

MEDICATION GUIDE

CAMBIA (Cam-bē-ə or Cam-bē-a) (diclofenac potassium for oral solution)

Read the Patient Information that comes with CAMBIA before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about CAMBIA?

CAMBIA, which contains diclofenac, (a non-steroidal anti-inflammatory drug or NSAID), may increase your chance of a heart attack or stroke that can lead to death. This chance is higher:

- with longer use of NSAID medicines
- in people who have heart disease

NSAID medicines, such as CAMBIA, should never be used right before or after a heart surgery called a “coronary artery bypass graft” (CABG).

NSAID medicines, such as CAMBIA, can cause ulcers and bleeding in your stomach and intestines at any time during treatment.

Ulcers and bleeding:

- can happen without warning symptoms
- may cause death

The chance of a person getting an ulcer or bleeding increases with:

- the use of medicines called steroid hormones (corticosteroids) and blood thinners (anticoagulants)
- longer or regular use
- smoking
- drinking alcohol
- older age
- having poor health

CAMBIA should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What is CAMBIA?

CAMBIA is a prescription medicine used to treat migraine attacks in adults. It does not prevent or lessen the number of migraines you have, and it is not for other types of headaches. CAMBIA contains diclofenac potassium (a Non-Steroidal Anti-Inflammatory Drugs or NSAID).

How should I take CAMBIA?

Take CAMBIA exactly as your healthcare provider tells you to take it.

Take 1 dose of CAMBIA to treat your migraine headache:

- remove one single dose packet from a set of three packets
- open packet only when you are ready to use it
- empty contents of packet into 1 to 2 ounces (2 to 4 tablespoons) of water
- mix well and drink the water and powder mixture
- throw away empty packet in a safe place and out of the reach of children
- taking CAMBIA with food may cause a reduction in effectiveness compared to taking Cambia on an empty stomach
- do not take more CAMBIA than directed by your healthcare provider. In case of overdose, get medical help or contact a Poison Control Center right away.

Who should not take CAMBIA?

Do not take Cambia:

- right before or after heart bypass surgery. See “What is the most important information I should know about Cambia?”
- if you have or have had an asthma attack, hives, or other allergic reaction with aspirin, diclofenac, or any other NSAID medicine.

Before you take CAMBIA, tell your

healthcare provider about all your medical conditions, including if you:

- have a history of stomach ulcer or bleeding in your stomach or intestines
- have kidney or liver problems
- have any allergies to any medicines
- have chest pain, shortness of breath, irregular heartbeats
- are pregnant, think you might be pregnant, or are trying to become pregnant. Cambia

should not be used by pregnant women, especially during the last 3 months of pregnancy unless directed by your healthcare provider to do so. Cambia may cause problems in your unborn child or complications during your delivery.

- are breastfeeding or plan to breast-feed. It is not known if CAMBIA passes into your breast milk. You and your doctor should decide if you will take CAMBIA or breast feed. You should not do both.
- have a headache that is different from your usual migraine

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

CAMBIA and other medicines may affect each other causing side effects. CAMBIA may affect the way other medicines work, and other medicines may affect how CAMBIA works.

Especially tell your doctor if you take

- aspirin
- any anticoagulant medicines (warfarin, Coumadin, Jantoven)

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

What are the possible side effects of CAMBIA?

Serious side effects include:

- heart attack
- stroke
- high blood pressure
- heart failure from body swelling (fluid retention)
- kidney problems including kidney failure
- bleeding and ulcers in the stomach and intestine
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- liver problems including life-threatening liver failure
- asthma attacks in people who have asthma

Get emergency help right away if you have any of the following symptoms of heart attack or stroke:

- shortness of breath or trouble breathing
- chest pain
- swelling of your face or throat
- weakness in one part or one side of your body
- slurred speech

Common side effects include:

- nausea
- dizziness

Stop CAMBIA and call your healthcare provider right away if you have any of the following symptoms:

- nausea that seems out of proportion to your migraine
- stomach pain
- sudden or severe pain in your belly
- vomit blood
- blood in your bowel movement or it is black and sticky like tar
- itching
- skin rash or blisters with fever
- yellow skin or eyes
- swelling of your arms and legs, hands and feet
- unusual weight gain
- more tired or weaker than usual
- flu-like symptoms

Tell your healthcare provider if you have any side effects that bother you or do not go away.

These are not all the side effects with NSAID medicines. Talk to your healthcare provider or pharmacist for more information about NSAID medicines.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store CAMBIA?

- Store CAMBIA in a dry place at room temperature between 59° to 86°F (15° to 30°C).

- Keep CAMBIA and all medicines out of reach of children.

General information about CAMBIA

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CAMBIA for a condition for which it was not prescribed.
- Do not give CAMBIA to other people, even if they have the same problem you have. It may harm them.
- This Medication Guide contains the most important information about CAMBIA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information written for healthcare professionals.
- For more information call Kowa Pharmaceuticals America, Inc. at 1-877-334-3464 (weekdays 9 AM to 5 PM EST) or through our web site at:
www.kowapharma.com.

What are the ingredients in CAMBIA?

Active ingredients: diclofenac potassium

Inactive ingredients: aspartame (equivalent to 25 mg phenylalanine), flavoring agents (anise and mint), glyceryl behenate, mannitol, potassium bicarbonate, and saccharin sodium.

Rx only

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This Medication Guide has been approved by the U.S. Food and Drug Administration.