PATIENT INFORMATION LEAFLET FOR

K-FENAK OTC TABLETS

SCHEDULING STATUS

S2

K-FENAK OTC 50 mg tablets

Diclofenac potassium

Contains sugar: Lactose monohydrate 81,00 mg

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

K-FENAK OTC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use K-FENAK OTC carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- Do not share K-FENAK OTC with any other person.
- Ask your 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 OTC is and what it is used for
2. What you need to know before you take K-FENAK OTC
3. How to take K-FENAK OTC
4. Possible side effects
5. How to store K-FENAK OTC
6. Contents of the pack and other information.

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

K-FENAK OTC (diclofenac potassium) belongs to a class of medicines known as nonsteroidal anti-inflammatory drugs (NSAIDS). It works by reducing hormones that cause inflammation, pain and fever.

K-FENAK OTC is indicated for:

- The emergency (short-term) treatment of sudden gout attacks for a maximum treatment period of 3 days.
- The treatment of fever or mild to moderate pain of inflammatory origin, for a maximum period of 5 days (see **"HOW TO TAKE K-FENAK OTC"**).

2. What you need to know before you take K-FENAK OTC

Do not take K-FENAK OTC

- If you are allergic (hypersensitive) to diclofenac or to any of the inactive ingredients of K-FENAK OTC (listed in **section 6**).
- If you are allergic (hypersensitive) to other non-steroidal anti-inflammatory medicines (NSAIDs) e.g. aspirin, ibuprofen, naproxen.
- If you have been diagnosed with a stomach ulcer or ulcer of the gut.
- If you have a history of bleeding or perforation of the stomach or gut related to previous NSAID or K-FENAK OTC use.
- If you currently have, or previously had, recurrent ulcers / bleeding / perforations of the stomach or gut.
- If you have been diagnosed with asthma or if previous use of aspirin (acetylsalicylic acid) or other NSAIDs have caused asthma attacks or difficult breathing, runny nose or hives (see **Warnings and Precautions**).
- If you are pregnant or breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).
- If you have been diagnosed with porphyria.

- If you have kidney or liver failure (see **Warnings and Precautions**).
- If you have heart failure or have experienced heart problems, stroke or reduced blood flow to your limbs (peripheral arterial disease) (see **Warnings and Precautions**).

Warnings and Precautions

Take special care with K-FENAK OTC:

Please inform your doctor or pharmacist if any of the following applies to you, as you may require medical supervision or special precautions while you are taking K-FENAK OTC:

- If you have a history of high blood pressure or heart failure, as you may experience swelling of the ankles or lower limbs, which may cause further heart problems.
- If you have high blood cholesterol levels, diabetes mellitus or if you are a smoker.
- If you are elderly, as you may experience adverse reactions of the gut more frequently that may cause ulcers or bleeding and which may be life-threatening.
- If you have been diagnosed with any disease of the gut, or if you have a history of stomach ulcer, perforation or bleeding from the gut. Do not take K-FENAK OTC, unless under supervision of your doctor (see **"Do NOT take K-FENAK OTC"**). The risk of such side effects is higher with increasing doses of K-FENAK OTC.
- If you have been diagnosed with inflammatory bowel diseases (such as ulcerative colitis or Crohn's disease), hiatus (diaphragmatic) hernia, acid reflux, or abnormal blood vessels in the gut (angiodysplasia).
- If you are taking blood thinning medicines, corticosteroids or certain antidepressants (see **Other medicines and K-FENAK OTC**). You should report to your doctor if you experience any symptoms of your gut or stomach.
- If you are pregnant or breastfeeding your baby (see **"Do NOT take K-FENAK OTC"**).
- If you have fever or other symptoms of infection.

- If you are taking other medicines for pain and inflammation, e.g. aspirin, ibuprofen, naproxen, or celecoxib (see **Other medicines and K-FENAK OTC**).
- If you are taking methotrexate, an immune suppressant (see **Other medicines and K-FENAK OTC**).
- If you are elderly, very frail or have a low body weight, as you may require a reduction in dosage of K-FENAK OTC.
- If you have asthma, swelling or growths inside your nose, runny nose, airway infections or difficult breathing, as you may be more prone to adverse reactions to K-FENAK OTC, such as worsening of asthma, hives or swelling of the face, lips, or tongue.

