

# NOUMED CELECOXIB

## 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 NOUMED CELECOXIB?

NOUMED CELECOXIB contains the active ingredient celecoxib. NOUMED CELECOXIB 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. NOUMED CELECOXIB also provides short-term pain relief in conditions such as menstrual cramps or period pain, after surgery, muscle and joint injuries. For more information, see Section [1. Why am I using NOUMED CELECOXIB?](#) in the full CMI.

### 2. What should I know before I use NOUMED CELECOXIB?

Do not use if you have ever had an allergic reaction to celecoxib 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 use NOUMED CELECOXIB?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with NOUMED CELECOXIB 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 use NOUMED CELECOXIB?

- Follow all directions 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.

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

### 5. What should I know while using Noumed Celecoxib?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Noumed Celecoxib.</li><li>• If you become pregnant while taking NOUMED CELECOXIB, tell your doctor immediately.</li><li>• If you are about to start any new medicines, tell your doctor and pharmacist that you are taking NOUMED CELECOXIB.</li><li>• If you develop any skin rash (e.g. hives, spots) while being treated with NOUMED CELECOXIB, 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.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give NOUMED CELECOXIB to anyone else, even if they have the same symptoms or condition as you.</li><li>• Do not use NOUMED CELECOXIB to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful when driving or operating machinery until you know how this medicine affects you</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink large amounts of alcohol while using the medicine</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep NOUMED CELECOXIB in a cool, dry place where the temperature stays at or below 30°C.</li><li>• 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.</li></ul>

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

### 6. Are there any side effects?

**Common side effects:** stomach pain, diarrhoea, indigestion, wind, swollen hands, ankles and feet, unexplained weight gain, dizziness, sore throat, runny nose, sinusitis and upper respiratory tract infection. **Serious side effects:** 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. Refer to the CMI for the full list. 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.

# NOUMED CELECOXIB

Active ingredient(s): *[celecoxib]*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using NOUMED CELECOXIB. **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 NOUMED CELECOXIB.**

Where to find information in this leaflet:

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

## 1. Why am I using NOUMED CELECOXIB?

NOUMED CELECOXIB contains the active ingredient **celecoxib**. NOUMED CELECOXIB belongs to a group of medicines called Coxibs which are used to relieve pain and inflammation in a number of conditions.

Although NOUMED CELECOXIB can relieve the symptoms of pain and inflammation, it will not cure your condition. Your doctor, however, may have prescribed NOUMED CELECOXIB for another purpose.

**NOUMED CELECOXIB 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. NOUMED CELECOXIB also provides short-term pain relief in conditions such as menstrual cramps or period pain, after surgery, muscle and joint injuries.**

## 2. What should I know before I use NOUMED CELECOXIB?

### Warnings

**Do not use NOUMED CELECOXIB if:**

- you are allergic to celecoxib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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 are undergoing cardiac surgery called coronary artery bypass graft (CABG)
- 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 NOUMED CELECOXIB, these symptoms may be severe.

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

**Check with your doctor or pharmacist if any of this applies to you:**

- you are already taking an NSAID
- you have Irritable Bowel Disease
- you are a smoker
- 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.
- 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 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 currently have an infection. If you are given NOUMED CELECOXIB while you have an infection, it may hide some of the signs of an infection

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

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.

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 NOUMED CELECOXIB during pregnancy.

NOUMED CELECOXIB may affect your developing baby if taken in the last 3 months of pregnancy.

NOUMED CELECOXIB use is not recommended in pregnancy unless your doctor considers it essential.

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

NOUMED CELECOXIB passes into breast milk in small amounts, therefore, the use of NOUMED CELECOXIB during breastfeeding should be discussed with your doctor.

