

PATIENT INFORMATION LEAFLET FOR
K-FENAK GEL

SCHEDULING STATUS

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

Diclofenac diethylammonium corresponding to 1 % (*m/m*) diclofenac sodium

Read all of this leaflet carefully because it contains important information for you

- K-FENAK GEL is available without a doctor's prescription, for you to treat a mild illness.
Nevertheless, you still need to use K-FENAK GEL carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share K-FENAK GEL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet:

1. What K-FENAK GEL is and what it is used for
2. What you need to know before you use K-FENAK GEL
3. How to use K-FENAK GEL
4. Possible side effects
5. How to store K-FENAK GEL
6. Contents of the pack and other information.

1. What K-FENAK GEL is and what it is used for

K-FENAK GEL belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) and provides a local anti-inflammatory and analgesic effect in inflammatory reactions. This means it will help to relieve pain and reduce swelling affecting the joints.

K-FENAK GEL is used for:

- the symptomatic relief of localised, traumatic inflammation and pain.

2. What you need to know before you use K-FENAK GEL

Do not use K-FENAK GEL:

- if you are allergic to diclofenac, acetylsalicylic acid (aspirin) and other non-steroidal anti-inflammatory drugs such as ibuprofen, as well as to isopropyl alcohol or propylene glycol, or any of the other ingredients of K-FENAK GEL (listed in **section 6**).
- if you are allergic to aspirin or other anti-inflammatory drugs (NSAIDs), which may arise as asthma, rhinitis, angio-oedema or urticaria.
- if you have porphyria.
- if you are a child.
- if you are pregnant or breastfeeding your baby (see “**Pregnancy, breastfeeding and fertility**”).

Warnings and precautions

Take special care with K-FENAK GEL:

- when applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- if you are using any other medicines containing diclofenac or painkillers known as NSAIDs,

such as aspirin or ibuprofen.

- if you have liver and kidney problems.
- if local irritation develops.
- temporary skin discolouration or staining of clothing may occur if K-FENAK GEL is not rubbed in completely.
- do not apply the gel to skin that has a rash, eczema, cuts or an open wound. K-FENAK GEL should only be applied to skin surfaces that are intact.
- K-FENAK GEL should only be applied to the skin and should not be taken by mouth.
- if you have asthma and have experienced asthma attacks, hives or runny nose when taking acetylsalicylic acid (aspirin) or other painkillers such as naproxen, or ibuprofen.
- if you are sunbathing or using sun lamps as your skin may be more sensitive to sunlight.
- K-FENAK GEL can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.
- if you currently, or previously suffered from a stomach or duodenal ulcer tell your doctor or pharmacist before using K-FENAK GEL.
- Risk of renal impairment and low potassium levels are associated with non-steroidal anti-inflammatory medicine (NSAID) usage.
- if you are pregnant or breastfeeding your baby (see **“Do not use K-FENAK GEL”**).

Other medicines and K-FENAK GEL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Ask your doctor or pharmacist for advice before you use K-FENAK GEL if you are also taking lithium (used for mood disorders), or acetylsalicylic acid (aspirin).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before using K-FENAK GEL.

K-FENAK GEL should not be used while you are pregnant or breastfeeding your baby.

K-FENAK GEL may harm your unborn baby during pregnancy and may cause problems during delivery. At around 20 weeks or later in pregnancy K-FENAK GEL may cause kidney problems in your unborn baby, which may lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn baby's lungs and muscles develop. Complications can occur with low levels of this fluid.

Driving and using machines

K-FENAK GEL is not expected to have any effect on your ability to drive and use machines.

It is not always possible to predict to what extent K-FENAK GEL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which K-FENAK GEL affects them.

K-FENAK GEL contains propylene glycol

K-FENAK GEL contains propylene glycol. Propylene glycol may cause skin irritation.

3. How to use K-FENAK GEL

Do not share medicines prescribed for you with any other person.

Always use K-FENAK GEL exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 skin and rub in gently.

After application, your 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.

Treatment should be reviewed after two weeks.

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

Children:

Not recommended.

If you use more K-FENAK GEL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use K-FENAK GEL

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

K-FENAK GEL can have side effects.

Not all side effects reported for K-FENAK GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using K-FENAK GEL, please consult your healthcare provider for advice.

If any of the following happens, stop using K-FENAK GEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- hypersensitivity (allergic) reaction manifested by cutaneous rash (skin eruption with redness), shortness of breath, and difficulty of swallowing.
- wheezing, shortness of breath or feeling of tightness in the chest (bronchospasm, or asthma).
- blistering skin rash (erythema multiforme), or hives (urticaria).

These are all very serious side effects. If you have them, you may have had a serious reaction to K-FENAK GEL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- yellowing of the skin and eyes (jaundice), dark urine, pale stool and tiredness which may be symptoms of liver problems (hepatitis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- skin rash, or dry, scaly patches on the skin (eczema).
- reddening of the skin (erythema), skin inflammation (dermatitis), or itching (pruritis).

Less frequent side effects:

- pimple forming skin rash.
- bruising of the skin, unusual bleeding, pinpoint red spots on the skin, bleeding from the gums, pale skin, shortness of breath upon exertion, unusual tiredness or weakness, fever

and chills, as these symptoms may be due to abnormal blood cell and platelet counts.

- swelling of the legs, ankles or feet (peripheral oedema).
- nausea, stomach pain, bloody or tarry stools, or vomiting blood or a substance that looks like coffee grounds, as these may be symptoms of a stomach ulcer or bleeding.
- skin rash in areas exposed to the sun.
- decreased urine or foamy urine, swelling of the ankles or feet, shortness of breath and loss of appetite, as these may be symptoms of kidney problems or kidney failure.

Side effects with unknown frequency:

- headache, or slight dizziness.
- stomach pain, eructation (burping or belching), nausea, diarrhoea.
- skin irritation, peeling or flaky skin (desquamation), skin discolouration.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction 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: drugsafety@cipla.com.

By reporting side effects, you can help provide more information on the safety of K-FENAK GEL.

5. How to store K-FENAK GEL

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in a well closed container, protected from moisture.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

6. Contents of the pack and other information

What K-FENAK GEL contains

The active substance is diclofenac diethylammonium 1,16 % *m/m*.

Preservatives:

Chlorocresol 0,12 % *m/m*

Benzyl alcohol 1 % *m/m*

The other ingredients are sodium sulphite, carbomer 940, disodium EDTA, isopropyl alcohol, lavender English, liquid paraffin, polysorbate 80, propylene glycol, purified water, triethanolamine.

What K-FENAK GEL looks like and contents of the pack

Translucent off-white gel with characteristic lavender odour.

30 g metal tubes.

Holder of certificate of registration

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7530

This leaflet was last revised

19 July 2023

Registration number

30/3.1/0031