

Caldolor[®] kal-do-lor

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 being treated with Caldolor?

Caldolor contains the active ingredient ibuprofen. Caldolor is used to relieve pain, inflammation, and fever.

For more information, see Section [1. Why am I being treated with Caldolor?](#) in the full CMI.

2. What should I know before I am treated with Caldolor?

Do not use if you have ever had an allergic reaction to any medicine containing ibuprofen or aspirin 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 am treated with Caldolor?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Caldolor 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 is Caldolor used?

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.

More instructions can be found in Section [4. How is Caldolor used?](#) in the full CMI.

5. What should I know while Caldolor is being used?

Things you should do	<ul style="list-style-type: none"> Remind any doctor, nurse, dentist, or pharmacist that you are using Caldolor. Tell your doctor if you are pregnant or intend to become pregnant. Tell your doctor if you have allergies to any other medicine, food, preservatives, or dyes. Tell your doctor if you get any visual disturbances such as blurred vision. Tell your doctor if you feel the medicine is not helping your condition.
Things you should not do	<ul style="list-style-type: none"> Do not take any other medicines to relieve pain and reduce inflammation while you are taking Caldolor without first telling your doctor. Do not take Caldolor to treat any other complaints unless your doctor tells you to. Do not give Caldolor to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> Caldolor may cause dizziness or 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.
Looking after your medicine	<ul style="list-style-type: none"> Caldolor will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while Caldolor is being used?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. If you are over 65 years of age, you may have an increased chance of getting side effects. 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.

Caldolor[®]

Active ingredient: ibuprofen

Consumer Medicine Information (CMI)

This leaflet provides important information about using Caldolor. **You should also speak to your doctor, nurse, or pharmacist if you would like further information or if you have any concerns or questions about using Caldolor.**

Where to find information in this leaflet:

- [1. Why am I being treated with Caldolor?](#)
- [2. What should I know before I am treated with Caldolor?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Caldolor used?](#)
- [5. What should I know while I am being treated with Caldolor?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with Caldolor?

Caldolor contains the active ingredient ibuprofen. 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 Caldolor has been prescribed for you. Your doctor may have prescribed it for another reason.

Caldolor is a Prescription Only Medicine.

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

2. What should I know before I am treated with Caldolor?

Warnings

You should not be given Caldolor if:

- you are allergic to any medicine containing ibuprofen or aspirin, or any of the ingredients listed at the end of this leaflet and any other NSAIDs.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- hives, itching or skin rash
- stomach ache, fever, chills, nausea, and vomiting
- fainting

Do not use Caldolor if:

- you are having heart bypass surgery.
- you have (or have previously) vomited blood or material that looks like coffee grounds.
- you are (or have previously) bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhea.
- you have a condition resulting in an increased tendency to bleed.
- you have a peptic ulcer (i.e., stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.
- you have, or have a history of, Ulcerative Colitis or Crohn's Disease.
- you have severe heart failure.
- you have severe liver disease.
- you have severe kidney disease

Check with your doctor if you:

- take any medicines for any other condition.
- have any allergies to any other substances, such as medicines, foods, preservatives or dyes.
- are pregnant or intend to become pregnant. Like most NSAID medicines, Caldolor is not recommended to be used during pregnancy. It may also impair female fertility.
- are breast-feeding or plan to breast-feed. Like most NSAID medicines, Caldolor is not recommended while you are breast-feeding.
- have or have had any medical conditions, especially the following:
 - heart disease or high blood pressure or heartburn, indigestion, stomach ulcer or any other stomach problems

- vomiting blood or bleeding from the back passage
 - severe skin reactions such as Stevens-Johnson syndrome
 - asthma
 - vision problems
 - liver or kidney disease
 - tendency to bleed or other blood problems
 - bowel or intestinal problems such as ulcerative colitis or Crohn’s Disease
 - heart failure
 - swelling of the ankles or feet
 - diarrhoea
- currently have an infection. If you take Caldolor while you have an infection, it may hide some of the signs and symptoms of an infection. This may make you think, mistakenly, that you are better or that it is not serious.
 - plan to have surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor 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.

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

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

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.

Your doctor can discuss with you the risks and benefits involved in using Caldolor.

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 Caldolor and affect how it works.

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.

