

Caldolor[®] kal-do-lor

ibuprofen (eye-bue-pro-fen)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Caldolor[®].

It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Caldolor[®] against the benefits they expect it will have for you. Your doctor has been provided with full information and can answer any questions you may have.

If you have any concerns about being given this medicine, ask your doctor.

Please read this leaflet carefully and keep it in a safe place.

You may need to read it again.

What Caldolor[®] is used for

Caldolor[®] contains ibuprofen, a medicine that relieves pain, inflammation (swelling, redness, heat) and fever (high temperature).

Caldolor[®] is a solution of ibuprofen which is given by infusion into a vein after it has been diluted. Caldolor[®] must only be given to you by a doctor or nurse.

Caldolor[®] is used:

- to relieve pain following surgery, sometimes in addition to other medication
- to reduce fever (high temperature).

Although Caldolor[®] can relieve the symptoms of pain and fever it will not cure your condition.

This medicine belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs).

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

Your doctor may have prescribed it for another reason.

Caldolor[®] is only available with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you are given Caldolor[®]

When you must not be given Caldolor[®]

You must not be given Caldolor[®] if:

1. you have an allergy to:

- any medicine containing ibuprofen or aspirin
- any of the ingredients listed at the end of this leaflet
- any other NSAIDs.

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

Symptoms of an allergic reaction may include:

- asthma, wheezing or coughing, shortness of breath, difficulty breathing
- swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- stomach ache, fever, chills, nausea and vomiting,
- fainting.

2. you are having heart bypass surgery.

It may increase your chance of a heart attack or a stroke (damage to part of the brain caused by an interruption to its blood supply).

3. you have (or have previously):

- vomited blood or material that looks like ground coffee

- bled from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
- had a peptic ulcer (i.e. ulcer in the stomach or part of the small intestine), a recent history of one, or have had peptic ulcers before
- had ulcerative colitis (inflammation of the colon) or Crohn's disease.

4. you have a spinal cord injury.

It may increase the risk of bleeding in this area.

5. you are in the last three months of pregnancy:

It may affect the development of your baby and it may delay labour and birth.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given Caldolor[®]

Tell your doctor if:

1. you have allergies to:

- any other medicines including aspirin or any other NSAID
- any other substances such as, foods, preservatives or dyes.

2. you are pregnant or intend to become pregnant.

Like most NSAIDs, Caldolor[®] is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.

3. you are breast-feeding or planning to breast-feed.

It is not known whether Caldolor[®] passes into breast milk. Your doctor will discuss the risks and benefits of using it if you are breast-feeding.

4. you have, or have had, any of the following medical conditions:

- heart disease or high blood pressure
- heart failure
- swelling of ankles or feet

- shortness of breath
- fatigue, chest pain, palpitations
- heartburn, indigestion, or an uncomfortable feeling in the stomach or belching after eating
- diarrhoea
- vomiting blood or material that looks like ground coffee
- bled from the back passage, have black sticky bowel motions (stools) or bloody diarrhoea
- a peptic ulcer (i.e. ulcer in the stomach or part of the small intestine), a recent history of one, or have had peptic ulcers before
- ulcerative colitis (inflammation of the colon) or Crohn's disease
- any other stomach or bowel problem
- a severe skin rash, flaking or peeling of the skin or reactions such as Stevens-Johnson syndrome
- asthma, breathlessness, wheezing, a cough sometimes brought on by exercise and/or a feeling of tightness in the chest
- vision problems
- liver or kidney disease or impairment
- dehydration
- tendency to bleed, disease of blood clotting or other blood problems
- recent spinal or epidural pain relief
- tiredness, headaches, dizziness and looking pale
- systemic lupus erythematosus (SLE) and/or related connective tissue diseases
- signs or symptoms of an infection.

If you have not told your doctor about any of the above, tell him/her before you are given Caldolor®.

Taking other medicines

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

Some medicines and Caldolor® may interfere with each other. These include:

- aspirin, salicylates or other NSAIDs, medicines used to treat pain, inflammation or swelling
- aminoglycoside medicines, used to treat certain infections
- warfarin or other medicines used to prevent blood clots
- cardiac glycosides, medicines used to treat heart failure such as digoxin
- medicines used to treat high blood pressure or other heart conditions
- corticosteroids, such as prednisone or cortisone
- cyclosporine or tacrolimus, medicines used to treat certain problems with the immune system or to help prevent organ transplant rejection
- diuretics, may also be called water tablets,
- ginkgo biloba, a herbal medicine
- lithium, a medicine used to treat some types of depression including bipolar disorder
- methotrexate, a medicine used to treat arthritis and some types of cancer
- mifepristone, a medicine used for medical abortion
- quinolone antibiotics, medicines used to treat certain infections
- zidovudine, a medicine used to treat HIV.

