SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
SULJEL 3% gel, 30 g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 g gel contains

Active substance:
Nimesulide 30 mg

For excipients see 6.1.

3. PHARMACEUTICAL FORM
Gel
Yellowish to light yellow colored gel

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
SULJEL,

- Localized soft tissue rheumatic diseases such as osteoarthritis, rheumatoid arthritis, tendonitis, tenosynovitis, bursitis; soft tissue trauma such as strain, contusion; musculoskeletal diseases characterized by pain, inflammation and muscle strain.

4.2. Posology and method of administration
Posology / Frequency and duration of administration
Adults:
SULJEL should be applied in a thin layer (corresponding to a line 6-7 cm long) to the affected site 2 or 3 times per day and massaged until it is completely absorbed.

Duration of treatment: 7 – 15 days.

Additional information on special populations
Pediatric population:
SULJEL has not been studied in children. Therefore, safety and efficacy have not been established and the product should not be used in children under 12 years (see section 4.3).

Geriatric population:
The use of SULJEL in elderly patients is similar to that of adults.

Renal/Hepatic failure:
SULJEL should not be used in patients with severe renal and/or hepatic failure.

4.3. Contraindications

SULJEL should not be used in those patients who have known hypersensitivity to nimesulide and who have previously shown a hypersensitivity reaction (such as bronchospasm, rhinitis, urticaria) to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs. It should not be used in children under 12 years. It should not be used on injured or abraded skin or in the presence of local infection. It should not be used simultaneously with other topical products

4.4. Special warnings and precautions for use

SULJEL should not be applied to skin wounds or open injuries.

SULJEL should not be allowed to come into contact with the eyes or mucous membranes; in case of accidental contact, wash immediately with water.

The product should never be taken by mouth. Hands should be washed after applying the product.

SULJEL should not be used with occlusive dressings.

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration.

Patients with gastro-intestinal bleeding, active or suspected peptic ulcer, severe renal or hepatic dysfunction, severe coagulation disorders or severe/non controlled heart failure should be treated with caution.

Since SULJEL has not been studied in hypersensitive subjects, particular caution should be used when treating patients with known hypersensitivity to other NSAIDs. The possibility of developing hypersensitivity in the course of therapy cannot be excluded.

To reduce the risk of photosensitivity, patients should be warned against exposure to direct and solarium sunlight.

If symptoms persist or the condition is aggravated medical advice should be taken.

4.5. Interaction with other medicinal products and other forms of interaction
No interactions of SULJEL with other medicinal products are known or to be expected via the topical route.

4.6. Pregnancy and lactation
General recommendation:
Pregnancy category is C.

It can be used by pregnant and lactating women under physician supervision. It should be used in pregnant women after the benefit / risk ratio in the treatment with SULJEL is evaluated by a physician.

Pregnancy
Animal studies showed that nimesulide had no harmful effect on the fetus. However, there are no controlled studies in pregnant women. Nimesulide use during pregnancy has been associated with oligohydramnios, renal insufficiency in the newborn, and early closure of ductus arteriosus. SULJEL gel should not be used during pregnancy unless clearly necessary.

Lactation
There is no study for the secretion to breast milk and probable effects to children taking breast milk. Therefore, SULJEL is not recommended for use during lactation until more data is obtained.

4.7. Effects on ability to drive and use machines
No studies on the effect of SULJEL on the ability to drive and use machines have been performed.

4.8. Undesirable effects
The adverse reactions reported have been listed by the following frequency (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), not known (cannot be estimated from available data).

Skin and subcutaneous tissue disorders
Common: Itching and erythema

4.9. Overdose
Overdose with nimesulide as a result of topical application of SULJEL is not to be expected since the highest plasma levels of nimesulide following application of SULJEL are far below those found following systemic administration.

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic properties
Pharmacotherapeutic Group: Nimesulide.
ATC Code: M02AA26

Nimesulide is a non-steroidal anti-inflammatory drug (NSAID). Nimesulide differs from other nonsteroidal antiinflammatory agents containing carboxyl and enols groups by virtue of the functional sulfonanilide group incorporated into its structure

Nimesulide is an inhibitor of the prostaglandin synthesis enzyme cyclo-oxygenase.

Cyclo-oxygenase produces prostaglandins, some of them being implicated in the development and maintenance of inflammation.

5.2. Pharmacokinetic properties

Absorption and bioavailability:
After topical application, nimesulide penetrated from skin to muscle or synovial fluid continuously and slowly the balance is rapidly provided between skin, muscle or synovial fluid.

Distribution:
Nimesulide releases slowly to systemic circulation (after topical application nimesulide is found in significant levels in plasma from 30 minutes to 8th hour). Eight hours after topical application plasma concentrations of nimesulide varies between 14-57.5 ng/ml. The rate of protein binding is 99% and tmax is 120 minutes.

When SULJEL is applied topically, plasma concentrations of nimesulide are very low in comparison with those achieved following oral intake. After a single application of 200 mg of nimesulide, in the gel form, the highest plasma level of 9.77ng/ml was noted after 24 hours. No trace of the main metabolite 4-hydroxy-nimesulide, was detected. At steady-state (day 8) peak plasma concentrations were higher (37.25 ± 13.25 ng/ml) but almost 100 times lower than those measured following repeated oral administration.

Biotransformation:
It is metabolized in the liver.

Elimination:
50.5-62.5% of the drug is excreted in the urine and 17.9-36.2% in the faeces. Unchanged drug rates excreted are less than 0.1%. Elimination half-life is calculated as approximately 10 hours

5.3. Preclinical safety data
The local tolerance and the irritation and sensitization potential of SULJEL have been tested in several recognized animal models. The results of these studies indicate that SULJEL is well tolerated.

Preclinical data for systemically administered nimesulide reveal no special hazards for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential. In repeated dose toxicity studies, nimesulide showed gastrointestinal, renal and hepatic toxicity. In reproductive toxicity studies, embryotoxic and teratogenic effects (skeletal malformations, dilatation of cerebral ventricles) were observed in rabbits, but not in rats, at maternally toxic dose levels. In rats, increased mortality of offspring was observed in the early postnatal period and nimesulide showed adverse effects on fertility

6. PHARMACEUTICAL PROPERTIES
6.1. List of excipients
Ethanol
Disodium edetate
Liquid paraffin
Methyl paraben (E218)
Propyl paraben (E217)
Ethyl paraben (E214)
Carbomer 980
Triethanolamine
Purified water

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
24 months

6.4. Special precautions for storage
Store at room temperature below 25ºC.

6.5. Nature and contents of container
It is marketed in aluminum tubes closed with HDPE caps.

6.6. Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with “Directive on Control of Medical Waste” and “Directive on the Control of Packaging and Packaging Waste”.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

247/50

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 28.12.2012
Date of latest renewal: 05.10.2018

10. DATE OF REVISION OF THE TEXT

23.01.2017