PATIENT INFORMATION LEAFLET FOR

K-FENAK ANTI-INFLAMMATORY (TABLETS)

SCHEDULING STATUS

S3

K-FENAK ANTI-INFLAMMATORY (50 mg Tablets)

Diclofenac potassium

Contains sugar (lactose monohydrate 81 mg)

Read all of this leaflet carefully before you start taking K-FENAK ANTI-INFLAMMATORY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- K-FENAK ANTI-INFLAMMATORY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What K-FENAK ANTI-INFLAMMATORY is and what it is used for:

K-FENAK ANTI-INFLAMMATORY is in a class of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). It works by reducing hormones that cause inflammation, pain and fever in the body.

K-FENAK ANTI-INFLAMMATORY is used to treat painful conditions of muscles, tendons, joints and bones (rheumatism, rheumatoid arthritis, ankylosing spondylitis, osteoarthrosis, spondylarthritis, muscle pain, non-articular rheumatism), acute gout attacks, post-trauma pain, swelling and inflammation, pain after operations, and menstrual pain.

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

Do not take K-FENAK ANTI-INFLAMMATORY:

- if you are hypersensitive (allergic) to diclofenac or any of the other ingredients of K-FENAK ANTI-INFLAMMATORY (listed in **section 6**).
- if you have currently or previously had a gastric or intestinal ulcer, bleeding or perforation, or a history of such a side effect to other nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin, ibuprofen, or naproxen.
- if you have asthma and have previously experienced an asthma attack, severe allergic reaction, hives, sneezing or a runny nose when taking aspirin or other NSAIDs.
- if you have porphyria, K-FENAK ANTI-INFLAMMATORY may trigger an attack.
- if you are pregnant (see **Pregnancy, breastfeeding and fertility**).
- if you are under the age of 14 years.
- if you have liver or kidney failure.
- if you have heart failure, have suffered a heart attack or stroke, or have blood circulation problems.

- if you are allergic to peanuts or soya, as K-FENAK ANTI-INFLAMMATORY contains lecithin (soya).

Warnings and precautions

Take special care with K-FENAK ANTI-INFLAMMATORY:

- you should take the lowest effective dose for the shortest duration possible to reduce the risk of developing side effects. If you are not sure, check with your doctor or pharmacist.
- if you are taking other medicines for the treatment of pain or inflammation, such as aspirin, ibuprofen, naproxen or celecoxib.
- if you are elderly (over 65 years of age).
- if you develop signs of allergic reaction, such as swelling of the face, mouth, throat or tongue, difficult breathing, a blistering skin rash, hives, itching, or chest pain. You should stop taking K-FENAK ANTI-INFLAMMATORY and contact your doctor or healthcare provider.
- K-FENAK ANTI-INFLAMMATORY may mask the signs and symptoms of infection.
- if you have symptoms relating to a gastrointestinal disease, such as an ulcer, vomiting blood, or passing black tarry stools. You should stop taking K-FENAK ANTI-INFLAMMATORY and contact your doctor or healthcare provider.
- if you have a history of gastrointestinal ulceration, ulcerative colitis or Crohn's disease, hiatus hernia, acid reflux, angiodysplasia (an abnormality of the blood vessels in the gut), or surgery of the gut.
- if you are taking corticosteroids (such as prednisone or hydrocortisone), anticoagulants (such as warfarin), selective serotonin-reuptake inhibitors (SSRIs) (such as citalopram, fluoxetine, sertraline), anti-platelet medicines (such as acetylsalicylic acid), or methotrexate.

