

## Diclofenac AN®

Diclofenac sodium

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some of the common questions about Diclofenac AN. 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 Diclofenac AN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may want to read it again.

#### What Diclofenac AN tablets are used for

The name of your medicine is Diclofenac AN. It contains the active ingredient diclofenac sodium.

Diclofenac AN is used for treating the symptoms of inflammatory and degenerative forms of rheumatism, rheumatoid arthritis and osteoarthritis. It is also used in conditions where back pain, muscle strains, sprains and tendonitis (e.g. tennis elbow) are observed. It is also used to relieve states of acute or chronic in which there is an inflammatory component, as well as for the symptomatic treatment of dysmenorrhoea (heavy, painful periods).

Your doctor may have prescribed Diclofenac AN for another reason. Ask your doctor if you have any questions about why Diclofenac AN was prescribed for you.

Diclofenac AN belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It also has analgesic and antipyretic properties.

Diclofenac acts by reducing pain (at rest and on movement), morning stiffness and swelling of the joints associated with rheumatic diseases, as well as improving function.

In addition, it has been shown to relieve pain in dysmenorrhoea.

There is no evidence that Diclofenac AN is addictive.

#### Before you take Diclofenac AN tablets

##### When you must not take Diclofenac AN Tablets

Diclofenac AN tablets should not be used by children. In adults, they should not be taken if:

- You are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description.
- You have had allergic reactions such as asthma, itchy rash or severe hay fever, swelling of the face, lips, tongue or other parts of the of the body; rash, itching or the hives on the skin.
- After taking aspirin or any other NSAIDs.
- You suffer from a stomach ulcer, bleeding from the stomach or bowel
- Severe kidney, liver or heart problems.

- It has passed its expiry date or the packaging appears to have been tampered with.
- You are pregnant or breast feeding, or if there is a possibility that pregnancy may occur.
- Do not use Diclofenac AN during the first 6 months of pregnancy, except on doctor's advice. Do not use during the last three months of the pregnancy as this 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.

##### Before you start to take Diclofenac AN Tablets

Tell your doctor if you plan on becoming pregnant or will be breast feeding while you are using Diclofenac AN.

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

- problems with your heart, liver or kidney function.
- any infection.
- a stomach ulcer, severe attacks of indigestion, or any other stomach or bowel disorder in the past.
- a tendency to bleed or other blood problems such as anaemia.
- seasonal allergies (e.g. hay fever)
- repeated chest infections
- polyps in the nose
- diabetes
- recent major surgery
- tell your doctor if you are pregnant or trying to become pregnant or breast feeding
- currently having an infection, lactose intolerance or allergy to other foods, medicines, dyes or preservatives.

##### Taking other medicines

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

In particular, tell your doctor if you take any of the following:

- Lithium or selective serotonin-reuptake inhibitors (SSRIs), a medicine used to treat some types of depression
- Digoxin, a heart tablet
- Diuretics, also called fluid or water tablets
- Medicines which lower blood pressure
- Aspirin or any other anti-inflammatory (NSAID or COX-2 inhibitor) medications
- Anticoagulants, tablets for thinning the blood
- Corticosteroids, medicines such as prednisone or cortisone, which reduce the activity of your immune system
- Antidiabetic agents, for diabetes
- Methotrexate, a medicine used for treatment of rheumatoid arthritis, as well as some types of cancers

- Cyclosporin, a medicine used after organ transplants, as well as in the treatment of rheumatoid arthritis
- Glucocorticoids, used to treat arthritis
- Certain antibiotics called quinolones.
- Voriconazole, a medicine used to treat fungal infections
- Sulfapyridine, a medicine used to treat gout.
- Phenytoin, a medicine used in treatment of epilepsy

These medicines may be affected by Diclofenac AN, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

**Tell your doctor or pharmacist if you are currently taking a diuretic and other medicine(s) to help lower blood pressure at the same time. Sometimes diuretics and certain blood pressure lowering drugs are combined in the one product. If you are taking these drug combinations, your doctor may advise a blood test to check your kidney function before you start to take Diclofenac AN.**

#### How to take Diclofenac AN Tablets

The daily dose should generally be prescribed in two or three divided doses. The prescribed dose should be swallowed whole with a glass of water. You may take it with or immediately after food in order to reduce the chance of stomach upset. The dosage and duration of treatment will be determined for you by your doctor.

