

PART III: CONSUMER INFORMATION**PR** CAMBIA®

(diclofenac potassium powder for oral solution)

This leaflet is part III of a three-part "Product Monograph" published when CAMBIA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CAMBIA®.

Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

Your doctor has prescribed CAMBIA® for you to treat a migraine attack. CAMBIA® is only for use in adults 18 years and older.

Use only a single dose of CAMBIA® to treat one migraine attack.

Do not use CAMBIA® continuously to prevent or reduce the number of migraines you experience. CAMBIA® should not be used to relieve pain other than that associated with migraine.

What it does:

CAMBIA® is a nonsteroidal anti-inflammatory drug (NSAID), and can reduce the chemicals prostaglandins produced by your body, which cause pain and swelling.

CAMBIA® does NOT prevent migraines or cure your condition.

When it should not be used:

DO NOT TAKE CAMBIA® if you have any of the following medical conditions:

- Heart bypass surgery (planning to have or recently had)
- Severe, uncontrolled heart failure
- Bleeding in the brain or other bleeding disorders
- Currently or planning to become pregnant
- Currently breastfeeding (or planning to breastfeed)
- Allergy to diclofenac or ASA (Acetylsalicylic Acid) or other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs) or any of the non-medical ingredients in CAMBIA®
- Ulcer (active)
- Bleeding 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)
- Have high potassium in the blood

Patients who took a drug in the same class as CAMBIA® after heart surgery, such as coronary artery bypass grafting were more likely to have heart attack, stroke, blood clots in the legs or lungs, and infections or other complications than those who did NOT take that drug.

CAMBIA® should NOT be used in patients under 18 years of age.

What the medicinal ingredient is:

diclofenac potassium

What the non-medical ingredients are:

Aspartame (equivalent to 25 mg phenylalanine), flavoring agents (anise and mint), glycerol behenate, mannitol, potassium bicarbonate, and saccharin sodium

What dosage forms it comes in:

Each individual sachet of CAMBIA® contains 50 mg of diclofenac potassium powder, to add to water for oral use.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

CAMBIA® can increase your risk of fatal heart attack, angina, heart failure, high blood pressure, stroke or mini-stroke. The risk may be greater if you had any of these conditions or you are at risk for getting them. The risk may increase with continued use of CAMBIA®.

CAMBIA® can cause fatal bleeding and ulcers in the stomach or gut at any time during treatment. Elderly patients are at a greater risk.

CAMBIA® is not for use during the last 3 months of pregnancy because it may harm the baby and cause complications during delivery.

If you have any of the above medical conditions, see your doctor to discuss treatment options other than CAMBIA®.

BEFORE you use CAMBIA® talk to your doctor or pharmacist if you have, or previously had:

- Congestive heart failure
- Heart attack or Angina
- Stroke or Mini-stroke
- High blood pressure
- High cholesterol
- Diabetes mellitus or on a low sugar diet
- Atherosclerosis (vascular disease)
- Poor circulation to your extremities
- Smoker or ex-smoker
- 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
- Family history of allergy to sulfonamide drugs
- Any other medical problem such as alcohol abuse

- A history of stomach upset

Also, before taking this medication, tell your doctor if you are planning to get pregnant. CAMBIA® is not recommended during pregnancy because it may harm the baby.

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 CAMBIA® is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping CAMBIA® should be considered.

Phenylketonurics: Contains Aspartame

INTERACTIONS WITH THIS MEDICATION

Talk to your doctor and pharmacist if you are taking any other medication (prescription or non-prescription); such as any of the medications listed below (this is NOT a complete list).