- Tell your doctor if you have any of the following as you may require a lower dose or special monitoring:
    - if you have impaired liver or kidney function, or porphyria.
    - if you have any heart problems, high blood pressure, high blood cholesterol levels, diabetes or are a smoker. If you experience chest pain, shortness of breath, weakness, or slurring of speech you should stop taking K-FENAK ANTI-INFLAMMATORY and report to your doctor.
    - if you are taking diuretics ("water tablets"), or are dehydrated.
    - if you have recently had an operation performed.
    - if you have systemic lupus erythematosus or other connective tissue disorders.
    - if you have a pre-existing blood disorder or bleeding disorder.
    - if you have asthma, a runny nose due to allergies, problems with the lining inside your nose (nasal polyps), chronic obstructive pulmonary disease or recurring infections of the lungs.
    - if you are a woman attempting to conceive a baby or are struggling to conceive.
- Risk of renal impairment and low potassium levels are associated with non-steroidal anti-inflammatory medicine (NSAID) usage.

Other medicines and K-FENAK ANTI-INFLAMMATORY

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

If you are taking the following in addition to K-FENAK ANTI-INFLAMMATORY please tell your doctor or pharmacist. In certain cases, your doctor may want to change the dose, or other precautions may be necessary:

- lithium (for depression), as K-FENAK ANTI-INFLAMMATORY may intensify its effect.

- cardiac glycosides, such as digoxin (for heart problems), as K-FENAK ANTI-INFLAMMATORY may intensify their effect and may worsen heart problems.
- diuretics (“water tablets”) and medicines for treating high blood pressure e.g. beta-blockers (such as propranolol, bisoprolol, atenolol), or angiotensin converting enzyme (ACE) inhibitors (such as captopril, enalapril, perindopril), as K-FENAK ANTI-INFLAMMATORY may decrease their blood pressure lowering effect.
- medicines that increase blood potassium levels, such as potassium-sparing diuretics (amiloride, spironolactone, triamterene), or ciclosporin, tacrolimus or trimethoprim.
- other NSAIDs or cyclooxygenase-2 selective inhibitors, such as aspirin, ibuprofen, naproxen or celecoxib, and corticosteroids (such as prednisone or hydrocortisone), as these may aggravate the gastrointestinal side effects.
- two or more NSAIDs, as these may promote the occurrence of side effects.
- acetylsalicylic acid containing medicine, as K-FENAK ANTI-INFLAMMATORY and acetylsalicylic acid counteract each other.
- anticoagulant therapy (“blood thinners"), such as warfarin, as it is reported to increase the risk of haemorrhage (bleeding).
- selective serotonin-reuptake inhibitors (SSRIs) for depression (such as citalopram, fluoxetine, sertraline), as it may increase the risk of bleeding.
- medicines for diabetes, as K-FENAK ANTI-INFLAMMATORY may increase or decrease the blood sugar level.
- methotrexate, as K-FENAK ANTI-INFLAMMATORY may increase the effects of methotrexate, which could be harmful.
- ciclosporin or tacrolimus (immune suppressants) may result in kidney toxicity.
- quinolones, such as ciprofloxacin or levofloxacin (antimicrobial medicines) may cause convulsions (seizures).

- phenytoin (for seizures), as K-FENAK ANTI-INFLAMMATORY may increase blood levels of phenytoin.
- colestipol or cholestyramine, as you may have to take K-FENAK ANTI-INFLAMMATORY at least one hour before or 4 to 6 hours after taking these medicines.
- mifepristone, as K-FENAK ANTI-INFLAMMATORY should not be taken for 8 to 12 days after mifepristone, as it can reduce the effect of mifepristone.
- potent CYP2C9 inhibitors, such as voriconazole or sulfinpyrazone, as the blood level of K-FENAK ANTI-INFLAMMATORY may be increased.
- zidovudine (for HIV infection), as it may increase the risk of developing blood or bleeding disorders.

K-FENAK ANTI-INFLAMMATORY with food and drink

K-FENAK ANTI-INFLAMMATORY must be swallowed whole with a glass of water, and should preferably be taken at mealtimes. Also see **section 3**.

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 taking K-FENAK ANTI-INFLAMMATORY.

K-FENAK ANTI-INFLAMMATORY is contraindicated in pregnancy (see **Do not take** K-**FENAK ANTI-INFLAMMATORY**).