  If you experience any of these side effects or if you have allergies to other medicines that cause itching, skin reactions or hives, stop taking K-FENAK OTC and report to your doctor immediately (see **"Do NOT take K-FENAK OTC"**).
- If you have been diagnosed with liver problems, or liver failure (see **"Do NOT take K-FENAK OTC"**).
- If you have kidney problems, as K-FENAK OTC may cause fluid retention (known as oedema) that may lead to heart failure (see **"Do NOT take K-FENAK OTC"** and **"POSSIBLE SIDE EFFECTS"**). Stop taking K-FENAK OTC and immediately report to your doctor if you develop swelling of the feet, ankles, lower legs, hands, or face.
- If you have been diagnosed with heart failure or heart problems, if you have a history of high blood pressure, if you are taking diuretics ("water pills") or medicines that can affect your kidney function, or if you are dehydrated from any cause (e.g. before or after surgery) (see **Other medicines and K-FENAK OTC**).

  Your doctor may need to monitor your kidney function while you are taking K-FENAK OTC. Stop taking K-FENAK OTC and immediately report to your doctor if you are unable to pass urine, produce much less urine than usual, if your urine turns the colour of coffee or tea, or if you experience pain with urination.

- If you have been diagnosed with bleeding / blood clotting disorders, as you may require blood tests.

Serious side effects of K-FENAK OTC, such as bleeding from the stomach or gut, ulcers, or perforation of the gut (which may be life-threatening) may occur at any time, without warning symptoms, in any person taking K-FENAK OTC, regardless of whether you are taking K-FENAK OTC for short periods of time only (see **"POSSIBLE SIDE EFFECTS"**).
The risk of developing bleeding from the gut is also higher with increasing doses of K-FENAK OTC and if you are elderly. Always take the lowest effective dose of K-FENAK OTC (see **"HOW TO TAKE K-FENAK OTC"**).

Stop taking K-FENAK OTC and immediately report to your doctor if you vomit blood or a substance resembling coffee grounds, if you pass black, foul-smelling, tarry stools, or if you develop stomach pain. If you develop heartburn or reflux of stomach acid while taking K-FENAK OTC, stop taking K-FENAK OTC and report to your doctor as soon as possible.

Life-threatening skin reactions and allergic reactions, including blistering skin rashes, have occurred with K-FENAK OTC (see **"POSSIBLE SIDE EFFECTS"**). If you develop a skin rash, especially a blister-forming skin rash, lesions inside your mouth, or swelling of your face, lips, or tongue, hives, itching or difficult breathing, stop taking K-FENAK OTC and immediately report to your doctor.
If you feel faint due to low blood pressure, or pain in a specific area that may be due to inflammation of a vein, or cough or shortness of breath, stop taking K-FENAK OTC and report to your doctor as soon as possible.

If you develop jaundice (yellow discolouration of the skin or whites of the eyes), nausea and vomiting, loss of appetite, pain below the right rib cage and develop a rash, you should stop

taking K-FENAK OTC and immediately report to your doctor (see **"POSSIBLE SIDE EFFECTS"**). K-FENAK OTC may cause liver damage, which may include inflammation of the liver (hepatitis) that can be life-threatening. Inflammation of the liver may occur even if you do not experience these side effects. If you are prescribed K-FENAK OTC on a long-term basis, your doctor may have to monitor your liver function.

K-FENAK OTC may temporarily reduce the ability of your blood platelets to form blood clots and you may find that you bleed longer than usual following minor injuries. Stop taking K-FENAK OTC and report to your doctor as soon as possible if you experience blood in the urine, bleeding of the gums, or easy bruising. If you are prescribed K-FENAK OTC on a long-term basis, your doctor may have to monitor your blood cell counts.

Risk of renal impairment and low potassium levels are associated with non-steroidal anti-inflammatory medicine (NSAID) usage.

Other medicines and K-FENAK OTC

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines).
Please discuss the use of K-FENAK OTC with your doctor or pharmacist if you are taking any of the following medicines, as you may require a dose adjustment or special precaution:

- Methotrexate to suppress the function of your immune system, as K-FENAK OTC may increase your risk of experiencing side effects due to methotrexate.
- Lithium for psychiatric disorders, as K-FENAK OTC may increase blood levels of lithium and you may have to go for blood tests to monitor your blood lithium levels.

