Insert leaflet

ARTROSILENE

ketoprofen lysine salt

Composition

Artrosilene 15% cutaneous foam: 100 ml of Artrosilene solution contain:
Active ingredient: ketoprofen lysine salt 15 g - Excipients: polysorbate 80, propylene glycol, polyvinylpyrrolidone, neurolene wash, benzyl alcohol, purified water.
One pressurised container contains:
Artrosilene solution 45.5 ml, propane-butane propellent 4.5 ml.

Artrosilene 5% gel: 100 g of gel contain:
Active ingredient: ketoprofen lysine salt 5 g - Excipients: carboxypolymethylene, triethanolamine, polyoxyethylene sorbitanmono-oleate, ethylalcohol, methyl p-hydroxybenzoate, nerolene wash, purified water.

Pharmaceutical forms

Artrosilene 15% Cutaneous foam: 50 ml pressurised container
Artrosilene 5% Gel: 50 g tube

Pharmaceutical class

Non-steroidal anti-inflammatory drug belonging to the class of propionic acid derivatives. Ketoprofen lysine salt exerts strong anti-inflammatory, analgesic and antipyretic action.

Marketing authorisation holder in Italy

Dompé farmaceutici S.p.A. - Via San Martino 12, 20122 Milano (Italy)

Manufacturer

Artrosilene 15% cutaneous foam
Zellaerosol GmbH, Wiesenstrasse 13, Zell I.W. (Germany)

Aerosol Service Italiana, Via del Maglio 6, Valmadrera, Lecco (Italy)

Manufacturer

Artrosilene 5% Gel

Doppel Farmaceutici Srl – via Martiri delle Foibe 1, 29016 Cortemaggiore, Piacenza (Italy)

Therapeutics indications

For the local treatment of pain and inflammation of a rheumatic or traumatic nature, affecting the joints, muscles, tendons and ligaments.

Contraindications

Do not use if history of allergy to ketoprofen, tiaprofenic acid, fenofibrate, UV blockers or perfumes is known.
Stop using Artrosilene 15% cutaneous foam or Artrosilene 5% gel immediately if you experience any skin reaction including cutaneous reactions after co-application of octorylene containing products (Octorylene is one of the excipient of several cosmetic and hygiene products such as shampoo, after-shave, shower and bath-gels, skin

creams, lipsticks, anti-ageing creams, make-up removers, hair sprays in order to delay photodegradation).
Do not expose treated areas to sunlight or UV light from solarium during the treatment and the 2 weeks following its discontinuation.
Hypersensitivity to the active substance or to any of the excipients.

Precautions for use
The product should not be applied to open sores or wounds, only to unbroken skin. Avoid contact with the eyes or mucous membranes. To avoid hypersensitivity or photosensitivity, avoid exposure to direct sunlight, included solarium, during use and for the two weeks after the end of treatment.

Interactions
Although in bioavailability studies an interaction with other drugs taken through topic and systemic way results improbable, in treatments at high dosages and prolonged in time the possibility of competition between absorbed ketoprofen and other drugs that bond readily to blood proteins must be kept present.

Warnings
The exposure to the sun (even hazy) or to UVA of areas in touch with Artrosilene 15% cutaneous foam or Artrosilene 5% gel can induce potentially serious cutaneous reactions (photosensitisation).
Therefore it is necessary to:

- **protect treated areas by wearing clothing during the treatment and for two weeks after its discontinuation to avoid any risk of photosensitisation**
- **wash your hands thoroughly after each application of Artrosilene 15% cutaneous foam or Artrosilene 5% gel**

Treatment should be discontinued immediately upon development of any skin reaction after application of Artrosilene 15% cutaneous foam or Artrosilene 5% gel
Use during pregnancy and breast-feeding - As with other non-steroidal anti-inflammatory drugs, the product should not be taken during confirmed or suspected pregnancy or when breast-feeding.

Dosage and method of administration
Cutaneous use. Depending on the size of the area to be treated, apply the product 2-3 times per day or as specified in the doctor's prescription. Massage directly to encourage absorption. During ionographic treatment, the drug should be applied at the negative pole.
Cutaneous foam: Turn the can upside down, shake before use and spray by pressing the ribbed button.

Duration of the treatment
The drug is used for acute and chronic pathologies for periods ranging from a few days to 3-4 weeks.
Artrosilene 5% gel contains methyl p-hydroxybenzoate which may cause allergic reactions (possibly delayed)
Artrosilene 15% cutaneous foam contains propylene glycol which may cause skin irritations

Adverse effects
Cutaneous and local symptoms have been reported.
Cases of more severe reactions such as bullous or phlyctenular eczema which may spread or become generalized have occurred rarely.
Allergic skin reactions, erythema, burning, pruritus, dermatitis, contact eczema, photosensitivity reactions, urticaria, bullosis eruptions.
Severe skin reaction during an exposure to the sun light.
Very rare systemic adverse reactions, as renal disorders, have been reported. If any other adverse effect should appear, please notify your doctor or chemist.

Expiry and storage
The expiry date refers to the product in an undamaged, correctly stored package.

Attention: do not use the medicine after the expiry date printed on the package

Keep all medicines out of the reach of children.

Date of revision of leaflet: September 2019