Taking K-FENAK ANTI-INFLAMMATORY around 20 weeks or later in pregnancy may cause rare but serious kidney problems in an unborn baby. This can lead to low levels of amniotic fluid surrounding the baby and possible complications.

K-FENAK ANTI-INFLAMMATORY should not be taken while you are breastfeeding your baby as it passes into breast milk.

If you are planning to have a baby, you should not take K-FENAK ANTI-INFLAMMATORY as it may impair fertility.

Driving and using machines

If you experience blurry vision, dizziness, a feeling that the world is spinning, sleepiness, drowsiness or fatigue while taking K-FENAK ANTI-INFLAMMATORY, you should refrain from driving or operating machinery.

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

K-FENAK ANTI-INFLAMMATORY contains lactose

K-FENAK ANTI-INFLAMMATORY contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take K-FENAK ANTI-INFLAMMATORY.

3. How to take K-FENAK ANTI-INFLAMMATORY

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

Always take K-FENAK ANTI-INFLAMMATORY exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with K-FENAK ANTI-INFLAMMATORY will last. If you have the impression that the effect of K-FENAK ANTI-INFLAMMATORY is too strong or too weak, tell your doctor or pharmacist.

Children

K-FENAK ANTI-INFLAMMATORY should not be given to children under 14 years of age (see **Do not take** K-FENAK ANTI-INFLAMMATORY).

Adults

Take the lowest effective dose for the shortest possible duration.

The usual dose is 1 tablet taken 2 to 3 times per day.

The maximum dose is 3 tablets (150 mg) per day and should not be exceeded.

For menstrual pain, the usual dose is 1 tablet taken 1 to 3 times per day, depending on the individual.

Start by taking 1 tablet, 1 to 2 times per day and, if necessary, the dose may be increased over the course of several menstrual cycles up to a maximum of 1 tablet taken 4 times per day.

You may take K-FENAK ANTI-INFLAMMATORY with the start of symptoms, and continue for a few days depending on the intensity of the pain.

K-FENAK ANTI-INFLAMMATORY tablets should be swallowed whole with a glass of water, and should preferably be taken at mealtimes.

The elderly

If you are 65 years or older you may require close monitoring. The dose of K-FENAK ANTI-INFLAMMATORY may be reduced especially if you are frail or have low body mass. Check with

your doctor or pharmacist if the dosage you are taking is correct.

If you take more K-FENAK ANTI-INFLAMMATORY than you should

If you take more K-FENAK ANTI-INFLAMMATORY than you should, you may experience an increase in side effects listed below (see **section 4**).

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 take K-FENAK ANTI-INFLAMMATORY

Take K-FENAK ANTI-INFLAMMATORY as prescribed. If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take only your next regularly scheduled dose.

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

4. Possible side effects

K-FENAK ANTI-INFLAMMATORY can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, with or without chest pain.
- blistering skin rash that may be life-threatening, itching (pruritus), hives (urticaria),

flakiness or scaling of the skin (eczema or exfoliative dermatitis), redness (erythema), or pinpoint red spots on the skin (purpura or allergic purpura).

These are all very serious side effects. If you have them, you may have had a serious reaction to K-FENAK ANTI-INFLAMMATORY. 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, tiredness or weakness, fever and/or chills, as a combination of these symptoms may be due to abnormal blood cell and platelet counts.
- fever, painful headaches, body aches, sensitivity to light, and/or vomiting, as these may be symptoms of meningitis.
- difficulty walking, dizziness, loss of balance, difficulty speaking or understanding others, numbness or paralysis on one side of the body, as these may be symptoms of a stroke (cerebrovascular accident).
- pounding heartbeat (palpitations), or chest pain.
- shortness of breath with exercise or when lying down, weakness, swelling of the legs, ankles and feet, and rapid or irregular heartbeat, as these may be symptoms of heart failure.
- tightness in the chest, with pain in the chest, back or jaw, shortness of breath and sweating, as these may be symptoms of a heart attack (myocardial infarction).
- Asthma (including difficulty breathing), or shortness of breath with a dry cough (symptoms of lung inflammation or pneumonitis).
- black, tarry or bloody stools (melaena or haemorrhagic diarrhoea), vomiting blood (haematemesis), with or without stomach cramps, as these may be symptoms of bleeding

of the gut (gastrointestinal haemorrhage), or an ulcer. This may be life-threatening, particularly in the elderly.

