

## APO-Diclofenac Enteric Coated Tablets

Contains the active ingredient, diclofenac sodium

### Consumer Medicine Information

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

#### What is in this leaflet

##### Read this leaflet carefully before taking your medicine.

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

##### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

##### Keep this leaflet with your medicine.

You may want to read it again.

#### What this medicine is used for

The name of your medicine is APO-Diclofenac. It contains the active ingredient, diclofenac sodium.

It is used to treat the symptoms of:

- Rheumatoid arthritis
- Osteoarthritis
- Pain with swelling (back pain, muscle damage and tendonitis)
- Painful periods (dysmenorrhoea)

#### How it works

Diclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It also has analgesic (painkilling) and antipyretic (fever reducing) 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 period pain (dysmenorrhoea).

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

Your doctor may have prescribed diclofenac for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

#### Use in children

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

#### Before you take this medicine

##### When you must not take it

Do not take this medicine if:

- **You have had an allergic reaction to:**
  - diclofenac
  - aspirin or any other NSAIDs
  - any of the ingredients listed at the end of this leaflet.
- **You are intolerant or allergic to lactose.** These tablets contain a small amount of lactose.  
**Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.**
- **You have asthma and NSAIDs cause your asthma symptoms to worsen.**
- **You suffer from a stomach or duodenal ulcer and/or bleeding from the stomach or bowel (black, sticky motions).**
- **You suffer from severe heart failure.**
- **You suffer from liver or kidney problems.**
- **You are in the last 3 months (last trimester) of pregnancy.** Diclofenac may affect your developing baby, and may delay labour and birth, if you take it at this stage of your pregnancy.
- Do not take this medicine after the expiry date (EXP) printed on the pack.
- Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

##### Before you start to take it

##### Tell your doctor if:

1. **You have allergies to:**
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. **You have, or have had in the past, any medical conditions, especially the following:**
  - problems with your heart, liver or kidney
  - asthma, rhinitis, nasal polyps or lung disease or other breathing problems
  - repeated chest infections
  - problems with blood clotting or other blood disorders
  - high blood pressure
  - diabetes
  - dehydration (e.g. by sickness or diarrhoea, before or after recent major surgery)
  - intolerance or allergy to lactose
  - a stomach or duodenal ulcer, severe attacks of indigestion, or any other stomach or bowel disorder (e.g. ulcerative colitis or Crohn's Disease)
  - problems with fluid retention.
3. **You are pregnant or planning to become pregnant**
  - If you are trying to become pregnant your doctor will advise you whether to keep taking this medicine, as it may affect your chances of becoming pregnant
  - If you are in the first 6 months of pregnancy your doctor will discuss with you the risks and benefits of taking this medicine
  - **You must not take this medicine in the last 3 months of pregnancy.**

##### 4. You are breastfeeding or planning to breastfeed

This medicine passes into breast milk. Your doctor will discuss with you the benefits and risks of taking it whilst breastfeeding. It is not recommended that you take this medicine whilst breastfeeding.

##### 5. You get an infection

Diclofenac can cover up some of the symptoms of infections so that you may think the infection is not serious.

##### 6. You are about to have, or have just had, an operation

Diclofenac can slow down blood clotting and may affect kidney function, or the healing process.

##### 7. You smoke or drink large amounts of alcohol

This can increase the chances of you having stomach problems or ulcers whilst taking this medicine.

