in a tube. 1 tube in a carton package.

Conditions of supply.
Without prescription.

Manufacturer.
Kusum Healthcare Pvt Ltd.

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SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

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