PROFESSIONAL INFORMATION FOR

K-FENAK GEL

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

K-FENAK GEL (1,16 % *m/m* diclofenac diethylammonium gel)

2. QUALITATIVE AND QUANTITAVE COMPOSITION

10 g K-FENAK GEL contains 0,116 g (1,16 % *m/m*) diclofenac diethylammonium corresponding to 1 % *(m/m)* diclofenac sodium.

Preservatives:

Chlorocresol .....0,12 % *m/m*

Benzyl alcohol ..... 1 % *m/m*

For full list of excipients, see **section 6.1.**

3. PHARMACEUTICAL FORM

Gel.

Translucent off-white gel with characteristic lavender odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

K-FENAK GEL is indicated for the symptomatic relief of localised, traumatic inflammation and pain.

4.2 Posology and method of administration

Depending on the size of the painful site to be treated, apply 2 g to 4 g K-FENAK GEL three to four times daily to the affected parts and rub in gently.

After application, the hands should be washed, unless they are the site being treated.

The duration of treatment will be determined by the initial indication and the relief obtained.

It is recommended that treatment be reviewed after two weeks.

Use the lowest effective dose for the shortest possible duration of treatment.

Children:

Not recommended, as safety and efficacy have not been established in children.

4.3 Contraindications

K-FENAK GEL is contraindicated in:

- Patients who have previously exhibited hypersensitivity to diclofenac, acetylsalicylic acid and other non-steroidal anti-inflammatory drugs, as well as to isopropyl alcohol or propylene glycol, or any of the other ingredients of K-FENAK GEL.
- Patients in whom aspirin and other non-steroidal anti-inflammatory medicine induce

symptoms of asthma, rhinitis, angio-oedema or urticaria.

- Patients with porphyria.
- Pregnant and lactating women as safety has not been established.
- Children.

4.4 Special warnings and precautions for use

The possibility of experiencing systemic adverse events from application of K-FENAK GEL cannot be excluded if the preparation is used at higher dosages/large amounts over large areas of skin and over a prolonged period.

During prolonged treatment with K-FENAK GEL, blood counts and monitoring of hepatic and renal function are indicated as precautionary measures.

Concomitant use of systemic NSAIDs should be cautioned since the possibility of an increase in incidence of untoward effects, particularly systemic side effects, cannot be ruled out.

K-FENAK GEL contains propylene glycol, which may cause mild, localised skin irritation in some people.

If local irritation develops, use of the gel should be discontinued and appropriate therapy should be instituted.

Mild but transient skin discolouration and staining of clothing may occur if the gel is not rubbed in completely.

K-FEANK GEL should be applied only to intact skin surfaces, and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes.

Not to be taken by mouth.

K-FENAK GEL should be used with caution in asthmatic patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or by other medicines with prostaglandin-synthetase inhibiting activity.

Patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity.

K-FENAK GEL can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

Occlusion can lead to an increase in the amount of diclofenac absorbed and may thus cause an increase in side effects.

Some possibility of gastrointestinal bleeding in those with a significant history of this condition has been reported in isolated cases.

Risk of renal tubular acidosis and hypokalaemia are associated with non-steroidal anti-inflammatory medicine (NSAID) usage.

K-FENAL GEL is contraindicated in pregnancy and lactation (see **section 4.3**).

4.5 Interaction with other medicines and other forms of interaction

Since systemic absorption of diclofenac from a topical application is very low such interactions are unlikely.

Interactions with systemically absorbed diclofenac:

When administered concomitantly with lithium, the concentration of lithium in the blood may rise.

The bioavailability of K-FENAK GEL is reduced by acetylsalicylic acid, and that of acetylsalicylic acid by K-FENAK GEL when the two medicines are administered together.

4.6 Fertility, pregnancy and lactation

Pregnancy

K-FENAK GEL should not be used during pregnancy, as safety and efficacy in pregnancy has not been established (see **section 4.3**).

For NSAIDs, such as K-FENAK GEL, with systemic uptake:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. An increased risk of miscarriage and of cardiac malformation and gastroschisis has been reported after use of a prostaglandin synthesis inhibitor in early pregnancy. The risk is believed to increase with dose and duration of therapy.

Use of NSAIDs during the third trimester of pregnancy may result in premature closure of the foetal ductus arteriosus *in utero* and possibly in persistent pulmonary hypertension of the newborn.

