

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CAMBIA?

CAMBIA contains the active ingredient diclofenac potassium. CAMBIA is used to relieve pain and reduce swelling and redness. For more information, see Section [1. Why am I taking CAMBIA?](#) in the full CMI.

2. What should I know before I take CAMBIA?

Do not use if you have ever had an allergic reaction to diclofenac or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take CAMBIA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CAMBIA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take CAMBIA?

- Stir the sachet into a glass of water. Take CAMBIA immediately after mixing and preferably before meals. Your doctor will advise the correct dose for your condition.
- Do not use CAMBIA for more than one week at a time.

More instructions can be found in Section [4. How do I take CAMBIA?](#) in the full CMI.

5. What should I know while taking CAMBIA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking CAMBIA.• Elderly patients should be careful to only take the minimum dosage required.• Remind your doctor if you have recently had surgery.
Things you should not do	<ul style="list-style-type: none">• Do not take CAMBIA during the first 6 months of pregnancy, except on doctor's advice. Do not use during the last three months (trimester) of pregnancy.• Do not exceed the recommended dose or take CAMBIA for longer than your doctor says.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving, operating machinery or doing jobs that require you to be alert until you know how CAMBIA affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store CAMBIA below 25°C. Protect from moisture.• Keep CAMBIA in the sachet until it is time to take it.

For more information, see Section [5. What should I know while taking CAMBIA?](#) in the full CMI.

6. Are there any side effects?

Common side effects are stomach upset/ pains, vomiting, loss of appetite, diarrhoea, constipation, heartburn, pain near the breastbone, sore mouth, altered taste, hearing or visual changes, ringing ears, headache, hair loss, dizziness, drowsiness, disorientation, forgetfulness, mood changes, shakiness, sleeplessness, nightmares, tingling or numb hands or feet, fast or irregular heart-beat, unusual weight gain or swelling limbs, rapid sunburn, flaking, peeling or inflamed skin.

Serious side effects are red – purple or painful skin, severe rash, blisters, peeling, itching skin or hives; severe stomach pain, dark, bloody or severe vomiting; black or bloody stools, pale bowel motions; swelling of the face, lips, mouth, throat, or other body parts; fainting, troubled breathing, chest tightness or sudden chest pain; yellow skin or eyes, persistent or severe nausea, loss of appetite; unusual tiredness, upper right abdomen pain; flu-like symptoms including chills, fever, sore throat, aching joints or muscles, swollen glands, tiredness, lacking energy; bleeding or bruising more easily, bleeding lips, eyes, mouth, nose or genitals, sudden or severe headache, stiff neck, dizziness, numbness, difficulty in speaking, paralysis, convulsions, urine colour or amount passed changes, burning or blood in the urine, swelling feet or legs.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CAMBIA

Active ingredient(s): *diclofenac potassium* (di-clo-fen-ac pot-ass-e-um)

Consumer Medicine Information (CMI)

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:

- [1. Why am I taking CAMBIA?](#)
- [2. What should I know before I take CAMBIA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take CAMBIA?](#)
- [5. What should I know while taking CAMBIA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking CAMBIA?

CAMBIA contains the active ingredient diclofenac potassium. CAMBIA belongs to a group of medicines called non-steroidal anti-inflammatory 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 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
- You are in your third trimester of pregnancy

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 anti-inflammatory medicines in the past
- diseases of the bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative or ischemic colitis)
- a past history of haemorrhoids (piles) or irritation of the rectum (back passage)
- 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.

- are due to have surgery
- 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 (trimester) 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 serotonin-reuptake 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)
- ciclosporin, 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
- sulfapyrazone (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.

4. How do I take CAMBIA?

How much to take

Take CAMBIA immediately after mixing and preferably before meals.

Follow all directions given to you by your doctor and pharmacist carefully. These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

There are different ways to take CAMBIA depending on your condition. Your doctor will tell you exactly how many sachets of CAMBIA to take.

Do not exceed the recommended dose.

To treat migraine

The usual dose is 50 mg (one sachet) at the first sign of an attack. If the pain is not relieved within 2 hours, another sachet can be taken. After that, you must wait at least 4 hours before taking any more CAMBIA.

Do not take more than 200 mg (4 sachets) in 24 hours even if you have more than one migraine attack within that 24 hour period.

To treat menstrual cramps (period pain)

The usual dose is 50 mg to 100 mg (1 to 2 sachets) beginning as soon as cramps begin. This is usually followed by 1 sachet three times each day until the pain goes away, but for no longer than 3 days.

To treat other painful conditions

The usual dose is 100 mg to 150 mg (2 to 3 sachets) each day. In milder cases, as well as in children over 14 years old, 75 mg to 100 mg each day is usually enough.

