

# APO-DICLOFENAC

*Diclofenac sodium*

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## Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

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### What is in this leaflet

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This leaflet answers some common questions about this medicine. 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.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine 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 need to read it again.

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### What this medicine is used for

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APO-Diclofenac 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).

APO-Diclofenac 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)

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 reason.

This medicine is available only with a doctor's prescription. It is not addictive.

There is not enough information to recommend the use of this medicine for children.

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### Before you use this medicine

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*When you must not take it*

**Do not use this medicine if you are allergic (hypersensitive) to:**

- diclofenac
- or any of the other ingredients listed at the end of this leaflet
- aspirin
- ibuprofen
- any other NSAID
- lactose, or are lactose intolerant - these tablets contain a small amount of lactose

**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 angiodema)
- 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 APO-Diclofenac, these symptoms may be severe.

**Do not use APO-Diclofenac 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 APO-Diclofenac 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 after the expiry date printed on the pack or**

**if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

*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 APO-Diclofenac 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 APO-Diclofenac, 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 or ischemic 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 APO-Diclofenac 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 APO-Diclofenac during the first 6 months of pregnancy and it must not be used during the last 3 months. APO-Diclofenac 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 APO-Diclofenac 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 APO-Diclofenac passes into breast milk and may affect your baby.

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

APO-Diclofenac 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 or pharmacist if you are taking any other medicines, including any that you get without a prescription from your 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)
- ciclosporin, 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 APO-Diclofenac. 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 take this medicine

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### *When to 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*

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

They may differ from the information contained in this leaflet.

**If you do not understand the directions, ask your doctor or pharmacist for help.**

There are different ways to take APO-Diclofenac 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 APO-Diclofenac 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 usual starting dose of APO-Diclofenac 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.

### *How to take it*

The daily dose should be divided into two or three doses taken during the day.

The tablets should be swallowed whole with a full glass of water or other liquid.

Do not break, crush or chew the tablets.

### *How long to take it*

**Continue taking your medicine for as long as your doctor tells you.**

If you are using APO-Diclofenac 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 it*

**If it is almost time to take 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 it as soon as you remember, and then go back to taking your medicine as you would normally.**

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

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

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

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

### *If you take too much (overdose)*

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

**You may need urgent medical attention.**

**If you take too much APO-Diclofenac, 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 using this medicine

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### *Things you must do*

**If you take APO-Diclofenac 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 APO-Diclofenac, 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 APO-Diclofenac, 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 APO-Diclofenac 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 APO-Diclofenac.**

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

**If you get an infection while using APO-Diclofenac, 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 APO-Diclofenac.**

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

### *Things you must not do*

**Do not take any of the following medicines while you are using APO-Diclofenac 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 APO-Diclofenac, 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 APO-Diclofenac 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, especially those with a low body weight, may be more sensitive to the effects of APO-Diclofenac 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 APO-Diclofenac.**

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 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

**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 APO-Diclofenac, 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)
- coincidental occurrence of chest pain and allergic reactions (signs of Kounis syndrome)

**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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## Storage and Disposal

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### *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 medicine in a cool dry place where the temperature stays below 25°C.**

**Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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### *What APO-Diclofenac looks like*

APO-Diclofenac 25 mg Tablets: Brown, yellow film coated tablet, biconvex with an intact surface and uniform colour. AUST R 160729.

Blister packs of 50 tablets.

APO-Diclofenac 50 mg Tablets: Brown, yellow film coated tablet, biconvex with facet on both sides, intact surface and uniform colour. AUST R 160730.

Blister packs of 50 tablets.

\*Not all strengths, pack types and/or pack sizes may be available.

### *Ingredients*

Each tablet contains 25 or 50 mg of diclofenac as the active ingredient.

In addition, the tablets contain the following inactive ingredients:

- lactose monohydrate
- calcium hydrogen phosphate dihydrate
- microcrystalline cellulose
- maize starch
- sodium starch glycollate
- magnesium stearate
- colloidal anhydrous silica
- methacrylic acid copolymer
- triethyl citrate
- purified talc
- titanium dioxide
- iron oxide yellow.

This medicine contains sugars as lactose.

This medicine is gluten-free, sucrose-free, tartrazine-free and other azo dyes-free.

### *Sponsor*

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