

Clonac

diclofenac sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CLONAC.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking CLONAC against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with your medicine.

You may need to read it again.

What CLONAC is used for

CLONAC belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to treat pain and reduce inflammation (swelling and redness) that may occur in the following:

- different types of arthritis including rheumatoid arthritis and osteoarthritis
- other painful conditions where swelling is a problem such as back pain, rheumatism, muscle strains, sprains and tendonitis (eg. tennis elbow)
- menstrual cramps (period pain).

These medicines can relieve the symptoms of pain and

inflammation, but they will not cure your condition.

Your doctor may have prescribed this medicine for another reason.

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

Your doctor may have prescribed it for another purpose.

CLONAC is available only with a doctor's prescription.

This medicine is not addictive.

Before you take it

When you must not take it

Do not take CLONAC if you are allergic (hypersensitive) to:

- diclofenac (the active ingredient in CLONAC) of any of the other ingredients listed at the end of this leaflet
- Other medicines containing diclofenac
- aspirin
- ibuprofen
- any other NSAID.

If you are not sure if you are taking any of the above 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, throat, and/or extremities (signs of angioedema)
- rash, itching or hives on the skin.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are allergic to aspirin or NSAID medicines and take CLONAC, these symptoms may be severe.

Do not take this medicine if you have had any of the following medical conditions:

- a stomach or intestinal ulcer
- bleeding from the stomach or bowel (symptoms of which may include blood in your stools or black stools)
- severe kidney or liver problems
- severe heart failure
- heart bypass surgery.

Do not use CLONAC during the first 6 months of pregnancy, except on doctor's advice. Do not use during the last three months of pregnancy.

Use of this medicine during the last 3 months of pregnancy may affect your baby and may delay labour and birth.

Use of non-aspirin NSAIDs can increase the risk of miscarriage, particularly when taken close to the time of conception.

Do not take this medicine if the expiry date (Exp.) printed on the pack has passed.

Do not take it if the packaging is torn or shows signs of tampering.

Do not give this medicine to children.

CLONAC is not recommended for use in children, as there is not enough information on its use in this age group.

Before you start to take it

Tell your doctor if you have, any medical conditions, especially the following:

- established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, peripheral arterial disease or atherosclerotic cardiovascular disease), as treatment with CLONAC is generally not recommended
- established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe CLONAC, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks
- a past history of ulcers (stomach or intestinal)
- gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past
- diseases of the bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative colitis)
- past history of haemorrhoids (piles) or irritation of the rectum (back passage)
- liver or kidney problems
- a rare liver condition called porphyria
- bleeding disorders or other blood disorders (e.g. anaemia)
- asthma or any other chronic lung disease that causes difficulty in breathing
- hay fever (seasonal allergic rhinitis)
- repeated chest infections

- polyps in the nose
- diabetes
- dehydration (e.g. by sickness, diarrhoea, before or after recent major surgery)
- swollen feet.

Your doctor may want to take special care if you have any of these conditions.

It is generally important to take the lowest dose that relieves your pain and/ or swelling and for the shortest time possible in order to keep your risk for heart problems or high blood pressure as small as possible.

Tell your doctor if you are pregnant or plan to become pregnant.

There is not enough information to recommend CLONAC during the first 6 months of pregnancy and it must not be used during the last 3 months. This medicine may also reduce fertility and affect your chances of becoming pregnant. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you currently have an infection.

If you take CLONAC while you have an infection, some of the signs of the infection such as pain, fever, swelling and redness may be hidden. You may think, mistakenly, that you are better or that the infection is not serious.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Like most NSAID medicines, CLONAC is not recommended for use during breast-feeding because CLONAC passes into breast milk and may affect your baby.

Tell your doctor if you are lactose intolerant.

CLONAC tablets contain lactose.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies, especially if you get skin reaction with redness, itching or rash.

If you have not told your doctor about any of the above, tell them before you start taking CLONAC.

