PART III: CONSUMER INFORMATION

[Pr]DICLOFENAC-K
(diclofenac potassium)

Read this information each time you refill your prescription in case new information has been added.

This leaflet is Part III of a three-part "Product Monograph" published when DICLOFENAC-K was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DICLOFENAC-K. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the Medication is used for:

Your healthcare provider has prescribed DICLOFENAC-K for short term treatment of acute, mild to moderately severe pain that may be accompanied with swelling (inflammation) in conditions such as sprains, tooth extraction, episiotomy (a surgical cut made just before delivery to enlarge vaginal opening), and dysmenorhea (painful menstrual periods).

What it does:

DICLOFENAC-K (diclofenac potassium), as a nonsteroidal anti-inflammatory drug (NSAID), can reduce the chemicals prostaglandins produced by your body which cause pain and swelling.

DICLOFENAC-K, as a nonsteroidal anti-inflammatory drug (NSAID) does NOT cure your illness or prevent it from getting worse. DICLOFENAC-K can only relieve pain and reduce swelling as long as you continue to take it.

When it should not be used:

***DO NOT TAKE DICLOFENAC-K* if you have any of the following conditions:**

- **Heart bypass surgery (planning to have or recently had)**
- **Severe, uncontrolled heart failure**
- **Bleeding in the brain or other bleeding disorders**
- **Current pregnancy (after 28 weeks of pregnancy)**
- **Currently breastfeeding (or planning to breastfeed)**
- **Allergy (hypersensitivity) to diclofenac potassium, or ASA (Acetylsalicylic Acid), or other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs), or any of the nonmedicinal ingredients in DICLOFENAC-K**
- **Ulcer (active)**
- **Bleeding or perforation from the stomach or gut (active)**
- **Inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis)**
- **Liver disease (active or severe)**
- **Kidney disease (severe or worsening)**
- **High potassium in the blood**

Patients who took a drug in the same class as DICLOFENAC-K after a type of heart surgery (coronary artery bypass grafting (CABG)) were more likely to have heart attacks, strokes, blood clots in the leg(s) or lung(s), and infections or other complications than those who did NOT take that drug.

DICLOFENAC-K should NOT be used in patients under 16 years of age since the safety and effectiveness have NOT been established.

What the medicinal ingredient is:

DICLOFENAC-K contains the active ingredient diclofenac potassium.

What the non-medicinal ingredients are:

Each DICLOFENAC-K tablet contains the following inactive ingredients: calcium phosphate, corn starch, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate
The film coating contains: hydroxypropyl methylcellulose, maltodextrin, polydextrose, polyethylene glycol, synthetic red iron oxide, synthetic yellow iron oxide, titanium dioxide, triacetin.

What dosage forms it comes in:
DICLOFENAC-K 50 mg tablet: reddish brown, round, biconvex.

Check with your pharmacist if the identifying markings or colour appear different.

WARNINGS AND PRECAUTIONS

If you have, or previously had, any of the following conditions, see your health care provider to discuss treatment options other than DICLOFENAC-K .

- **Heart Attack or Angina**
- **Stroke or Mini-stroke**
- **Loss of Vision**
- **Current Pregnancy (less than 28 weeks)**
- **Congestive Heart Failure**
- **High blood pressure**
- **Diabetes**
- **High levels of fats in your blood**
- **Smoking**

It is important to take the lowest dose of DICLOFENAC-K that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk of side effects on the heart and blood vessels as small as possible.

Use of NSAIDS, such as DICLOFENAC-K can result in increased blood pressure and /or worsening of congestive heart failure

Use of NSAIDs, such as DICLOFENAC-K may cause stomach and bowel problems (such as ulceration, perforation, obstruction and bleeding).

