

# CELECOXIB AN

*celecoxib*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about CELECOXIB AN. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CELECOXIB AN against the benefits it is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Read this leaflet carefully before you start CELECOXIB AN and keep it with the medicine.**

You may need to read it again.

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### What CELECOXIB AN is used for

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CELECOXIB AN is used to relieve the symptoms of joint pain, tenderness, swelling and stiffness in:

- osteoarthritis,
- rheumatoid arthritis and
- ankylosing spondylitis, a chronic inflammatory rheumatic disorder that primarily affects, but is not limited to, the spine.

CELECOXIB AN also provides short-term pain relief in conditions such as:

- menstrual cramps or period pain
- after surgery
- muscle and joint injuries.

CELECOXIB AN belongs to a group of medicines called Coxibs which are used to relieve pain and inflammation in number of conditions.

Although CELECOXIB AN can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor, however, may have prescribed CELECOXIB AN for another purpose.

**Ask your doctor if you have any questions about why CELECOXIB AN has been prescribed for you.**

CELECOXIB AN is not recommended for use in children or adolescents under 18 years of age.

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

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### Before you take CELECOXIB AN

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*When you must not take it*

**Do not take CELECOXIB AN if:**

- **your doctor has told you that you have severe heart or blood vessel disease affecting the circulation in your brain or limbs**
- **you have severe liver problems**  
Your doctor will decide if your condition is too severe to take this medicine.
- **you have problems with your kidney function**

- **you have had an attack of asthma, hives, itching, skin rash or a runny nose after taking aspirin or Non-Steroidal Anti-Inflammatory Drugs (NSAIDs, medicines used to treat pain and inflammation), including other Coxib medicines**

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or an NSAID.

If you are allergic to aspirin, NSAIDs, or other Coxib medicines and use CELECOXIB AN, these symptoms may be severe.

- **you have an allergy to:**
  - CELECOXIB AN
  - any of the ingredients listed at the end of this leaflet
  - sulfonamides, a group of medicines which include, for example, certain antibiotics (if you are not sure if you are taking one of these medicines ask your pharmacist).

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting.

If you are allergic to sulfonamides or any of the capsule ingredients and take CELECOXIB AN, these symptoms may be severe.

**Ask your doctor or pharmacist if any of this applies to you.**

- you are already taking an NSAID
- you have an ulcer or gastric bleeding
- you have Irritable Bowel Disease
- you have heart failure
- the expiry date printed on the packaging has passed, even though the capsules may look alright

If you take this medicine after the expiry date has passed, it may not work as well.

- the packaging is torn or shows signs of tampering.

**If you are not sure if you should be taking CELECOXIB AN, talk to your doctor.**

*Before you start to take it*

**You must tell your doctor if:**

- you currently have diabetes, high blood pressure, high cholesterol levels, heart failure or have a history of heart problems or stroke, or problems with the circulation in your limbs
- you have any allergies to:
  - any other medicines
  - any other substances such as foods, dyes or preservatives.

- you are pregnant or intend to become pregnant  
Related medicines, NSAIDs, have been associated with reversible infertility in some women. Use of NSAIDs in early pregnancy can increase the risk of spontaneous abortion. There is no information on the use of CELECOXIB AN during pregnancy. CELECOXIB AN may affect your developing baby if taken in the last 3 months of pregnancy. CELECOXIB AN use is not recommended in pregnancy unless your doctor considers it essential.

**Discuss this with your doctor.**

- you are breast-feeding or intend to breast-feed  
CELECOXIB AN passes into breast milk in small amounts, therefore, the use of CELECOXIB AN during Breast feeding should be discussed with your doctor.
- you have any other health problems including:
  - liver or kidney problems
  - asthma, hives, itching, skin rash or a runny nose
  - high blood pressure or fluid retention
  - peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before
  - vomiting blood or material that looks like coffee grounds
  - bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.
- you are taking CELECOXIB AN together with any medicines used to treat high blood pressure and some other heart problems such as ACE inhibitors, angiotensin receptor antagonists and diuretics (also called fluid or water tablets).  
When taken together these medicines can cause kidney problems.
- you drink large amounts of alcohol
- you are a smoker
- you currently have an infection.  
If you are given CELECOXIB AN while you have an infection, it may hide some of the signs of an infection.

**If you have not told your doctor or pharmacist about these things, tell them before you start taking CELECOXIB AN.**

*Taking other medicines*

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

**Some medicines and CELECOXIB AN may interfere with each other. These include:**

- any medicines used to treat high blood pressure and some other heart problems such as ACE inhibitors, angiotensin receptor antagonists or diuretics (also called fluid or water tablets)
- fluconazole, an antifungal agent
- lithium, a medicine used to treat some types of depression
- warfarin, a medicine used to stop blood clots
- antacids, medicines used to treat indigestion
- certain medicines used to treat pain and inflammation called non-steroidal anti-inflammatories (NSAIDs) or (cortico) steroids.

Your doctor may need to adjust the dosage of these medicines, or provide additional advice if you are also taking CELECOXIB AN.

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## How to take CELECOXIB AN

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**Follow all instructions given to you by your doctor and pharmacist carefully.**

They may differ from the information in this leaflet.

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

*How much to take*

### **Osteoarthritis**

200mg once daily or 100mg twice daily.