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

4. How is Caldolor Used?

How much to use

- Caldolor is diluted and then given as a 30-minute infusion (slow injection) into a vein. Caldolor must only be given by a doctor or nurse.
- Your doctor will decide what dose of Caldolor you will receive and for how long you will receive it. This depends on your medical condition and other factors.

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.

If you use too much Caldolor

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

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

- abdominal pain
- nausea
- vomiting
- drowsiness
- dizziness

5. What should I know while I am being treated with Caldolor?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Caldolor.
- Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine. NSAID medicines can slow down blood clotting.
- If you are pregnant or intend to become pregnant while being given this medicine, tell your doctor immediately.
- If you develop an infection or have an infection tell your doctor. Caldolor may hide some of the signs of an infection and may make you think mistakenly that you are better or that it is not serious. Signs of an infection may include fever, pain, swelling and redness.
- Tell your doctor if you get any visual disturbances such as blurred vision. You may need to have an eye examination to make sure Caldolor is not causing any side effects.
- Tell your doctor if you feel the medicine is not helping your condition. This will help your doctor to determine the best treatment for you.
- Keep all of your doctor's appointments so that your progress can be checked.
- Your doctor may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

Things you should not do

Do not take any other medicines to relieve pain and reduce inflammation while you are taking Caldolor without first telling your doctor. This includes:

- aspirin (also called acetylsalicylic acid)
- other medicines containing ibuprofen, the active ingredient in Caldolor
- any other NSAID medicine

Driving or using machines

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

As with other NSAID medicines, Caldolor may cause dizziness, tiredness or 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.

Looking after your medicine

Caldolor is usually stored at the hospital. The injection is kept in a cool dry place where the temperature stays below 25°C.

It will be kept where young children cannot reach it.

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, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Digestion related:</p> <ul style="list-style-type: none"> • nausea or vomiting • loss of appetite • heartburn / indigestion or an uncomfortable feeling in the stomach or belching after eating • cramps, wind, constipation or diarrhoea <p>Nervous system related:</p> <ul style="list-style-type: none"> • headache • sleeplessness • dizziness • changes in mood, for example depression, confusion, or nervousness <p>Other:</p> <ul style="list-style-type: none"> • buzzing or ringing in the ears or other trouble hearing. • tiredness • cough • difficulty passing urine • itching. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction related:</p> <ul style="list-style-type: none"> 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 <p>Skin related:</p> <ul style="list-style-type: none"> severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Steven-Johnson Syndrome) <p>Stomach and gut related:</p> <ul style="list-style-type: none"> severe pain or tenderness in the stomach bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea vomiting blood or material that looks like ground coffee. <p>Bleeding:</p> <ul style="list-style-type: none"> bleeding or bruising more easily than normal, reddish or purplish blotches under the skin <p>Eye:</p> <ul style="list-style-type: none"> eye problems such as blurred vision, sore red eyes, itching <p>Infections:</p> <ul style="list-style-type: none"> frequent infections such as fever, severe chills, sore throat or mouth ulcers swollen lymph nodes <p>Liver:</p> <ul style="list-style-type: none"> yellowing of skin and/or eyes also called jaundice <p>Nervous system related:</p> <ul style="list-style-type: none"> severe or persistent headaches <p>Cardiovascular system related:</p> <ul style="list-style-type: none"> fast or irregular heartbeats, also called palpitations tiredness, headaches, being short of breath when exercising, dizziness and looking pale <p>General:</p> <ul style="list-style-type: none"> unusual weight gain, swelling of ankle or legs excessive thirst, weakness, tiredness fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck. 	<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>

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

Caldolor is a prescription medicine and is only administered under a doctor's supervision.

What Caldolor contains

Active ingredient (main ingredient)	100 mg/mL ibuprofen
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> arginine water for injections hydrochloric acid (for pH adjustment)

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

Caldolor does not contain lactose, sucrose, gluten, tartrazine, or any other azo dyes or preservatives.

What Caldolor 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.

Australian Registration Numbers:

800 mg/8 mL AUST R 175191

400 mg/4 mL AUST R 175190

Who distributes Caldolor

Caldolor is supplied in Australia by:

Phebra Pty Ltd

19 Orion Road, Lane Cove West,

NSW 2066, Australia.

Telephone: 1800 720 020

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