These medicines may be affected by Caldolor® or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will advise you.

Your doctor has more information on medicines to be careful with or to avoid while being given Caldolor®

How Caldolor® is given

How it is given

Caldolor® will be given to you by a doctor or nurse.

It is diluted and given as a 30 minute infusion (slow injection) into a vein.

How much is given

Your doctor will decide how much Caldolor® you need.

Pain following Surgery

You will usually be given a 400 to 800 mg dose of Caldolor® every 6 hours, as necessary.

Fever

You will usually be given a 400 mg dose of Caldolor® every 4 to 6 hours, as necessary.

Your doctor may give you a different amount depending on your condition.

How long is it given for

Your doctor will decide how long you need to be given Caldolor®.

If you are given too much (overdose)

Caldolor® must only be given by a doctor or nurse so overdose is unlikely.

If you are given too much Caldolor®, you may feel or experience the following symptoms

- abdominal pain
- nausea
- vomiting
- drowsiness
- dizziness.

If you think you have been given too much Caldolor®:

- tell your doctor or nurse immediately, or
- telephone the Poisons Information Centre on 13 11 26

While you are being given Caldolor®

Things you must not do

Do not start taking any other medicine including any that you buy without a prescription from your pharmacy, supermarket, health food shop, naturopath or herbalist without first telling your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Caldolor® affects you.

As with other NSAIDs, Caldolor® may cause dizziness, light-headedness, drowsiness, or blurred vision in some people.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Caldolor®.

This medicine helps most people with pain following surgery and fever, but it may have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting certain side effects.

Tell your doctor or nurse if you notice any of the following and they worry you:

- nausea or vomiting
- loss of appetite
- difficulty passing urine
- cough
- heartburn /indigestion or an uncomfortable feeling in the stomach or belching after eating.
- cramps, wind, constipation or diarrhoea
- headache
- tiredness
- dizziness
- buzzing or ringing in the ears or other trouble hearing
- sleeplessness

- changes in mood, for example depression, confusion or nervousness
- itching.

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- severe pain or tenderness in the stomach
- eye problems such as blurred vision, sore red eyes, itching
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- yellowing of the skin and/or eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- severe or persistent headache
- fast or irregular heartbeats, also called palpitations
- excessive thirst, weakness, tiredness.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, breathlessness sudden or severe itching, skin rash, hives
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson Syndrome)
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck

- vomiting blood or material that looks like ground coffee.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or nurse if you notice anything else that is making you feel unwell.

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

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

You may not experience any of them.

After being given Caldolor

Storage

Caldolor® is usually stored at the hospital. However, if you need to store Caldolor®:

- **Keep it where children cannot reach it**
- **Keep it in the original pack until it is time for it to be given**
- **Keep it in a cool dry place where the temperature stays below 25°C.**

Caldolor® should not be given to you:

- if the expiry date (EXP) printed on the pack has passed
- if the package is torn or shows signs of tampering.

Your doctor or nurse will check these things for you.

Product description

What it looks like

Caldolor® is a clear, colourless to slightly yellow solution. It is supplied in a clear glass vial that is closed with a stopper and an aluminium seal that is covered with a plastic flip-off cap.

Each vial of Caldolor® contains:

- 800 mg/8 mL in a 10 mL vial
- 400 mg/4 mL in a 5 mL vial.

Each box of Caldolor® contains 10 vials.

Not all pack sizes may be available.

Ingredients

Active ingredients:

- 100 mg/mL ibuprofen.

Inactive ingredients:

- arginine
- water for injections
- hydrochloric acid for pH adjustment.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Ask your doctor, nurse or pharmacist if you are unsure about anything or want more information about Caldolor®.

Sponsor

bioCSL Pty Ltd

ABN 26 160 735 035

63 Poplar Road,

Parkville, VIC, 3052

Australia

This leaflet was prepared on
13 August 2015

Australian Registration Numbers:

400 mg in 4 mL: AUST R 175190

800 mg in 8 mL: AUST R 175191

Caldolor® is a registered trademark of Cumberland Pharmaceuticals Inc. used under licence.