Taking other medicines

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

Some medicines that are important to mention include:

- other anti-inflammatory medicines, e.g. aspirin, salicylates or ibuprofen
- warfarin or other "blood thinners" (medicines used to prevent blood clotting)
- digoxin, a medicine for heart problems
- lithium or selective serotonin-reuptake inhibitors (SSRIs), a medicine used to treat some types of depression
- diuretics, medicines used to increase the amount of urine
- ACE inhibitors or beta-blockers, medicines used to treat high blood pressure, heart conditions, glaucoma and migraine
- prednisone, cortisone, or other corticosteroids, medicines used to provide relief for inflamed areas of the body
- medicines (such as metformin) used to treat diabetes, except insulin
- methotrexate, a medicine used to treat arthritis and some cancers
- cyclosporin and tacrolimus, medicines used in patients who have received organ transplants
- trimethoprim used to treat urinary tract infections
- some medicines used to treat infection, quinolone antibacterials
- glucocorticoid medicines, used to treat arthritis
- sulfinpyrazone, a medicine used to treat gout

- voriconazole, a medicine used to treat fungal infections
- phenytoin, a medicine used to treat seizures
- rifampicin (an antibiotic medicine used to treat bacterial infections).

You may need to take different amounts of your medicines or to take different medicines while you are using CLONAC. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/ her before you start using this medicine.

How to take CLONAC

When take it

It is recommended to take the tablets before meals or on an empty stomach. If they upset your stomach, you can take them with food or immediately after food.

They will work more quickly if you take them on an empty stomach but they will still work if you have to take them with food to prevent stomach upset

How much to take

To treat arthritis or other painful conditions

The usual starting dose of CLONAC tablets is 75 mg to 150 mg each day.

After the early stages of treatment, it is usually possible to reduce the dose to 75 mg to 100 mg each day.

To treat menstrual cramps (period pain)

The tablets are usually taken during each period as soon as cramps begin and continued for a few days until the pain goes away.

The usual starting dose of CLONAC tablets is 50 mg to 100 mg each day, beginning as soon as cramps begin and continuing until

the pain goes away, but for no longer than 3 days.

If necessary, the dose can be raised over several menstrual periods to a maximum of 200 mg each day.

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

These instructions may differ from the information contained in this leaflet.

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

There are different ways to take this medicine depending upon your condition. Your doctor will tell you exactly how many tablets to take.

Do not exceed the recommended dose.

How to take the tablets

CLONAC tablets are usually taken in 2 or 3 doses during the day.

Swallow the tablets whole with a full glass of water. Do not chew them.

The tablets have a special coating to stop them dissolving until they have passed through the stomach into the bowel. Chewing them would destroy the coating.

How long to take it

Do not use CLONAC for longer than your doctor says.

If you are using CLONAC for arthritis, it will not cure your disease but it should help control pain and inflammation. It usually begins to work within a few hours but several weeks may pass before you feel the full effects of the medicine.

If you forget to take it

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and

then go back to taking your tablets as you would normally.

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

This may increase the chance of you getting unwanted side effect.

Ask your doctor or pharmacist if you are not sure what to do.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much CLONAC. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

If you take too much, you may experience:

- vomiting
- bleeding from the stomach or bowel
- diarrhoea
- dizziness
- ringing in the ears
- convulsions (fits).

While you are taking it

Things you must do

If you take CLONAC for more than a few weeks, you should make sure you visit your doctor for regular check-ups to ensure that you are not suffering from unnoticed undesirable side effects.

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

Your doctor can discuss with you the risk of using it while you are pregnant.

Be sure to keep all your doctor's appointments so that your progress can be checked.

Your doctor will periodically re-evaluate whether you should

continue treatment, if you have established heart disease or significant risks for heart disease, especially in case you are treated for more than 4 weeks.

Your doctor may want to check your kidneys, liver and blood from time to time to help prevent unwanted side effects.

If, at any time while taking CLONAC you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately. These may be signs of cardiovascular toxicity.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking CLONAC.

NSAID medicines can slow down blood clotting and affect kidney function.

If you get an infection while using CLONAC, tell your doctor.

This medicine may hide some of the signs of an infection (pain, fever, swelling, redness). You may think, mistakenly, that you are better or that the infection is not serious.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using CLONAC.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking CLONAC.

Things you must not do

Do not take any of the following medicines while you are using CLONAC without first telling your doctor:

- aspirin (also called ASA or acetylsalicylic acid)
- other salicylates
- other medicines containing diclofenac (e.g. Voltaren tablets, Voltaren Emulgel)
- ibuprofen
- any other NSAID medicines.

If you take these medicines together with CLONAC, they may cause unwanted effects.

If you need to take something for headache or fever, it is usually okay to take paracetamol. If you are not sure, your doctor or pharmacist can advise you.

Do not stop any other forms of treatment for arthritis that your doctor has told you to follow.

This medicine does not replace exercise or rest programs or the use of heat/cold treatments.

Do not use it to treat any other conditions unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how CLONAC affects you.