Before taking this medication, tell your health care provider if you have any of the following:

- Disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease), as treatment with DICLOFENAC-K in these cases is not recommended.
- Risk factors for cardiovascular disease (see above) such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke,
- Diabetes mellitus or on a low sugar diet
- Atherosclerosis
- Poor circulation to your extremities
- Kidney disease or urine problems
- Previous ulcer or bleeding from the stomach or gut
- Previous bleeding in the brain
- Bleeding problems
- Family history of allergy to NSAIDs, such as acetylsalicylic acid (ASA), celecoxib, diclofenac, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, rofecoxib, sulindac, tenoxicam, tiaprofenic acid, tolmetin, or valdecoxib (NOT a complete list)
- Family history of asthma, nasal polyps, long-term swelling of the sinus (chronic sinusitis) or hives
- Any other medical problem such as alcohol abuse
- Any side effects from medicines for arthritis, rheumatism or sore joints that you have taken in the past
- A history of stomach upset
- Are on any special diet, such as a low-sodium diet

Also, before taking this medication, tell your health care provider if you are planning to get pregnant.

While taking this medication:

- Tell any other doctor, dentist, pharmacist or other health care professional that you see, that you are taking this medication, especially if you are planning to have heart surgery;
- Do NOT drink alcoholic beverages while taking this medication because you would be more likely to develop stomach problems;
- Fertility may be decreased. The use of DICLOFENAC-K is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping DICLOFENAC-K should be considered.
- If you have cardiovascular disease or risks for cardiovascular disease, your doctor will periodically re-evaluate whether you should continue treatment with DICLOFENAC-K.
- Your doctor will monitor your kidney function, your liver function and your blood count to decide if DICLOFENAC-K needs to be discontinued.

If, at any time while taking DICLOFENAC-K you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.

Long-term use of DICLOFENAC-K might increase the risk of heart attacks or strokes

INTERACTIONS WITH THIS MEDICATION

Talk to your health care provider and pharmacist if you are taking any other medication (prescription or

non-prescription) such as any of the following (NOT a complete list):

- Acetaminophen
- Acetylsalicylic Acid (ASA) or other NSAIDs e.g. ASA, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen
- Alcohol
- Antacids
- Anti-depressants
    - Selective Serotonin Reuptake Inhibitors (SSRIs) e.g. citalopram, fluoxetine, paroxetine, sertraline
- Blood pressure medications
    - ACE (angiotensin converting enzymes) inhibitors e.g. enalapril, lisinopril, perindopril, ramipril
    - ARBs (angiotensin II receptor blockers) e.g. candesartan, irbesartan, losartan, valsartan o Beta-blockers e.g. metoprolol
- Blood thinners (medicines used to prevent blood clotting) e.g. warfarin, ASA, clopidogrel
- Corticosteroids (including glucocorticoids) (medicines used to provide relief for inflamed areas of the body) e.g. prednisone
- Cyclosporine (a medicine primarily used in patients who have received organ transplants)
- Digoxin (a medicine used for heart problems)
- Diuretics (medicines used to increase the amount of urine) e.g. furosemide, hydrochlorothiazide
- Lithium
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis)
- Oral hypoglycemics (diabetes medications such as metformin)
- Phenytoin (a medicine used to treat seizures)
- Probenecid
- Quinolone antibacterials (medicines used against infection)
- Rifampin (an antibiotic medicine used to treat bacterial infections)
- Sulfinpyrazone (a medicine used to treat gout)
- Tacrolimus (a medicine primarily used in patients who have received organ transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infection)
- Voriconazole (a medicine used to treat fungal infections).

Your health care provider may prescribe low dose ASA (acetylsalicylic acid) as a blood thinner to reduce your risk of having a heart attack or stroke while you are taking DICLOFENAC-K. Take only the amount of ASA prescribed by your health care provider. You are more likely to upset or damage your stomach if you take both DICLOFENAC-K and ASA than if you took DICLOFENAC-K alone.