### **Children or Adolescents under 18 years of age**

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

## **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.

**If you are taking NOUMED CELECOXIB 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.**

**Some medicines may interfere with NOUMED CELECOXIB and affect how it works. 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 or similar medicines including Eliquis (apixaban), Xarelto (rivaroxaban) or Pradaxa (dabigatran), a medicine used to stop blood clots
- aspirin or salicylates, medicines used to treat pain
- antacids, medicines used to treat indigestion
- some medicines used to treat diabetes

- methotrexate, a medicine used to treat arthritis and some cancers
- ciclosporin, medicine used to suppress the immune system
- certain medicines used to treat pain and inflammation called non-steroidal anti-inflammatories (NSAIDs) or (cortico) steroids.

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

## **4. How do I use NOUMED CELECOXIB?**

### **How much to take / use**

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

- 200mg twice daily, you may take NOUMED CELECOXIB for up to 5 days.

Muscle and joint injuries or after surgery

- 200mg once or twice daily as required. You may take NOUMED CELECOXIB for up to 5 days.

### **When to take / use NOUMED CELECOXIB**

- NOUMED CELECOXIB should be swallowed whole with a glass of fluid.
- NOUMED CELECOXIB can be taken with or without food.

### **If you forget to use NOUMED CELECOXIB**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

### **If you use too much NOUMED CELECOXIB**

If you think that you have used too much NOUMED CELECOXIB, 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.**

## 5. What should I know while using NOUMED CELECOXIB?

### Things you should do

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

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

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

### Call your doctor straight away if you:

- If you develop any skin rash (e.g. hives, spots) while being treated with NOUMED CELECOXIB, 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.

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

### Things you should not do

- Do not give NOUMED CELECOXIB to anyone else, even if they have the same symptoms or condition as you.
- Do not use NOUMED CELECOXIB to treat any other complaints unless your doctor tells you to.

### Driving or using machines

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

### Drinking alcohol

Tell your doctor if you drink large amounts of alcohol.

### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it 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"> <li>• stomach pain, diarrhoea, indigestion, wind</li> <li>• swollen hands, ankles and feet, unexplained weight gain</li> <li>• dizziness</li> <li>• sore throat, runny nose, sinusitis, upper respiratory tract infection.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• skin rash, including hives, raised red, itchy spots</li> <li>• blistering and bleeding in the lips, eyes, mouth, nose and genitals</li> <li>• swelling, blistering or peeling of the skin, which may be accompanied by fever, chills, headache, sore throat, diarrhoea</li> <li>• aching joints and muscles</li> <li>• 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</li> <li>• collapse or fainting, shortness of breath or tiredness, irregular heartbeat, chest pain, swollen or sore leg veins</li> <li>• severe stomach or throat pain, vomiting blood or black sticky bowel motions</li> <li>• bleeding or bruising more than usual, reddish or purple blotches under the skin</li> <li>• nausea, lethargy, itchiness, flulike symptoms or yellowing of the skin or eyes (jaundice)</li> <li>• signs of anaemia such as tiredness, being short of breath and looking pale</li> <li>• loss or deterioration of hearing</li> <li>• confusion</li> <li>• redness, irritation or watering of the eye(s)</li> <li>• experience sensations with any of the senses (sight, sound, touch, taste or feel) which may</li> </ul>	<p><b>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.</b></p>

<p>not be real</p> <ul style="list-style-type: none"> <li>• severe or persistent headache, fever, stiff neck, sensitivity to light and vomiting.</li> </ul>	
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This leaflet was prepared in June 2022.

**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](http://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 NOUMED CELECOXIB contains

<b>Active ingredient (main ingredient)</b>	celecoxib
<b>Other ingredients (inactive ingredients)</b>	sodium lauryl sulfate carrageenan microcrystalline cellulose colloidal anhydrous silica purified talc magnesium stearate
<b>Potential allergens</b>	lactose

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

### What NOUMED CELECOXIB looks like

100 mg Capsules: Opaque, white capsules with blue cap containing white to slightly yellowish pellets.

200 mg Capsules: Opaque, white capsules with orange cap containing white to slightly yellowish pellets.

NOUMED CELECOXIB 100 mg - AUST R 285667

NOUMED CELECOXIB 200 mg - AUST R 285668

### Who distributes NOUMED CELECOXIB

#### Sponsor

Avallon Pharmaceuticals Pty Ltd  
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