CLONAC may cause dizziness, drowsiness, spinning sensation (vertigo) or blurred vision in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Elderly patients should take the minimum number of tablets that provides relief of symptoms.

Elderly patients may be more sensitive to the effects of CLONAC than other adults.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CLONAC.

Like all other medicines, CLONAC may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment 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. Report any side effects to your doctor.

As people grow older, they are more likely to get side effects from medicines.

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

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- stomach upset including nausea (feeling sick), vomiting, indigestion, cramps, loss of appetite, wind
- heartburn or pain behind or below the breastbone (possible symptoms of an ulcer in the tube that carries food from the throat to the stomach)
- stomach or abdominal pain
- constipation, diarrhoea
- sore mouth or tongue
- altered taste sensation
- headache
- dizziness, spinning sensation
- drowsiness, disorientation, forgetfulness
- feeling depressed, anxious or irritable
- strange or disturbing thoughts or moods
- shakiness, sleeplessness, nightmares
- tingling or numbness of the hands or feet
- feeling of fast or irregular heart beat
- unusual weight gain or swelling of arms, hands, feet, ankles or legs due to fluid build-up
- symptoms of sunburn (such as redness, itching, swelling, blistering of the lips, eyes, mouth, and/or skin) that happen more quickly than normal

- skin inflammation with flaking or peeling
- vision disorders* (e.g. blurred or double vision)
- buzzing or ringing in the ears, difficulty hearing
- hypertension (high blood pressure)
- hair loss or thinning

NSAIDs, including diclofenac, may be associated with increased risk of gastro-intestinal anastomotic leak. Close medical surveillance and caution are recommended when using this medicine after gastrointestinal surgery.

***If symptoms of vision disorders occur during treatment with CLONAC, contact your doctor as an eye examination may be considered to exclude other causes.**

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- red or purple skin (possible signs of blood vessel inflammation)
- severe pain or tenderness in the stomach, vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea (possible stomach problems)
- rash, skin rash with blisters, itching or hives on the skin; swelling of the face, lips, mouth, tongue, throat, or other part of the body which may cause difficulty to swallow, low blood pressure (hypotension), fainting, shortness of breath (possible allergic reaction)
- wheezing, troubled breathing, or feelings of tightness in the chest (signs of asthma)
- yellowing of the skin and/or eyes (signs of hepatitis/ liver failure)
- persistent nausea, loss of appetite, unusual tiredness,

vomiting, pain in the upper right abdomen, dark urine or pale bowel motions (possible liver problems)

- constant "flu-like" symptoms including chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy, bleeding or bruising more easily than normal (possible blood problems)
- painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals, which may be accompanied by fever and chills, aching muscles and feeling generally unwell (possible serious skin reaction)
- signs of a possible effect on the brain, such as sudden and severe headache, stiff neck (signs of viral meningitis), severe nausea, dizziness, numbness, difficulty in speaking, paralysis (signs of cerebral attack), convulsions (fits)
- change in the colour or amount of urine passed, frequent need to urinate, burning feeling when passing urine, blood or excess protein in the urine (possible kidney disorders)
- sudden and oppressive chest pain which may be a sign of myocardial infarction or heart attack
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- coincidental occurrence of chest pain and allergic reactions (signs of Kounis syndrome).

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using CLONAC

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store CLONAC or any other medicine in the bathroom or near a sink.

Do not leave CLONAC in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking CLONAC, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

CLONAC comes in 2 strengths of tablets:

- CLONAC 25 – pale yellow, round, enteric coated tablets plain on both sides
- CLONAC 50 - pale brown, round, enteric coated tablets plain on both sides

Each pack contains 50 tablets.

Ingredients

Active ingredient:

- CLONAC 25mg tablet - 25 mg of diclofenac sodium
- CLONAC 50mg tablet - 50 mg of diclofenac sodium

Inactive ingredients:

- colloidal anhydrous silica
- microcrystalline cellulose
- lactose monohydrate
- magnesium stearate
- maize starch
- povidone
- hypromellose
- iron oxide yellow
- titanium dioxide
- sodium starch glycollate type A
- PEG-40 hydrogenated castor oil
- methacrylic acid-ethyl acrylate copolymer (1:1)
- triethyl citrate
- iron oxide red (50 mg tablet only)

This medicine contains sugars as lactose.

Supplier

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne, Victoria, 3121

This leaflet was revised in
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Australian register numbers:

25 mg Tablet: AUST R 272878
(Blister)

50 mg Tablet: AUST R 272874
(Blister)