PROPER USE OF THIS MEDICATION

Usual dose:

Medical Condition	Usual Dose	Maximum Dose (per day)	Maximum Duration of Treatment
Pain and Swelling	50 mg every 6-8 hours (if needed)	100 mg	One week
Painful menstrual cramps	First dose of 50 mg or (if needed) 100 mg followed by 50 mg every 6-8 hours after initial dose (if needed)	100 mg. First day may be increased to 200 mg	when required

Take DICLOFENAC-K as directed by your health care provider. **Do NOT take more of it, do NOT take it more often and do NOT take it for a longer period of time than your health care provider recommended. If possible, you should take the lowest dose of this medication for the shortest time period.** Taking too much DICLOFENAC-K may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly and frail or if you have a low body weight,, have other diseases or take other medications.

If you are not getting adequate relief from your medication, speak to your doctor before you stop taking it.

This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

DICLOFENAC-K is NOT recommended for use in patients under 16 years of age since safety and effectiveness have NOT been established.

Take DICLOFENAC-K with a meal or food to reduce the possibility of stomach upset.

DICLOFENAC-K: DICLOFENAC-K are immediate release tablets. The tablets should be swallowed whole with water, and must not be divided or chewed.

Missed dose:

If you forget to take one or more doses of DICLOFENAC-K (diclofenac potassium), you should not increase the dose of DICLOFENAC-K to make up for the missed dose or doses, but you should continue taking your tablet at the next prescribed or regular time.

Overdose:

If you have accidentally taken more than the prescribed dose of DICLOFENAC-K **contact your doctor, pharmacist or poison control centre immediately or go to the hospital emergency unit at once.** You may require medical attention.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

DICLOFENAC-K may cause some side effects, especially when used for a long time or in large doses. When these side effects occur, you may require medical attention. Report all symptoms or side effects to your health care provider.

DICLOFENAC-K may cause you to become drowsy or tired. Be careful about driving or participating in activities that require you to be alert. If you become drowsy, dizzy or light-headed after taking DICLOFENAC-K, do NOT drive or operate machinery.

DICLOFENAC-K may cause you to become more sensitive to sunlight. Any exposure to sunlight or sunlamps may cause sunburn, skin blisters, skin rash, redness, itching or discolouration, or vision changes. If you have a reaction from the sun, check with your health care provider

Check with your health care provider IMMEDIATELY if you develop chills, fever, muscle aches or pains, or other flu-like symptoms, especially if they occur before or together with a skin rash. These symptoms may be the first sign of a SERIOUS ALLERGIC REACTION to this medication.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom	STOP taking DICLOFENAC-K and get emergency medical attention IMMEDIATELY	STOP taking DICLOFENAC-K and talk to your physician or pharmacist
Bloody or black tarry stools, vomiting blood	√	
Spontaneous bleeding or bruising (signs of thrombo-cytopenia)	√	
Shortness of breath, wheezing, any trouble breathing or chest tightness	√	
Skin rash, hives, swelling or itching	√	
Skin rash with flacking or peeling (signs of dermatitis exfoliative).	√	
Purple skin patches (signs of purpura or Henoch-Schonlein purpura if caused by an allergy).	√	
Blurred vision, or any visual disturbance	√	
Any change in the amount or colour of your urine (red or brown)	√	
Any pain or difficulty experienced while urinating		√
Swelling of the feet, lower legs; weight gain		√

Swelling mainly of the face and throat (signs of angioedema)		√
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea		√
Yellow discolouration of the skin or eyes (signs of liver failure), with or without itchy skin		√
Malaise, fatigue, loss of appetite or « flu-like » symptoms		√
Headaches, stiff neck, fever, nausea, vomiting (signs of aseptic meningitis)		√
Mental confusion, depression		√
Dizziness, lightheadedness		√
Hearing problems		√
Right upper abdominal discomfort or pain		√

This is NOT a complete list of side effects. If you develop any other symptoms while taking DICLOFENAC-K see your health care provider.

HOW TO STORE IT

Store between 15°C to 30°C.

Do NOT keep outdated medicine or medicine no longer needed. Any outdated or unused medicine should be returned to your pharmacist.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting Sanis Health Inc., at:

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