How long to take it

Do not take CAMBIA for longer than your doctor says. It is usually taken for a short time only (up to one week) but it may be prescribed on repeated occasions, depending on your condition.

When to use CAMBIA

CAMBIA should be taken as advised by your doctor.
Take CAMBIA just before, with or immediately after meals.

If you forget to take CAMBIA

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much CAMBIA

If you think that you have used too much CAMBIA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include vomiting, bleeding from the stomach or bowel, diarrhoea, dizziness, ringing in the ears, convulsions (fits).

5. What should I know while taking CAMBIA?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using CAMBIA.

Elderly patients should take the minimum number of sachets that provides relief of symptoms. Elderly patients, especially those with a low body weight, may be more sensitive to the effects of CAMBIA than other adults.

Remind your doctor if you have recently had surgery, as increased risk of gastro-intestinal anastomotic leak.

Things you should not do

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.

Do not exceed the recommended dose or take CAMBIA for longer than your doctor says.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CAMBIA affects you.

CAMBIA may cause dizziness in some people

Looking after your medicine

Store CAMBIA below 25°C in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• stomach upset including nausea (feeling sick), vomiting, indigestion, cramps, loss of appetite, wind• heartburn or pain behind or below the breastbone (possible symptoms of an ulcer in the tube that carries food from the throat to the stomach)• stomach or abdominal pain• constipation, diarrhoea• sore mouth or tongue• altered taste sensation• headache• dizziness, spinning sensation	Speak to your doctor if you have any of these less serious side effects and they worry you.

<ul style="list-style-type: none"> • drowsiness, disorientation, forgetfulness • feeling depressed, anxious or irritable • strange or disturbing thoughts or moods • shakiness, sleeplessness, nightmares • tingling or numbness of the hands or feet • feeling of fast or irregular heart-beat • unusual weight gain or swelling of arms, hands, feet, ankles or legs due to fluid build-up • symptoms of sunburn (such as redness, itching, swelling, blistering of the lips, eyes, mouth, and/or skin) that happen more quickly than normal • skin inflammation with flaking or peeling • vision disorders* (e.g. blurred or double vision) • buzzing or ringing in the ears, difficulty hearing • hypertension (high blood pressure) • hair loss or thinning 	
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NSAIDs, including diclofenac, may be associated with increased risk of gastro-intestinal anastomotic leak. Close medical surveillance and caution are recommended when using this medicine after gastrointestinal surgery.

If symptoms of vision disorders occur during treatment with CAMBIA, contact your doctor as an eye examination may be considered to exclude other causes.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • red or purple skin (possible signs of blood vessel inflammation) • severe pain or tenderness in the stomach, vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea (possible stomach problems) • rash, skin rash with blisters, itching or hives on the skin; swelling of the face, lips, mouth, tongue, throat, or other part of the body, which may cause difficulty to swallow, low blood pressure (hypotension), fainting, shortness of breath (possible allergic reaction) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> • wheezing, troubled breathing, or feelings of tightness in the chest (signs of asthma) • yellowing of the skin or eyes (signs of hepatitis/liver failure) • persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, dark urine or pale bowel motions (possible liver problems) • constant "flu-like" symptoms, including chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy; bleeding or bruising more easily than normal (possible blood problem) • painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals, which may be accompanied by fever and chills, aching muscles and feeling generally unwell (possible serious skin reaction) • signs of a possible effect on the brain, such as sudden and severe headache, stiff neck (signs of viral meningitis), severe nausea, dizziness, numbness, difficulty in speaking, paralysis (signs of cerebral attack), convulsions (fits) • a change in the colour or amount of urine passed, frequent need to urinate, burning feeling when passing urine, blood or excess of protein in the urine (possible kidney disorders) • sudden and oppressive chest pain (which may be a sign of myocardial infarction or a heart attack) • breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure) • Coincidental occurrence of chest pain and allergic reactions (signs of Kounis syndrome) 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CAMBIA contains

Active ingredient (main ingredient)	diclofenac potassium
Other ingredients (inactive ingredients)	potassium bicarbonate, mannitol, aspartame, saccharin sodium, glyceryl behenate, mint flavour and anise flavour.
Potential allergens	mannitol, aspartame, saccharin sodium, potassium

Do not take this medicine if you are allergic to any of these ingredients.

What CAMBIA looks like

CAMBIA sachets each contain 50 mg of a white to light yellow powder.

Each carton contains 9 sachets.

(AUST R 123192)

Who distributes CAMBIA

Southern XP Pty Ltd
Unit 5/118 Church Street
Hawthorn VIC 3122
Australia

Sponsor:

Southern XP IP Pty Ltd
Unit 5/118 Church Street
Hawthorn, 3122, Victoria
Australia

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