SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF PROPRIETARY DRUG
ARTROSILENE 5% gel.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
100 g of gel contain the active ingredient:
ketoprofen lysine salt 5 g
The excipients are listed in paragraph 6.1

3. PHARMACEUTICAL FORM
Gel

4. CLINICAL INFORMATION
4.1 Therapeutic indications
For local treatment of pain and inflammation of the joints, muscles, tendons or ligaments of a rheumatic or traumatic nature.

4.2 Dosage and method of administration
Depending on the size of the area to be treated, apply Artrosilene 5 % gel 2/3 times a day or as prescribed by the doctor, massaging gently to aid absorption. In the case of iontophoresis treatment, the drug should be applied to the negative pole.
Duration of treatment: the drug is used for both acute and chronic disorders, for periods ranging between a few days and 3/4 weeks.

4.3 Contraindications
Established individual hypersensitivity to the product or products of the same class.
History of any photosensitivity reaction.
Known hypersensitivity reactions, such as symptoms of asthma, allergic rhinitis to ketoprofen, fenofibrate, tiaprofenic acid, acetylsalicylic acid, or to other NSAID.
History of skin allergy to ketoprofen, tiaprofenic acid, fenofibrate or UV blocker or parfumes.
Sun exposure, even in case of hazy sun, including UV light from solarium, during the treatment and 2 weeks after its discontinuation.

4.4 Warnings and precautions in use
Artrosilene 5% gel must not be applied to sores or open wounds, only on intact skin. Avoid contact with the eyes and mucous membranes.
To prevent possible reactions of hypersensitivity or photosensitisation, avoid exposure to the direct sunlight, included solarium, during use and for the next two weeks after the end of treatment.
Hands should be washed thoroughly after each application of the product.
Treatment should be discontinued immediately upon development of any skin reaction including cutaneous reactions after co-application of octocrylene containing products.
It is recommended to protect treated areas by wearing clothing during all the application of the product and two weeks following its discontinuation to avoid the risk of photosensitisation.

4.5 Interactions with other drugs or other forms of interaction
Although the bioavailability studies indicate that interaction with other drugs administered by the topical or systemic routes is unlikely, in the case of long-term treatment and treatment at high doses, the possibility of competition between the ketoprofen absorbed and other drugs that bond readily with the plasma proteins should be borne in mind.

4.6 Use during pregnancy and breastfeeding
Like other non-steroidal anti-inflammatory drugs, Artrosilene 5% gel should not be administered in the case of suspected or confirmed pregnancy, or during breastfeeding.

4.7 Effects on driving ability and the use of machinery
No effects on the attention level are known.

4.8 Adverse effects
Cutaneous and local symptoms have been reported such as erythema, pruritis and burning sensations., cases of more severe reactions such as bullous or phlyctenular eczema which may spread or become generalized have occurred rarely, hypersensitivity reactions and dermatological reactions: photosensitisation.
. Allergic local skin reactions, dermatitis, contact eczema, urticaria, bullosis eruptions. Very rare systemic adverse reactions , such as renal disorders, have been reported. If any other adverse effect should appear, please notify your doctor or chemist.

4.9 Overdose
No symptoms of overdose or specific treatments have been reported for the topical or systemic use of the drug.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antiinflammatory preparations, nonsteroids for topical use
ATC: M02AA10
A non-steroidal anti-inflammatory drug with marked anti-inflammatory, analgesic and antipyretic activity.
Artrosilene 5% gel therefore allows local treatment of all painful, inflammatory or traumatic disorders of the joints, tendons, ligaments and muscles, gradually attenuating pain and local inflammatory symptoms.

5.2 Pharmacokinetic properties
Ketoprofen lysine salt is rapidly absorbed, with peak blood concentrations 20-30 min. after administration by the intramuscular route, after 45-60 min. by the rectal route, and after 60-90 min. by the oral route. The half-life is 1-2 hrs. Ketoprofen passes into the synovial fluid, and persists at rates higher than the blood concentrations as from the 4th hour after oral administration.
Elimination is massive and mainly takes place with the urine: 50% of the product administered by the systemic route is excreted with the urine in 6 hrs. Metabolisation is high: approx. 55% of the product administered by the systemic route is found in the form of metabolites in the urine.

5.3 Safety preclinical data
The active constituent presents a low level of toxicity; depending on the administration route, the LD_{50} is approx. 300 mg/kg in the rat, equivalent to 80-100 times the active dose as an anti-inflammatory and analgesic.
The product is not teratogenic and not chemically correlated with drugs known to possess carcinogenic activity.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients
Carboxypolymethylene, triethanolamine, polyoxyethylene sorbitan mono-oleate,
95° ethyl alcohol, methyl p-hydroxybenzoate, nerolene lavender, purified water

6.2 Incompatibility
None.

6.3 Shelf life
Artrosilene 5% gel has a shelf life of 3 years.
The shelf life indicated refers to the product in its intact packaging, correctly stored.

6.4 Special storage precautions
None.

6.5 Nature of container, packaging and prices
Aluminium tube belonging to Class I, type I, conforming to the suitability tests laid down in Ministry of Health circular no. 84/1977. Packaging: 50 g tube

6.6 Instruction for use
Aqueous solutions of ketoprofen lysine salt can be used in physiotherapeutic treatments (iontophoresis, sonophoresis and laser therapy).
In the case of iontophoresis treatment, the drug should be applied to the negative pole.

7. Name and address of holder of marketing authorisation in Italy
Dompé Farmaceutici S.p.A.,
Via San Martino 12,
20122 MILAN,
Italy

8. Registration number and date of first marketing
MA118/00101

9. Date of the first marketing authorisation/ renewal
3rd January, 2007 / 8th November 2011

10. Date of last revision of the text
8th November 2011