

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ELEKTRA 1.25 % Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

1 gram of gel contains 18.45 mg of Dexketoprofen trometamol, equivalent to 12.5 mg of Dexketoprofen, as an active ingredient.

Excipients:

See 6.1 for excipients.

3. PHARMACEUTICAL FORM

Gel

Colorless, clear gel.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

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

4.2. Posology and method of administration

Posology/frequency and duration of administration:

ELEKTRA can be rubbed into the painful and inflamed area 2-3 times a day.

The total daily dose should not exceed 7.5 g (about 14 cm of gel).

The duration of treatment should be limited to a maximum of 7 days.

Method of administration:

ELEKTRA gel is applied topically. By rubbing gently, it should be ensured that the gel is completely absorbed.

Contact with mucous membranes and eyes should be avoided.

Additional information on special populations:

Renal/Hepatic impairment:

Although systemic effects in gel form are minimal, the systemic effects of non-steroidal anti-inflammatory drugs (NSAIDs) may occur depending on the transdermal transdermal translocation, the amount of gel applied, the surface applied, the degree of skin integrity, the duration of treatment and whether occlusive dressing is applied (effects on the digestive system and kidneys). Therefore, it should be used with caution, especially in those with severe renal impairment or severe hepatic impairment.

Pediatric population:

It is not recommended for use in children under 6 years of age.

Geriatric population:

No dose adjustment is required in elderly patients.

4.3. Contraindications

Dexketoprofen is contraindicated in those with hypersensitivity to ketoprofen or other excipients contained in ELEKTRA.

It is contraindicated in patients who show signs of sensitization such as asthma, allergic rhinitis or urticaria as a result of the use of aspirin or other non-steroidal anti-inflammatory drugs.

It should not be used in those with a history of bronchial asthma, skin allergies due to thioprofenic acid, fenofibrate or cosmetics.

Exudative dermatosis should not be applied to eczema, lesioned skin, burns, wounds, mucous membranes, eyes, anal or genital areas, regardless of the type of lesion.

4.4. Special warnings and precautions for use

Products used topically, especially for long periods of time, can cause sensitivity and local irritation. In order to prevent possible light sensitivity or hypersensitivity, direct sunlight, UVA and solarium should be avoided during the treatment and until two weeks have passed since the treatment.

It should not be applied to open wounds or permanently present skin lesions.

It should not be applied to the mucous membranes, eyes and anal or genital area.

ELEKTRA should not be administered with an hands should be washed thoroughly after.

Treatment should be discontinued immediately if a skin reaction occurs after administration of ELEKTRA.

4.5. Interactions with other medicinal products and other forms of interaction

Since dexketoprofen passes into the systemic circulation in very small amounts as a result of topical application, drug and other interactions are almost never seen.

It should not be used in combination with other non-steroidal anti-inflammatory drugs, as the risk of side effects may increase.

Additional information on special populations

No interaction studies have been conducted for special populations.

4.6. Pregnancy and lactation**General advice**

Pregnancy category: C

Women of childbearing potential / Contraception

Animal studies are inconclusive in terms of effects on pregnancy /and-or/ embryonal/fetal development/and-or/childbirth /and-or/ postnatal development.

The potential risk to humans is unknown.

ELEKTRA should not be used during pregnancy unless necessary.

Gestational period

Although experimental animal studies and epidemiological data have shown that dexketoprofen does not have a toxic effect on the embryo, due to the possible toxic effects of non-steroidal anti-inflammatory drugs, the use of ELEKTRA in pregnancy is also not recommended.

Lactation period

It is not known whether dexketoprofen is excreted in human milk. Therefore, the use of ELEKTRA in breastfeeding women is not recommended.

Reproductive ability/Fertility

No reproductive toxicity was seen in animal studies with dexketoprofen trometamol.

4.7. Effects on driving and using machines

There is no known effect on the use of vehicles and machines.

4.8. Undesirable effects

Local skin reactions that may develop secondarily at the site of application have been reported. Erythema
pruritus, photosensitization has been reported.

The following system is used to classify undesirable side effects:

Very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$),
uncommon
($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), unknown (cannot be estimated based on
available data).

Skin and subcutaneous tissue disorders

Rare: Dermatitis (erythema, pruritus, inflammation)

Very rare: Systemic hypersensitivity reactions (urticaria, bronchospasm)

Not known: Photosensitivity Ivity Reactions (erythema, inflammation and in some cases mild vesiculation)

Reporting of suspected adverse reactions

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9. Overdose and its treatment

Overdose due to topical application is not seen. If swallowed accidentally, it may cause systemic effects depending on the amount ingested. In this case, supportive and symptom-oriented treatment and gastric lavage should be applied. Dexketoprofen trometamol can be removed from the body by dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Topical non-steroidal anti-inflammatory drugs

ATC code: M02AA96

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

The mechanism of action of non-steroidal anti-inflammatory drugs is related to the reduction of prostaglandin synthesis by inhibition of the cyclooxygenase pathway. In particular, it occurs by inhibition of the transformation of arachidonic acid into cyclic endoperoxides, PGG₂ and PGH₂, forming prostaglandins PGE 1, PGE 2, PGE_{2α} and PGD₂, as well as prostacyclin PGI₂ and thromboxanes (TxA₂ and TxB₂). In addition, inhibition of prostaglandin synthesis affects other inflammatory mediators such as quinine, causing an indirect effect in addition to the direct effect.

In animal and human experiments, dexketoprofen has been shown to be an inhibitor of COX-1 and COX-2 activities.

Clinical studies in various pain models have shown that dexketoprofen trometamol has an effective analgesic effect. Onset of analgesic activity was achieved 30 minutes after administration in some studies. The analgesic effect lasts 4-6 hours.

5.2. Pharmacokinetic properties

Absorption:

Topically applied dexketoprofen shows percutaneous absorption in very small amounts. No systemic effects are expected due to low systemic bioavailability.

Distribution:

The distribution half-life of dexketoprofen trometamol is 0.35 hours. As with other drugs with high plasma protein binding (99%), the mean value of the volume of distribution is less than 0.25 l/kg.

Biotransformation:

The fact that only S-(+) enantiomer is obtained in the urine after administration of dexketoprofen trometamol indicates that there is no conversion to the R-(-) enantiomer in humans. In multi-dose pharmacokinetic studies, it was observed that the AUC (area under the curve) after the last administration was not different from that obtained after a single dose administration, indicating that drug accumulation did not occur.

Elimination:

The elimination half-life value of dexketoprofen trometamol is 1.65 hours. The major route of elimination of dexketoprofen is renal excretion following glucuronide conjugation.

Linearity/Non-linearity:

Dexketoprofen trometamol has demonstrated linear pharmacokinetics with a dose-dependent increase during systemic exposure following oral dosing.

5.3. Preclinical safety data

Conventional safety pharmacology reveals no special hazard to humans, which is based on studies of repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

6. PHARMACEUTICAL PROPERTIES

6.1. List of excipients

Lavender essence

Carbomer

Ethyl alcohol

Deionized water

Potassium hydroxide solution

6.2. Incompatibilities

There is no known incompatibility.

6.3. Shelf Life

24 months

6.4. Special measures for storage

Keep ELEKTRA out of sight and reach of children and in its packaging.

Store below 30°C.

6.5. Nature and content of the packaging

In the box, it is packaged in an aluminum tube (60 g) with a cap with a white HDPE opercle cone.

6.6. Disposal of residual substances of medicinal product for human use and other special measures

Unused products or waste materials must be disposed of in accordance with the "Regulation on the Control of Medical Wastes" and the "Regulation on the Control of Packaging and Packaging Wastes".

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]