### **Rheumatoid arthritis**

100mg twice daily or 200mg twice daily.

### **Ankylosing spondylitis**

100mg twice daily or 200mg once daily.

### **Menstrual cramps or period pain**

400mg as a single dose on the first day and 200mg twice daily on following days. You may take CELECOXIB AN for up to 5 days.

### **Muscle and joint injuries or after surgery**

400mg as a first dose followed by 200mg once or twice daily as required. You may take CELECOXIB AN for up to 5 days.

### *How to take it*

**Swallow the capsules whole with a glass of fluid. CELECOXIB AN can be taken with or without food.**

### *How long to take it*

Depending on your condition, you may need CELECOXIB AN for a few days or for longer periods.

CELECOXIB AN will not cure your condition but should help control pain, swelling and stiffness.

**Keep taking CELECOXIB AN for as long as your doctor advises.**

**Do not exceed the dosage recommended by your doctor.**

### *If you forget to take it*

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking your capsules as you would normally.**

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

### *If you take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much CELECOXIB AN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

You may take If you take too much CELECOXIB AN, you may feel tired, drowsy, sick, vomit, and have stomach pain. You may also have difficulty breathing and feel faint.

## While you are taking it

### *Things you must do*

**If you become pregnant while taking CELECOXIB AN, tell your doctor immediately.**

**If you are about to start any new medicines, tell your doctor and pharmacist that you are taking CELECOXIB AN.**

**Tell all doctors, dentists and pharmacists who are treating you that you are taking CELECOXIB AN.**

**If you develop any skin rash (e.g. hives, spots) while being treated with CELECOXIB AN, contact your doctor immediately.**

The onset of these events, if they occur, can occur at any time, but most often occur in the first month of treatment.

### *Things you must not do*

**Do not give CELECOXIB AN to anyone else, even if they have the same symptoms or condition as you.**

**Do not use CELECOXIB AN to treat any other complaints unless your doctor tells you to.**

## Side effects

**Check with your doctor as soon as possible if you have any problems while taking CELECOXIB AN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.**

Like other medicines, CELECOXIB AN can cause some side effects. If they occur, most are likely to be minor and temporary.

**Ask your doctor or pharmacist any questions you may have.**

**Tell your doctor if you notice any of the following:**

- stomach pain, diarrhoea, indigestion, wind
- swollen hands, ankles and feet, unexplained weight gain
- dizziness
- sore throat, runny nose, sinusitis upper respiratory tract infection.

**Tell your doctor immediately if you notice any of the following:**

- skin rash, including hives, raised red, itchy spots
- blistering and bleeding in the lips, eyes, mouth, nose and genitals
- swelling, blistering or peeling of the skin, which may be accompanied by fever, chills, headache, sore throat, diarrhoea, aching joints and muscles
- other signs of allergic reaction such as wheezing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- collapse or fainting, shortness of breath or tiredness, irregular heartbeat, chest pain, swollen or sore leg veins
- severe stomach or throat pain, vomiting blood or black sticky bowel motions
- bleeding or bruising more than usual, reddish or purple blotches under the skin
- nausea, lethargy, itchiness, flu-like symptoms or yellowing of the skin or eyes (jaundice)

- signs of anaemia such as tiredness, being short of breath and looking pale
- loss or deterioration of hearing
- confusion
- redness, irritation or watering of the eye(s)
- experience sensations with any of the senses (sight, sound, touch, taste or feel) which may not be real
- severe or persistent headache, fever, stiff neck, sensitivity to light and vomiting.

These are serious side effects. You may need urgent medical attention.

Not all of these side effects have been reported with CELECOXIB AN but have been seen with similar medicines.

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

**Do not be alarmed by this list of possible side effects.**

You may not get any of them.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

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## After taking CELECOXIB AN

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### Storage

**Keep your capsules where young children cannot reach them.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep CELECOXIB AN in a cool, dry place where the temperature stays at or below 25°C. Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep your capsules in their blister pack until it is time to take them.**

If you take the capsules out of their container they may not keep well.

### Disposal

**If your doctor tells you to stop taking CELECOXIB AN, or the capsules have passed their expiry date, ask your pharmacist what to do with any left over.**

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## Product description

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### What it looks like

- CELECOXIB AN 100mg - Opaque, white capsules with 2 blue bands and marked "100" on the body. The 100 mg capsules come in blister packs of 60.
- CELECOXIB AN 200mg - Opaque, white capsules with 2 gold bands and marked "200" on the body. The 200mg capsules come in blister packs of 30.

### Ingredients

#### Active ingredient

The active ingredient in CELECOXIB AN is celecoxib.

- CELECOXIB AN 100mg - 100 mg celecoxib/capsule
- CELECOXIB AN 200mg - 200 mg celecoxib/capsule

#### Other ingredients

- lactose
- sodium lauryl sulfate
- povidone
- croscarmellose sodium
- magnesium stearate
- gelatin
- titanium dioxide
- TekPrint™ SB-6018 Blue Ink (ARTG 2653) /100mg capsule
- TekPrint™ SB-3002 Gold Ink (ARTG 3426) /200mg capsule

CELECOXIB AN does not contain sucrose, gluten, tartrazine or other azo dyes.

### Supplier/Sponsor

**Amneal Pharma Australia Pty Ltd**  
12 River St,  
South Yarra, VIC-3141.,  
Australia

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