

# Diclofenac Amneal Tablets

*diclofenac sodium*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about Diclofenac Amneal tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

**You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.**

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will provide.

**If you have any concerns about this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What Diclofenac Amneal is used for

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Diclofenac Amneal belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to treat pain and reduce inflammation (swelling and redness).

Diclofenac Amneal is used to treat:

- 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 (e.g. tennis elbow)
- menstrual cramps (period pain)
- relieve pain in children after they have had an operation.

It can relieve the symptoms of pain and inflammation but it will not cure your condition.

**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 purpose.

Diclofenac Amneal is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend the use of Diclofenac Amneal tablets in children.

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### Before you use Diclofenac Amneal

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*When you must not use it*

**Do not use Diclofenac Amneal if you are allergic (hypersensitive) to:**

- diclofenac (the active ingredient in Diclofenac Amneal) or 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 or other parts of the body
- 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 you use Diclofenac Amneal, these symptoms may be severe.

**Do not use Diclofenac Amneal 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)
- kidney or liver problems
- severe heart failure
- heart bypass surgery

**Do not use Diclofenac Amneal 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.

**Do not use Diclofenac Amneal after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

In that case, return it to your pharmacist.

### *Before you start to use it*

**Tell your doctor if you have any of the following health problems / medical conditions:**

- 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 Diclofenac Amneal 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 Diclofenac Amneal, 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 precautions if you have any of the above conditions.

It is generally important to take the lowest dose of Diclofenac Amneal that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.

**Tell your doctor if you are pregnant or trying to become pregnant.**

There is not enough information to recommend the use of Diclofenac Amneal during the first 6 months of pregnancy and it must not be used during the last 3 months. Diclofenac Amneal 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 use Diclofenac Amneal 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 breast-feeding.**

Breast-feeding is not recommended while you are using this medicine. The active ingredient in Diclofenac Amneal passes into breast milk and may affect your baby.

**Tell your doctor if you are lactose intolerant.**

Diclofenac Amneal 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 reactions with redness, itching or rash.

### *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 used to treat diabetes, except insulin
- methotrexate (a medicine used to treat arthritis and some cancers)
- cyclosporin, tacrolimus (a medicine used in patients who have received organ transplants)
- trimethoprim (a medicine used to prevent or 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 Diclofenac Amneal. 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.**

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## How to use Diclofenac Amneal

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### *When to take it*

#### **Diclofenac Amneal Tablets**

**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 Diclofenac Amneal to take/ use*

**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 Diclofenac Amneal tablets depending on your condition. Your doctor will tell you exactly how many tablets to take.

**Do not exceed the recommended dose.**

### *To treat arthritis or other painful conditions*

The usual starting dose of Diclofenac Amneal tablets is 75mg to 150mg each day. After the early stages of treatment, it is usually possible to reduce the dose to 75mg to 100mg 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 Diclofenac Amneal tablets is 50mg to 100mg 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 200mg each day.

### *How to take the tablets*

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

**Swallow the tablets whole with a full glass of water or other liquid. Do not chew them.**

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

### *How long to take/use it*

**Do not use Diclofenac Amneal for longer than your doctor says.**

If you are using Diclofenac Amneal for arthritis, it will not cure your disease but it should help to 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/use it*

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

**Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.**

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

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

**If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.**

### *If you take/use too much Diclofenac Amneal (Overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much Diclofenac Amneal.**

**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 Diclofenac Amneal, you may experience:**

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

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## While you are taking/ using Diclofenac Amneal

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### *Things you must do*

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

**If you become pregnant whilst taking or using Diclofenac Amneal, tell your doctor immediately.**

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

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

Your doctor will periodically re-evaluate whether you should continue treatment with Diclofenac Amneal, 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 Diclofenac Amneal 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 are going to have surgery, make sure the surgeon and anaesthetist know that you are using Diclofenac Amneal.**

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

**If you get an infection while using Diclofenac Amneal, 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 Diclofenac Amneal.**

**Tell any other doctor, dentist or pharmacist who treats you that you are using Diclofenac Amneal.**

### *Things you must not do*

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

- aspirin (also called ASA or acetylsalicylic acid)
- other salicylates
- other medicines containing diclofenac
- ibuprofen
- any other NSAID medicine

If you take these medicines together with Diclofenac Amneal, they may cause unwanted side 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 give this medicine to anyone else, even if their condition seems similar to yours.**

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

### *Things to be careful of*

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

This medicine may cause dizziness, drowsiness, spinning sensation (vertigo) or blurred vision in some people. If you have any of these symptoms, do not drive, use

machines, 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 Diclofenac Amneal than other adults.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Diclofenac Amneal.**

All medicines can have side effects. 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 old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.**

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

**Do not be alarmed by these lists 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

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

**If any of the following signs appear, 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 problem)
- 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 of protein in the urine (possible kidney disorders)
- sudden and oppressive chest pain (which may be a sign of myocardial infarction or a heart attack)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)

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

Some people may have other side effects not yet known or mentioned in this leaflet.

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## After using Diclofenac Amneal

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### Storage

- Keep your medicine in the original container until it is time to use it.
- Store it in a cool dry place.
- Do not store Diclofenac Amneal or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

**Keep the 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 using Diclofenac Amneal or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.**

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## Product description

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### What it looks like

#### Diclofenac Amneal tablets

Diclofenac Amneal 25mg tablets are round, pale yellow, enteric coated tablets plain on both sides, blisters (Alu/PVC or ALu/PVC/PVdC) of 20 or 50\*.

Diclofenac Amneal 50mg tablets are round, pale brown, enteric coated tablets plain on both sides, blisters (Alu/PVC or ALu/PVC/PVdC) of 10, 20 or 50\*.

\* not all pack sizes may be marketed

## *Ingredients*

### **Diclofenac Amneal tablets**

Contain 25mg or 50mg diclofenac sodium as the active ingredient in gastro-resistant tablets.

The tablets also contain:

- colloidal anhydrous silica
- microcrystalline cellulose
- lactose monohydrate
- magnesium stearate
- maize starch
- povidone
- hypromellose
- iron oxide yellow CI77492
- iron oxide red CI77491 (50mg tablet only)
- titanium dioxide
- sodium starch glycollate
- purified talc
- PEG-40 hydrogenated castor oil
- methacrylic acid ethyl acrylate copolymer (1:1)
- triethyl citrate

Diclofenac Amneal tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

## *Supplier*

Diclofenac Amneal is supplied in Australia by:

Amneal Pharma Australia Pty Ltd  
12 River Street,  
South Yarra, Victoria 3141

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### **Australian Registration Numbers:**

25mg tablet blister  
AUST R 272878

50mg tablet blister  
AUST R 272874