The onset of labour may be delayed, and its duration increased (see **section 4.3**).

Use of NSAIDs, such as K-FENAK GEL, around 20 weeks gestation or later in pregnancy may cause a rare but serious foetal renal dysfunction leading to oligohyramnios and, in some cases, neonatal renal impairment.

Complications of prolonged oligohydramnios include limb contractures and delayed lung maturation, which may require invasive procedures such as exchange transfusion or dialysis, in some cases.

Breastfeeding

K-FENAK GEL should not be used during lactation, as safety and efficacy in lactation has not been established (see **section 4.3**).

Fertility

There are no data available on the use of topical formulations of diclofenac, such as K-FENAK GEL, and its effect on fertility in humans.

4.7 Effects on ability to drive and use machines

Cutaneous application of K-FENAK GEL has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Tabulated summary of adverse reactions

Infections and infestations

Less frequent: Rash pustular.

Blood and lymphatic system disorders

Less frequent: Dyshaemopoiesis (aplastic anaemia, thrombocytopenia, leucopenia).

Immune system disorders

Less frequent: Hypersensitivity reactions (e.g., bronchospasm, anaphylactic/anaphylactoid systemic reactions, erythema multiforme, urticaria, angioneurotic oedema.

Nervous system disorders

Frequency unknown: Headache, or slight dizziness.

Vascular disorders

Less frequent: Peripheral oedema

Respiratory, thoracic and mediastinal disorders

Less frequent: Asthma.

Gastrointestinal disorders

Less frequent: Gastro-intestinal ulceration or haemorrhage.

Frequency unknown: Epigastric pain, eructation, nausea, diarrhoea.

Hepato-biliary disorders

Less frequent: Jaundice, hepatitis.

Skin and subcutaneous tissue disorders

Frequent: Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritis.

Less frequent: Dermatitis bullous, photosensitivity reaction.

Frequency unknown: Mild to moderate skin irritation, reddening, desquamation, skin discolouration.

Renal and urinary disorders

Less frequent: Renal failure and nephrotic syndrome.

Investigations

Less frequent: Elevated transaminase levels.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Side effects may also be reported directly to Cipla Medpro (Pty) Ltd: drugsafetysa@cipla.com

4.9. Overdose

Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression; specific therapies such as forced diuresis, dialysis or haemoperfusion are not effective in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

In the event of significant systemic side effects occurring as a result of improper use or accidental overdosage, general therapeutic measures of the kind normally adopted in order to treat poisoning with non-steroidal anti-inflammatory agents should be resorted to.

The use of activated charcoal should be considered, especially within a short time (within one hour) of ingestion of a toxic dose.

5. PHARMACOLOGIAL PROPERTIES

5.1 Pharmacodynamic properties

A 3.1 Antirheumatics (anti-inflammatory agents).

Pharmacotherapeutic group:

Non-steroidal anti-inflammatory drug (NSAID).

ATC code:

M02AA15

Diclofenac is a non-steroidal anti-inflammatory, and analgesic agent. The gel is intended for topical use to provide a local anti-inflammatory, analgesic effect in inflammatory reactions.

Diclofenac exerts its therapeutic effects primarily through inhibition of prostaglandin synthesis by cyclo-oxygenase 2 (COX-2).

5.2 Pharmacokinetic properties

Absorption

The amount of diclofenac absorbed through the skin is relative to the contact time and the area covered with the gel. Protein binding is 99,7%.

Elimination

The mean terminal elimination half-life of the unchanged medicine is 1 to 2 hours.

Excretion

Diclofenac and its metabolites are excreted mainly in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol

Benzyl alcohol

Sodium sulphite

Carbomer 940

Disodium EDTA

Isopropyl alcohol

Lavender English

Liquid paraffin

Polysorbate 80

Propylene glycol

Purified water

Triethanolamine

6.2 Incompatibilities

None known.

6.3 Shelf-life

36 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Store in a well closed container, protected from moisture.

6.5 Nature and contents of container

30 g pure aluminium collapsible tubes packed in a carton. (3.2.P.7)

6.6 Special precautions for disposal

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

RSA

8. REGISTRATION NUMBER(S)

30/3.1/0031

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16 March 1998

10. DATE OF REVISION OF THE TEXT

19 July 2023