

CELEBREX(R)

celecoxib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CELEBREX. 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 CELEBREX 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 CELEBREX and keep it with the medicine.

You may need to read it again.

What CELEBREX is used for

CELEBREX is used to relieve symptoms including joint pain, tenderness, swelling and stiffness in:

- * osteoarthritis,
- * rheumatoid arthritis and
- * ankylosing spondylitis

CELEBREX is also used to relieve menstrual cramps (period pain).

CELEBREX belongs to a group of medicines called Coxibs.

CELEBREX is used to relieve pain and inflammation associated with arthritis and ankylosing spondylitis, a chronic inflammatory rheumatic disorder that primarily affects, but is not limited to, the spine.

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

Your doctor, however, may have prescribed CELEBREX for another purpose.

Ask your doctor if you have any questions about why CELEBREX has been prescribed for you.

CELEBREX has not been studied in children or adolescents under 18 years of age.

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

Before you take CELEBREX

When you must not take it

Do not take CELEBREX 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 CELEBREX, these symptoms may be severe.

* **you have an allergy to:**

- CELEBREX
- 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 CELEBREX, 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 CELEBREX, 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**

There is no information on the use of CELEBREX during pregnancy.
CELEBREX may affect your developing baby if taken in the last 3 months of pregnancy.
CELEBREX 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**
CELEBREX passes into breast milk in small amounts, therefore, the use of CELEBREX during breastfeeding 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 (ie 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 CELEBREX 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 CELEBREX 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 CELEBREX.

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 CELEBREX 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 CELEBREX.

How to take CELEBREX

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.

How much to take

Osteoarthritis

200 mg once daily or 100 mg twice daily.

Rheumatoid arthritis

100 mg twice daily or 200 mg twice daily.

Ankylosing Spondylitis

100 mg twice daily or 200 mg once daily.

Management of menstrual cramps (period pain)

400 mg on the first day and 200 mg once daily on following days. You may take an additional 200 mg on the following days if needed. You may take CELEBREX for up to 5 days.

How to take it

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

How long to take it

Depending on your condition, you may need CELEBREX for a few weeks or longer periods.

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

Keep taking CELEBREX 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 CELEBREX. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are using it

Things you must do

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

If you are about to start any new medicines, tell your doctor and

pharmacist that you are taking CELEBREX.

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

If you develop any skin rash (e.g. hives, spots) while being treated with CELEBREX, 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 CELEBREX to anyone else, even if they have the same symptoms or condition as you.

Do not use CELEBREX 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 CELEBREX, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, CELEBREX 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 heart beat, 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
- * 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
- * confusion
- * 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 CELEBREX 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.

After using CELEBREX

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 CELEBREX in a cool, dry place where the temperature stays at or below 25 degrees 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 CELEBREX, or the capsules have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

- * CELEBREX 100 mg - opaque, white capsules with two blue bands marked 7767 and 100.

The 100 mg capsules come in blister packs of 60.

- * CELEBREX 200 mg - opaque, white capsules with two gold bands marked 7767 and 200.

The 200 mg capsules come in blister packs of 10 and 30.

Ingredients

Active ingredient

The active ingredient in CELEBREX is celecoxib.

- * CELEBREX 100 mg - 100 mg celecoxib/capsule
- * CELEBREX 200 mg - 200 mg celecoxib/capsule

Other ingredients

- * lactose
- * sodium lauryl sulfate
- * povidone
- * croscarmellose sodium
- * magnesium stearate
- * gelatin
- * titanium dioxide
- * iron oxide yellow CI 77492/200 mg capsule
- * indigo carmine CI 73015/100 mg capsule.

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

Supplier

CELEBREX is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia

Toll Free Number 1800 675 229

Australian Registration Number:

CELEBREX 100 mg - AUST R 67901

CELEBREX 200 mg - AUST R 67902

This document was last revised in May 2009.

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