SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SERTOFEN 1.25% Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

1g gel contains 18.45 mg Dexketoprofen trometamol equivalent to 12.5 mg Dexketoprofen.

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel.

Opaque, homogenous gel

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is used in the treatment of traumatic or degenerative origin, painful and inflammatory conditions associated with joints, tendons, ligaments and muscles.

4.2 Posology and administration method:

Posology and frequency/time of administration

SERTOFEN, can be administered two to three times daily to the painful or inflamed region. The total daily dose should not pass 7.5 g (approximately 14 cm of gel). Treatment time should be limited with max. 7 days.

Administration method:

SERTOFEN gel is administered topically. Ensure absorption of gel completely by gently rubbing.

Avoid contact with eyes and mucosa.

Additional information for special populations

Renal/hepatic impairment:

Although systemic effects are minimal in the gel form, systemic effects of non-steroidal anti-inflammatory drugs (NSAIDs) may occur depending upon transdermal transition, administered gel amount, administered surface, integrity level of skin, treatment period and whether occlusive dressing performed or not (effects on the digestive system and kidneys). Because of this reason, it should be used with caution in patients with severe renal or hepatic impairment.

Pediatric population

Administration in children under 6 years of age is not recommended.

Geriatric population:

Dose adjustment is not necessary for elderly patients.

4.3 Contraindications

It is contraindicated in patients with hypersensitivity to Dexketoprofen, ketoprofen or other excipients in the SERTOFEN content.

It is contraindicated in patients showing signs of sensitivity such as asthma, allergic rhinitis or urticaria as a result of Aspirin or other nonsteroidal anti-inflammatory drug use.

It should not be used in the ones with bronchial asthma, tiaprofenic acid, fenofibrate or history of skin allergy due to cosmetics.

It should not be administered to exudative dermatosis, eczema, lesion-affected skin regardless of the type of lesion, burn, wound, mucosa, eye, anal or genital region.

4.4 Special warnings and precautions for use

Products used specifically for a long time topically may cause sensitivity and local irritation. For the prevention of light sensitivity or hypersensitivity cases that may occur, should not be exposed to direct sunlight, UV and solarium during treatment and up to two weeks after treatment.

It should not be administered to open wounds or permanent, existing lesions of the skin.

It should not be administered to mucous, eye and anal or genital areas.

SERTOFEN should not be administered with occlusive or obstructive dressings. Hands should be washed thoroughly after SERTOFEN use.

Treatment should be discontinued immediately upon development of any skin reaction after the administration of SERTOFEN.

4.5 Interaction with other medicinal products and other forms of interaction

Since Dexketoprofen slightly diffuses to systemic circulation as a result of topical administration, drug and other interactions are almost not observed.

Due to side effect risk may increase; it should not be used with other non-steroidal antiinflammatuar drugs.

Additional informations for special populations

No interaction study has been performed for special populations.

4.6 Pregnancy and lactation

General recommendation

Pregnancy category: C.

Women with childbearing potential/ Birth control (Contraception)

Studies performed on animals are insufficient regarding effects on pregnancy /and-or/ embrional/fetal development /and-or/childbearing/and-or/ postnatal development.

Potential risk for human is unknown.

SERTOFEN should not be used during pregnancy, unless it is necessary.

Pregnancy period

Although experimental animal studies and epidemiological data have shown that dexketoprofen has not a toxic effect on the embryo, the use of SERTOFEN in pregnancy is not recommended due to the toxic effects of nonsteroidal anti-inflammatory drugs.

Lactation period

It is not known whether Dexketoprofen is excreted into human milk or not. For this reason, it is not recommended to use SERTOFEN in breastfeeding women.

Reproductive Ability/Fertility

No reproductive toxicity has been observed in animal studies performed with Dexketoprofen trometamol.

4.7 Effects on ability to drive and use machines

There is no known effect on drive and use machines.

4.8 Undesirable effects

Local skin reactions which can develop secondarily on the administration area have been reported. Erithema, pruritus, photosensitization have been reported.

The system below is used for classification of undesirable effects:
Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000), unknown (can not be estimated with available data).

Skin and subcutaneous tissues diseases
Rare: Dermatitis (erythema, pruritis, inflammation)

Very Rare: Systemic hypersensitivity reactions (urticaria, broncospasm)

Unknown: Photosensitivity reactions (erythema, inflammation and in some cases slight vesiculation)

4.9 Overdose and treatment
Overdose related to topical administration is not observed. If accidentally ingested, it may cause systemic effects depending on the amount ingested. In this case, supportive and symptomatic treatment and gastric lavage should be administered. Dexketoprofen trometamol can be removed from the body by dialysis.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Nonsteroidal anti-inflammatory drugs which are used as topical.
ATC code: M02AA96

Dexketoprofen trometamol is the tromethamine salt of S-(+)-2-(3-benzoylphenyl) propionic acid, an analgesic, antiinflammatory and antipyretic drug, which belongs to the non-steroidal anti-inflammatory group of drugs (NSAIDs).

The mechanism of action of non-steroidal antiinflammatory drugs is related to the reduction of prostaglandin synthesis by the inhibition of cyclooxygenase pathway. Specifically, it occurs by the inhibition of the transformation of arachidonic acid into cyclic endoperoxides, PGG_2 and PGH_2, which produce prostaglandins PGE_1, PGE_2, $PGF_{2\alpha}$ and PGD_2 and at the same time prostacyclin PGI_2 and thromboxanes (TxA_2 and TxB_2). Furthermore, the inhibition of the synthesis of prostaglandins causes an indirect action in addition to direct effect by affecting other inflammation mediators such as kinins.

It has been seen that Dexketoprofen is an inhibitor of COX-1 and COX-2 activities in experiments on animals and humans.

Clinical studies performed on several pain models demonstrated Dexketoprofen trometamol has effective analgesic activity. The onset of the analgesic activity was obtained in some studies in 30 minutes post-administration. The analgesic effect persists for 4 to 6 hours.

5.2 Pharmacokinetic properties

Absorption

Dexketoprofen that is administered topically shows little percutaneous absorption. Due to low systematic bioavailability, systemic effect is not expected.

Distribution

The distribution half-life of Dexekoprofen trometamol is 0.35 hour. As with other medicinal drugs with a high plasma protein binding (99%), the mean value of the distribution volume is lower than 0.25 L / kg.

Biotransformation:

After administration of Dexketoprofen trometamol,l only the S-(+) enantiomer is obtained in urine demonstrates that no conversion to the R-(-) enantiomer occurs in humans. In multiple doses pharmacokinetic studies, observing that AUC (area under curve) after last administration is not different than the one obtained after single dose administration indicates that no drug accumulation

is present.

Elimination:

The elimination half-life value of Dexketoprofen trometamol is 1.65 hours. The main elimination route for Dexketoprofen is renal excretion following glucuronide conjugation.

Linearity/Non linearity:

Dexketoprofen trometamol shows linear pharmacokinetic properties with a dose-dependent increase during systemic exposure following oral dose.

5.3 Preclinical safety data

Traditional safety pharmacology, which is based on repeated dose toxicity, genotoxicity, carcinogenic potential and fertility toxicity studies, does not reveal any special hazard for human.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer Homopolymer
Menthol
Lavender oil
Ethanol (96%)
Sodium hydroxide
Purified water

6.2 Incompatibilities

There is not any known incompatibility.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C at room temperature.

6.5 Nature and contents of container

It was packaged in lacquered aluminum tube, which is closed with polyethylene cap.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

Renewal of the authorisation:

10. DATE OF REVISION OF THE SPC