##### If you forget to take your dose

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you are not sure what to do, ask your doctor or pharmacist.

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

##### If you take too much

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 has taken too much Diclofenac AN.

Do this even if there are no signs of discomfort or poisoning.

#### While you are using Diclofenac AN Tablets

##### Things you must do

- Always follow your doctor's instructions carefully.
- Keep all your doctor's appointments so that your progress can be checked.
- Inform the surgeon and anaesthetist before going to have a surgery.

- Tell your doctor if you get an infection while using Diclofenac AN.
- Tell your doctor if you become pregnant while taking Diclofenac AN.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Diclofenac AN.

#### **Things you must not do**

- Do not take any of the following medicines such as aspirin, other salicylates, any other NSAID and medicines containing diclofenac.
- Do not stop any other form of treatment that your doctor has told you to follow.
- Do not use Diclofenac AN to treat any other complaint unless your doctor says so.
- Do not give this medication to anyone else, even if their symptoms seem similar to yours.

#### **Things to be careful of**

Be careful driving or operating machinery until you know how Diclofenac AN affects you. Diclofenac AN may cause drowsiness, spinning sensation, blurred vision or light-headedness in some people.

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#### **Side effects**

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

The most common side effects seen in patients taking diclofenac preparations are:

- stomach pain
- nausea, vomiting, diarrhoea
- sore mouth or tongue
- altered taste sensation
- abdominal cramps
- flatulence
- anorexia
- rashes
- vertigo
- headache, dizziness
- drowsiness, disorientation, forgetfulness
- feeling depressed, anxious or irritable
- strange or disturbing thoughts or moods
- shakiness, sleeplessness, nightmares
- tingling or numbness of hands or feet
- feeling of fast or irregular heart beat
- unusual weight gain or swelling of ankles or legs due to fluid build-up
- blurred or double vision\*
- buzzing or ringing in the ears, difficulty hearing
- hair loss or thinning

\*If symptoms of vision disorders occur during treatment with Diclofenac AN, contact your doctor as an eye examination may be considered to exclude other causes. These are the more common side effects of Diclofenac AN. Mostly, these are mild and short-lived.

If any of the following happen, stop taking Diclofenac AN, and tell your doctor immediately, or go to accident and emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- peptic ulceration and gastrointestinal bleeding.
- signs of persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, yellowing of the skin and/or eyes, dark urine or pale brown motions
- signs of chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy
- signs of severe headache, stiff neck, severe nausea, dizziness, numbness, difficulty in speaking, paralysis, fits.
- a change in the colour or amount of urine passed, frequent need to urinate, burning feeling when passing urine, blood in the urine
- chest pain, which may be a sign of a heart attack

If you feel unusually weak and tired, or notice blood in your faeces, together with severe stomach pain, stop taking the tablets and see your doctor immediately.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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#### **After using Diclofenac AN**

##### **Storage**

Keep Diclofenac AN in the original packaging until you need to take it.

Do not store Diclofenac AN in the bathroom or near a sink.

Do not leave in the car or on window sills.

Store below 25 °C in a dry place, out of the reach of children.

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

##### **Disposal**

Return any unused or out of date medicine to your pharmacist.

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#### **Product Description**

##### **What Diclofenac AN Tablets look like**

Diclofenac AN 25 mg (*AUST R 188546*): round, brown-yellow film coated tablets. They are available in blister packs of 50 tablets.

Diclofenac AN 50 mg (*AUST R 188547*): round, brown-yellow film coated tablets. They are available in blister packs of 50 tablets.

##### **Ingredients**

Active Ingredient:

- DICLOFENAC AN 25mg tablet – 25 mg of diclofenac sodium.
- DICLOFENAC AN 50mg tablet – 50 mg of diclofenac sodium.

Inactive Ingredients:

- Lactose
- Calcium hydrogen phosphate dihydrate
- Microcrystalline cellulose
- Maize starch

- Sodium starch glycollate
- Magnesium stearate
- Colloidal silicon dioxide
- Methacrylic acid copolymer
- Triethyl citrate
- Talc
- Titanium dioxide
- Yellow ferric oxide.

##### **Supplier**

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

This leaflet was revised in May 2017.

##### **Australian register numbers:**

25 mg Tablet: AUST R 188546 (*Blister*)

50 mg Tablet: AUST R 188547 (*Blister*)