Achonid® Gel
Ketoprofen 2.5%

FORMS AND PRESENTATION
Achonid® Gel: Tube of 60 g.

COMPOSITION
Achonid® Gel: Each 1g contains Ketoprofen 25mg.
Excipients: ethanol, carbomer, trolamine salicylate, lavender high altitude essential oil.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: non-steroid anti-inflammatory drug (NSAID) of the propionics group, derivative of aryl-carboxylic acid, for topical use,
ATC code: M02AA10.
Mechanism of action
Ketoprofen is an inhibitor of both the cyclo-oxygenase and lipoxygenase pathways. Inhibition of prostaglandin synthesis provides for potent anti-inflammatory, analgesic and antipyretic effects. Lipoxygenase inhibitors appear to attenuate cell-mediated inflammation and thus retard the progression of tissue destruction in inflamed joints. In addition, Ketoprofen is a powerful inhibitor of bradykinin (a chemical mediator of pain and inflammation), it stabilises lysosomal membranes against osmotic damage and prevents the release of lysosomal enzymes that mediate tissue destruction in inflammatory reactions.

Pharmacokinetic properties
Applied locally in the form of a gel, ketoprofen is absorbed very gradually and is not accumulated in the body. The systemic passage of the gel compared to that of the oral formulations of ketoprofen is around 5 per cent, which enables a local effect to be obtained without systemic incidence.

INDICATIONS
Achonid® Gel is indicated in adults for symptomatic relief of pain in such conditions as soft tissue injuries, including sport injuries, sprains, strains, muscle tendonitis, swelling, backache and rheumatic pain.

CONTRAINDICATIONS
- Known hypersensitivity to the active substance or to any of the excipients listed.
- History of any photosensitivity reaction.
- Known hypersensitivity reactions, such as symptoms of asthma, allergic rhinitis or urticaria to fenofibrate, tiaprofenic acid, acetylsalicylic acid, or to other NSAIDs.
- History of skin allergy to ketoprofen, tiaprofenic acid, fenofibrate or UV blocker or perfumes.
- Sun exposure, even in case of hazy sun, including UV light from solarium, during the treatment and 2 weeks after its discontinuation.
- Exudative dermatoses, on pathological skin changes such as eczema or acne; or in infected skin lesions, open wounds, broken skin and sores.
- Third trimester of pregnancy.

PRECAUTIONS
- The gel should be used with caution in patients with reduced heart, liver or renal function: isolated cases of systemic adverse reactions affecting renal function have been reported.
- The topical use of large amounts of product may give rise to systemic effects such as hypersensitivity and asthma.
- The treatment should be interrupted if rash appears.
- The recommended length of treatment should not be exceeded due to the risk of developing contact dermatitis and photosensitivity reactions increases over time.
- Hands should be washed thoroughly after each application of the gel.
- 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 avoid exposure of treated skin to direct sunlight including solarium (sunbeds), and to protect treated areas by wearing clothing during treatment with the product and for two weeks following its discontinuation to avoid the risk of photosensitization.
- Do not use with occlusive dressings.
- The gel must not come into contact with mucous membranes or the eyes.
- Patients with asthma combined with chronic rhinitis, chronic sinusitis, and/or nasal polyposis have a higher risk of allergy to aspirin and/or NSAIDs than the rest of the population.
- The use of topical products, especially if it is prolonged, may give rise to phenomena of sensitization or local irritation.
- Ethanol may cause a burning sensation on damaged skin.
- Keep out of the sight and reach of children.
- Areas of skin treated with Achonid® Gel should not be exposed to direct sunlight, or solarium ultraviolet light, either during treatment or for two weeks following treatment discontinuation, in order to avoid, phototoxicity reactions and photo allergy.
- Should a skin rash occur after gel application, treatment must be stopped.
- Keep the gel away from naked flames. Do not incinerate.

Effects on ability to drive and use machines
Not known.

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PREGNANCY AND LACTATION
Pregnancy
During the first and second trimester:
There are no clinical data from the use of topical forms of ketoprofen during pregnancy. It is not known if the systemic ketoprofen exposure reached after topical administration can be harmful to an embryo/foetus. During the first and second trimester of pregnancy, ketoprofen should not be used unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible.
During the third trimester of pregnancy:
During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors including ketoprofen may induce cardiopulmonary and renal toxicity in the foetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed. Therefore, ketoprofen is contraindicated during the last trimester of pregnancy.
Breast-feeding
No data are available on excretion of ketoprofen in human milk. Ketoprofen is not recommended in nursing mothers.

DRUG INTERACTIONS
Interactions are unlikely as serum concentrations following topical administration are low. It is, however, advisable to monitor patients under treatment with coumarin substances. Serious interactions have been recorded after the use of high dose methotrexate with NSAIDs, including ketoprofen, when administered by the systemic route.

ADVERSE EFFECTS
Adverse effects are listed below by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000) and not known (cannot be estimated from the available data).
Infections and infestations: secondary impetigo (not known).
Blood and lymphatic system disorders: eosinophilia (not known).
Immune system disorders: anaphylactic reaction, angioedema, hypersensitivity (not known).
Eye disorders: eyelid oedema (not known).
Vascular disorders: vasculitis (not known).
Gastrointestinal disorders: peptic ulcer, gastrointestinal bleeding, diarrhoea, lip oedema (not known).
Skin and subcutaneous tissue disorders: rash (erythematous, generalised, maculo-papular, papular, pruritic, pustular, vesicular), eczema, pruritus, burning sensation, application site burn (uncommon); dermatitis (allergic, bullous, contact, exfoliative, vesicular), urticaria, blister, photosensitivity reaction, photosensitivity allergic reaction, skin exfoliation, skin oedema (rare).
Renal and urinary disorders: acute renal failure, insufficiency aggravated (very rare).
General disorders and administration site conditions: pyrexia (not known).
Injury, poisoning and procedural complications: wound complication (not known).

DOSAGE AND ADMINISTRATION
Posology
Achonid® Gel should be applied topically to the affected area two or three times daily. Maximum duration of use should not exceed 10 days.
Paediatric population
Not recommended in children under 12 years of age. The safety and efficacy of ketoprofen gel in children have not been established.
Method of administration
For cutaneous use.
Penetration of the gel by gentle and prolonged massage on the painful or inflamed surface for up to seven days.
Two to four daily applications of approximately 2 to 4 g gel, representing approximately 5 to 10 cm. The usual maximum dose is 15 g per day.
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

OVERDOSAGE
Overdose is unlikely to be caused by topical administration. If accidentally ingested, the gel may cause systemic adverse effects depending on the amount ingested. However, if they occur, treatment should be symptomatic and supportive in accordance with overdosage of oral anti-inflammatories.

STORAGE CONDITIONS
Store below 25°C.
Keep in original pack in intact conditions.

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Marketing Authorization Holder
Benta S.A.L. - Lebanon

Manufacturer
Manufactured by Benta Lyon SAS Saint Genis Laval, France
For Benta S.A.L. – Lebanon

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