- Digoxin for heart failure or heart rhythm disorders, as K-FENAK OTC in combination with digoxin may increase your risk of developing heart failure, kidney damage, and/or other side effects.
- Blood pressure lowering medicines, e.g. perindopril, enalapril or propranolol, or diuretics ("water pills"), e.g. hydrochlorothiazide or furosemide, as K-FENAK OTC may reduce the blood pressure lowering effect of these medicines (see **Warnings and Precautions**). You may have to monitor your blood pressure more frequently while you are taking K-FENAK OTC. You should drink enough water to remain hydrated, and your doctor may monitor your kidney function and blood potassium levels.
- Corticosteroids, such as prednisone or prednisolone, since these medicines in combination with K-FENAK OTC may increase your risk of bleeding from the gut or developing a stomach ulcer.
- Other medicines for pain and inflammation, such as NSAIDs (e.g. aspirin, ibuprofen or naproxen), and cyclo-oxygenase-2 selective inhibitors (e.g. celecoxib), as you may experience increased side effects of K-FENAK OTC.
- Antidiabetic medicines, such as metformin, gliclazide, glimepiride, as you may experience low or high blood sugar levels while you are taking K-FENAK OTC. You should monitor your blood sugar levels more frequently while you are taking K-FENAK OTC.
- Blood thinning medicines, e.g. warfarin, since combination with K-FENAK OTC may increase your risk of bleeding (see **Warnings and Precautions**).
- Medicines that reduce platelet function, such as aspirin or clopidogrel, since combining these medicines with K-FENAK OTC may increase your risk of bleeding from the gut (see **Warnings and Precautions**). Combining these medicines will decrease the effect of both aspirin and K-FENAK OTC.

- Antidepressants known as selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine, sertraline), since combining these medicines with K-FENAK OTC may increase your risk of bleeding from the gut.
- Ciclosporin to suppress the function of your immune system, since there is a possible increased risk of kidney damage when K-FENAK OTC is taken concurrently.
- Quinolone antibiotics, e.g. ciprofloxacin, norfloxacin, moxifloxacin, as K-FENAK OTC in combination with these antibiotics may increase your risk of experiencing convulsions / seizures.

K-FENAK OTC with food, drink and alcohol

K-FENAK OTC should preferably be taken with or after food.

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 health care provider for advice before taking K-FENAK OTC.

Pregnancy:

Do NOT take K-FENAK OTC while you are pregnant, as safety has not been established. Taking K-FENAK OTC while you are pregnant can harm your baby (see **"Do NOT take K-FENAK OTC"**).

Do not take K-FENAK OTC around 20 weeks or later in pregnancy as it 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 babies lungs and muscles develop. Complications can occur with low levels of this fluid.

Breastfeeding:

Do not take K-FENAK OTC while you are breastfeeding your baby, as K-FENAK OTC may pass into breast milk and may cause undesirable effects in your baby (see **"Do NOT take K-FENAK OTC"**).

Fertility:

The use of K-FENAK OTC may impair your chances of falling pregnant and you should not take K-FENAK OTC if you are planning a pregnancy. You should speak to your doctor about taking K-FENAK OTC if you have difficulties conceiving a baby or if you are undergoing investigation of infertility.

Driving and using machinery

K-FENAK OTC may cause dizziness, the feeling that you or your environment is moving or spinning, blurred vision, sleepiness, or other symptoms such as tiredness. You should refrain from driving a car or operating machinery until you know how K-FENAK OTC affects you.

It is not always possible to predict to what extent K-FENAK OTC 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 OTC affects them.

K-FENAK OTC contains Colloidal anhydrous silica, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, lecithin (soya), partially hydrolysed polyvinyl alcohol, talc, titanium dioxide and xanthan gum.

K-FENAK OTC contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

K-FENAK OTC contains lactose If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking K-FENAK OTC.

3. How to take K-FENAK OTC

Do not share your medicine with any other person.

Always take K-FENAK OTC exactly as directed. You should check with your pharmacist if you are unsure.

USE THE LOWEST EFFECTIVE DOSE FOR THE SHORTEST POSSIBLE DURATION OF TREATMENT.

Adults

- For the emergency (short-term) treatment of sudden gout attacks:

  100 mg to 150 mg (2 to 3 tablets) in two to three divided doses, with a maximum daily dose of 150 mg (3 tablets).

  THE MAXIMUM TREATMENT PERIOD OF 3 DAYS SHOULD NOT BE EXCEEDED.

- For the treatment of fever or mild to moderate pain of inflammatory origin:

  75 mg (1,5 tablets) daily.

  THE MAXIMUM TREATMENT PERIOD OF 5 DAYS SHOULD NOT BE EXCEEDED.

If you take more K-FENAK OTC than you should

In the event of an overdosage you may experience side effects such as bleeding of the gut, vomiting, diarrhoea (loose stools), ringing in the ears, dizziness or convulsions / seizures, kidney failure and liver damage.