Drugs that may interact with CAMBIA® include:

- Acetaminophen
- Acetylsalicylic Acid (ASA) or other NSAIDs, e.g. aspirin, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen. Do NOT take these medicines when you take CAMBIA®.
- Alcohol
- Antidepressants, including Selective Serotonin Reuptake Inhibitors (SSRIs), e.g. citalopram, fluoxetine, paroxetine, sertraline) and Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs), e.g. duloxetine, desvenlafaxine, venlafaxine)
- Blood pressure medications :
 - ACE (angiotensin converting enzyme inhibitors) e.g. enalapril, lisinopril, perindopril, ramipril
 - ARBs (angiotensin II receptor blockers), e.g. candesartan, irbesartan, losartan, valsartan
- Blood thinners, e.g. warfarin, ASA, clopidogrel
- Corticosteroids (including glucocorticoids), e.g. prednisone
- Cyclosporine
- Digoxin
- Diuretics, e.g. furosemide, hydrochlorothiazide
- Glucocorticoids
- Lithium
- Methotrexate
- Oral contraceptives
- Oral hypoglycemics (diabetes medications)
- Phenytoin
- Probenecid
- Quinolone antibacterials
- Sulfapyrazone
- Tacrolimus

- Voriconazole
- Warfarin-Type Anticoagulants

Your doctor 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 CAMBIA®. Take only the amount of ASA prescribed by your doctor. You are more likely to upset or damage your stomach if you take both CAMBIA® and ASA than if you took CAMBIA® alone.

PROPER USE OF THIS MEDICATION

Usual dose for adults over 18 years of age:

One individual dose sachet at any time during a migraine attack.

Directions for use:

Open individual dose sachet only when ready to use. Empty the contents of one individual dose sachet into 30 to 60 mL (1 to 2 ounces) of water. Do not use liquids other than water. Mix to ensure that the powder is completely dissolved. Drink the water-powder mixture immediately after mixing.

Taking CAMBIA® with a meal may delay pain relief; however food may reduce possible stomach and intestinal side-effects.

Take CAMBIA® only as directed by your doctor. **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 doctor recommended. If possible, you should take this medication for the shortest time period.**

Taking too much CAMBIA® may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

Repeated use of CAMBIA® can cause headaches. See your doctor regularly to discuss whether this medicine is working for you and if it is causing you any unwanted effects.

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.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Center immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

CAMBIA® 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 doctor.

CAMBIA® 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 CAMBIA®, do NOT drive or operate machinery.

CAMBIA® 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 doctor.

Check with your doctor 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 signs of a SERIOUS ALLERGIC REACTION to this medication.

SERIOUS SIDE EFFECTS, AND WHAT TO DO ABOUT THEM		
Symptom	STOP taking CAMBIA® and get emergency medical attention IMMEDIATELY	STOP taking CAMBIA® and talk to your doctor or pharmacist
Heart Attack: chest pain, shortness of breath, sweating and anxiety	✓	
Heart failure: shortness of breath especially after exercise, leg/ankle swelling (fluid retention)	✓	
Stroke: face weakness, inability to raise both arms equally and abnormal speech	✓	
Ulcer or bleeding of the stomach or gut: vomit blood or black stools, abdominal pain	✓	
Asthma: shortness of breath, wheezing, any trouble breathing or chest tightness	✓	
Allergic reaction: skin rash, hives, itching or swelling of the face, lips, tongue or throat, difficulty swallowing or breathing	✓	
Vision Changes: blurred vision, or any visual disturbance	✓	

SERIOUS SIDE EFFECTS, AND WHAT TO DO ABOUT THEM		
Symptom	STOP taking CAMBIA® and get emergency medical attention IMMEDIATELY	STOP taking CAMBIA® and talk to your doctor or pharmacist
Jaundice: yellow colour to skin and eyes, with or without itchy skin	✓	
Anemia: low red blood cells		✓
Any pain or difficulty experienced while urinating		✓
Any change in the amount or colour of your urine (red or brown)		✓
Swelling of the feet, lower legs; weight gain		✓
Vomiting that worsens or persistent indigestion, nausea that worsens, stomach pain or diarrhea		✓
Malaise, fatigue, loss of appetite		✓
Headache, stiff neck		✓
Mental confusion, depression		✓
Dizziness, lightheadedness		✓
Hearing problems		✓

This is not a complete list of side effects. For any unexpected effects while taking CAMBIA®, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature 15-30°C (59-86°F).

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 and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. 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 at:

<http://www.aralez.com/> or by contacting the sponsor, Aralez Pharmaceuticals Canada Inc. at: 1-866-391-4503 (toll-free).

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