- inflammation of the pancreas (pancreatitis), that may cause stomach pain that radiates to your back, fever, nausea and vomiting.
- yellowing of the skin and eyes (jaundice), dark urine, and tiredness which may be symptoms of liver problems, inflammation or injury of the liver (hepatitis, fulminant hepatitis, hepatic necrosis, or hepatic failure).
- blood or protein in the urine (haematuria, proteinuria, nephrotic syndrome), less or more urine than is normal for you, swelling in your legs, ankles or feet, shortness of breath, fatigue, nausea, fever, back pain, and/or cloudy urine, as these may be symptoms of kidney injury or disease (kidney failure, interstitial nephritis, or renal papillary necrosis).

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:

- Headache, or dizziness.
- Feeling like the world is spinning or moving (vertigo).
- Nausea, vomiting, loose stools (diarrhoea), indigestion (dyspepsia), stomach pain, gas (flatulence), or loss of appetite (anorexia).

Less frequent side effects:

- Disorientation, depression, sleeplessness, nightmares, irritability, or psychotic disorder.
- Sleepiness, tiredness, disturbances of sensation, pins and needles, memory loss, convulsions (seizures), anxiousness, tremor (shakiness), or taste disturbances.
- Vision disturbances, blurred vision, or double vision (diplopia).

- Ringing in the ears (tinnitus), or impaired hearing.
- Increased or decreased blood pressure, or inflammation of a blood vessel (vasculitis).
- inflammation of the lining of the stomach (gastritis).
- inflammation of the lining of the colon (colitis), including bleeding (haemorrhagic) colitis, sore-producing (ulcerative) colitis and colitis due to poor blood supply (ischaemic colitis), or inflammatory bowel disease (Crohn's disease).
- constipation.
- inflammation of the lining of the mouth or lips (stomatitis), including sore-producing stomatitis (ulcerative stomatitis), or inflammation of the tongue (glossitis).
- difficulty swallowing (oesophageal disorder), or narrowing or blockage of the intestines (intestinal strictures), that may cause stomach pain or bloating and constipation.
- hair loss, or sensitivity to the sun (photosensitivity reaction).
- swollen legs, feet and ankles (oedema).

Side effects with unknown frequency:

- confusion, hearing or seeing things that are not real (hallucinations), or a general feeling of being unwell.
- pain in your eye when you move it and blurred vision, or loss of vision (optic neuritis).

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: drugsafetysa@cipla.com

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

5. How to store K-FENAK ANTI-INFLAMMATORY

Store all medicines out of reach of children.

Store in a dry place at or below 25 °C.

Keep the blister strips 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.

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 ANTI-INFLAMMATORY contains

The active substance is diclofenac potassium 50 mg.

The other ingredients are colloidal anhydrous silica, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and the tablet coating Opadry AMBOY-B-28920 White, which contains lecithin (soya), polyvinyl alcohol partially hydrolysed, talc, titanium dioxide and xanthan gum.

What K-FENAK ANTI-INFLAMMATORY looks like and contents of the pack

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

K-FENAK ANTI-INFLAMMATORY tablets are supplied in aluminium foil blister strips packed in cartons of 10, 15, 21 and 30 tablets.

*Not all pack sizes may be marketed.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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K-FENAK 10's: Botswana: S2 BOT1001652A

K-FENAK 15's: Botswana: S2 BOT1001652B

K-FENAK 30's: Botswana: S2 BOT1001652C

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