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

If you forget to take K-FENAK OTC

Always take K-FENAK OTC as directed. If you forget a dose, take it as soon as you remember. If you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual dose.

4. Possible Side Effects

K-FENAK OTC can have side effects.

Not all side effects reported for K-FENAK OTC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking K-FENAK OTC, please consult your doctor, pharmacist or other healthcare professional for advice**.**

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

- Allergic reactions, which may cause fever and skin rash, tightness of the chest, wheezing, hives or itching, or swelling of the lips, face, tongue, or hands including very low blood pressure.
- Swelling of the feet or ankles, hands or face accompanied by shortness of breath and extreme fatigue.
- Yellow discolouration of the skin or whites of the eyes with or without pain over the liver area, as this may be due to liver damage or inflammation of the liver, which may be life-threatening. Your doctor may monitor your liver function as elevated liver enzyme levels (ALT, AST) may occur frequently.
- Any blister-forming skin rash or skin rash in areas exposed to the sun.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to K-FENAK OTC. 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:

- Easy bruising, 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/or chills, as a combination of these symptoms may be due to abnormal blood cell and platelet counts.
- Convulsions / seizures.
- Severe headache accompanied by nausea and/or vomiting with or without neck stiffness.
- Paralysis or weakness of one side of the body with or without loss of consciousness, slurred speech or loss of function of a body part.
- Chest pain radiating to the chin or down the left arm accompanied by nausea, vomiting or shortness of breath.
- Asthma (including shortness of breath), cough, fever, and difficult breathing.
- Vomiting of blood or a substance resembling coffee grounds, blood in the stool, or passing foul-smelling, black, tarry stools. These symptoms indicate serious bleeding of the stomach or gut, which may be life-threatening.
- Stomach pain and cramping, loose stools with or without blood or pus, vomiting or weight loss, fever, or rectal pain.
- Severe stomach pain, loss of appetite, vomiting, fever and generally feeling unwell, as this may indicate inflammation of the pancreas.

- Nausea, vomiting, belching, bloating, feeling full, loss of appetite, unexplained weight loss, which may be due to inflammation of the lining of the stomach.
- A red, scaly skin rash or purplish or reddish areas on the skin.
- Cloudy, dark or discoloured urine, reduced frequency of urination, difficulty passing urine, pain over the bladder or kidneys and swelling of the feet, legs or hands. Your doctor may monitor you for urinary changes, such as blood or protein in the urine.
- The feeling that you or your environment is moving or spinning.
- Rash and skin reactions.
- Psychotic reactions, causing symptoms such as seeing or hearing things that are not real, feeling confused, having disturbed thoughts or a lack of self-awareness.
- Disturbances of sensation, such as pins and needles, memory problems, anxiety.
- Loss of hearing, ringing in the ears.
- Blurred vision, double vision.
- Palpitations, chest pain.
- Pain in a specific area that may be due to inflammation of a vein.
- Increased blood pressure.
- Swollen tongue, with a smooth appearance and a change in colour, ulcers inside the mouth or on the lips, pain on swallowing, or difficult swallowing.
- Hives, itching.

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

Tell your doctor if you notice any of the following:

- Headache, dizziness, nervousness.

- Stomach pain, discomfort or cramps, nausea, vomiting, diarrhoea (loose stools), indigestion, flatulence (gas), belching / burping, loss of appetite.
- Disorientation, sleeplessness, irritability, depression, nightmares.
- Tiredness, tremors / shakiness, sleepiness, taste disturbances.
- Constipation, alteration in taste.
- Dry, red, scaly skin rash (eczema), hair loss.

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, pharmacist or nurse. 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 or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of K-FENAK OTC.

5. How to store K-FENAK OTC

Store at or below 25 °C

Store in a dry place

Store all medicines out of reach of children.

Keep the blister in the outer carton until required for use.

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

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What K-FENAK OTC contains

The active substance is diclofenac potassium.

The other ingredients are:

Tablet Core:

Colloidal anhydrous silica,

Crospovidone,

Lactose monohydrate,

Magnesium stearate,

Microcrystalline cellulose,

Povidone

Tablet Coating (Opadry AMB OY-28920 (White)):

Lecithin (soya),

Partially hydrolysed polyvinyl alcohol,

Talc,

Titanium dioxide,

Xanthan gum.

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

White, circular, biconvex, film-coated tablets plain on both sides

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care 080 222 6662

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