CAMBIA

diclofenac potassium (di-clo-fen-ac pot-ass-e-um)

Consumer Medicine Information

This leaflet provides important information about using CAMBIA. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CAMBIA.

Where to find information in this leaflet:

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1. Why am I taking CAMBIA?

CAMBIA contains the active ingredient diclofenac potassium.

CAMBIA belongs to a group of medicines called non-steroidal antiinflammatory drugs (NSAIDs). It relieves pain and reduces inflammation (swelling and redness).

CAMBIA is used for short-term treatment of the following conditions:

- migraine headaches and it its symptoms, such as nausea and vomiting
- the relief of period pain
- other painful conditions where swelling is a problem such as back or joint pain, dental pain,

muscle strains or sprains and tendonitis (e.g. tennis elbow).

CAMBIA can relieve the symptoms of pain and inflammation but it will not cure your condition.

2. What should I know before I take CAMBIA?

Warnings

Do not use CAMBIA if:

• you are allergic to diclofenac, aspirin, ibuprofen, any other NSAID, or any of the ingredients listed at the end of this leaflet.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are allergic to aspirin or NSAID medicines and you take CAMBIA, these symptoms may be severe.

Always check the ingredients to make sure you can use this medicine.

- You have a stomach or intestinal ulcer
- You have bleeding from the stomach or bowel (symptoms of which may include blood in your stools or black stools)
- You have kidney or liver problems
- You have severe heart failure
- You have had heart bypass surgery

Check with your doctor if you:

 have any other medical conditions including:
 disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, peripheral arterial disease or atherosclerotic cardiovascular disease), as treatment with CAMBIA is generally not recommended - established cardiovascular disease or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe CAMBIA, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks

- a history of ulcers (stomach or intestinal)

- gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking antiinflammatory medicines in the past

- diseases of the bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative or ischemic colitis)

- liver or kidney problems

- a rare liver condition called porphyria

bleeding disorders or other blood disorders (e.g. anaemia)
asthma or any other chronic lung disease that causes difficulty in breathing

- hay fever (seasonal allergic rhinitis)

- repeated chest infections
- polyps in the nose
- diabetes

- dehydration (e.g. by sickness, diarrhoea, before or after recent major surgery)

- swollen feet

- phenylketonuria (a condition in which an amino acid called phenylalanine cannot be broken down in the body)

- have any other infection. If you take CAMBIA while you have an infection, some of the signs of the infection such as pain, fever, swelling and redness may be hidden. You may think, mistakenly, that you are better or that the infection is not serious.

• take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take Cambia during the first 6 months of pregnancy, except on doctor's advice. Do not use during the last three months of pregnancy.

Use of this medicine during the last 3 months of pregnancy may affect your baby and may delay labour and birth.

Use of non-aspirin NSAIDs can increase the risk of miscarriage, particularly when taken close to the time of conception.

CAMBIA may also reduce fertility and affect your chances of becoming pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Breast-feeding is not recommended while you are using this medicine. The active ingredient in CAMBIA passes into breast milk and may affect your baby.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with CAMBIA and affect how it works. Some medicines that are important to mention include:

- other anti-inflammatory medicines, e.g. aspirin, salicylates, or ibuprofen
- warfarin or other "blood thinners" (medicines used to prevent blood clotting)
- digoxin (a medicine used for heart problems)
- lithium or selective serotoninreuptake inhibitors (SSRIs) (medicines used to treat some types of depression)
- diuretics (medicines used to increase the amount of urine)
- ACE inhibitors or beta-blockers (medicines used to treat high blood pressure, heart conditions, glaucoma and migraine)
- prednisone, cortisone, or other corticosteroids (medicines used to provide relief for inflamed areas of the body)
- medicines (such as metformin) used to treat diabetes, except insulin
- methotrexate (a medicine used to treat some kinds of cancer or arthritis)
- cyclosporin, tacrolimus (medicines used in patients who have received organ transplants)
- trimethoprim (a medicine used to prevent or treat urinary tract infections)

- some medicines used to treat infection (quinolone antibacterials)
- glucocorticoid medicines, used to treat arthritis
- sulfinpyrazone (a medicine used to treat gout)
- voriconazole (a medicine used to treat fungal infections).
- phenytoin (a medicine used to treat seizures).
- rifampicin (an antibiotic medicine used to treat bacterial infections).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CAMBIA.