##### 8. You are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

Some medicines and diclofenac may interfere with each other. These include:

- Lithium, and medicines called Selective-Serotonin Reuptake Inhibitors (SSRIs), used to treat some types of depression
- Digoxin, a heart tablet
- Antibiotic medicines called quinolones (e.g. ciprofloxacin or norfloxacin). The combination with diclofenac may cause convulsions
- Anticoagulants (e.g. warfarin) and other medicines for thinning the blood
- Antidiabetic medicines (tablets or injections) for diabetes
- Methotrexate, a medicine used to treat rheumatoid arthritis, as well as some types of cancers
- Cyclosporin, a medicine used after organ transplants, as well as to treat rheumatoid arthritis
- Corticosteroids (anti-inflammatory medicines), especially the group called glucocorticoids (e.g. hydrocortisone and prednisolone)
- Aspirin or any other anti-inflammatory (NSAID or COX-2 inhibitor) medications
- Medicines for blood pressure and heart problems, such as beta-blockers or ACE inhibitors
- Diuretics, also called fluid or water tablets
- Voriconazole, a medicine used to treat serious fungal infections
- Sulfinpyrazone, a medicine used to treat gout
- Phenytoin, a medicine used to treat seizures

These medicines may be affected by diclofenac or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Note especially that the combination of diclofenac, ACE inhibitors and certain diuretics may seriously damage your kidneys.**

Your doctor and pharmacist can tell you if you are taking any of these medicines.

Other interactions not listed above may also occur.

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## How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

### *How much to take*

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The initial dosage for arthritis and other painful inflammatory conditions is 75 to 150 mg per day.

For long-term treatment, 75 to 100 mg daily may be all that is needed.

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

For period pain, the daily dosage is generally 50 to 150 mg. The starting dose is normally 50 to 100 mg and, if necessary, can be increased over several months to a maximum of 200 mg/day. Treatment should be started when the period pain starts, and stopped after it goes away.

### *How to take it*

The tablets should be swallowed whole with liquid with a meal.

Do not break, crush or chew the tablets.

### *When to take it*

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

You may take it with, or immediately after food in order to reduce the chance of stomach upset.

### *How long to take it for*

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

### *If you forget to take it*

If it is almost time for your next dose, 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 experiencing side effects.

**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)*

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.**

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

You may need urgent medical attention.

If you take too much diclofenac, you may experience vomiting, diarrhoea, bleeding from the stomach or bowel, dizziness, ringing in the ears and/or convulsions (fits).

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## While you are taking this medicine

### *Things you must do*

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

Tell your doctor that you are taking this medicine if:

- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to be started on any new medicine
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

### **Go to your doctor regularly for a check-up.**

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

### *Things you must not do*

#### **Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other complaints unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without checking with your doctor.

### *Things to be careful of*

Be careful while driving or operating machinery until you know how diclofenac affects you.

Diclofenac may cause dizziness or light-headedness in some people.

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## Possible side effects

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Tell your doctor or pharmacist if you notice any of the following:**

- feeling of fullness and/or heartburn after eating, nausea, vomiting
- constipation, diarrhoea
- abdominal cramps or pain
- flatulence (wind)
- loss of appetite
- sore mouth or tongue
- strange taste
- skin rashes or itching
- giddiness (vertigo) or dizziness
- headache
- hair loss or thinning

The above list includes the more common side effects. Mostly, these are mild.

**Tell your doctor as soon as possible if you notice any of the following.**

These may be serious side effects and you may need medical attention.

- 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 and irregular heartbeat
- sharp pains in your abdomen
- unusual weight gain or swollen ankles or legs due to fluid build-up
- sunburn that happens after only a short time in the sun
- blurred or double vision
- buzzing or ringing in the ears, problems hearing
- signs of a possible blood problem such as persistent flu-like symptoms (sore throat, fever, swollen glands, aches), or bleeding or bruising more than normal.

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

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

- rash, itching, hives on the skin, swelling of the face, lips, mouth or throat, difficulty swallowing or breathing (signs of an allergic reaction)
- peptic ulceration and gastrointestinal bleeding may occur in some patients. You may feel unusually weak and tired, or notice blood in your faeces or have black, sticky faeces. You may vomit blood or material that looks like coffee grounds and may have severe stomach pain or tenderness.
- liver problems such as nausea, loss of appetite, tiredness, vomiting, pain in the upper right abdomen, yellow skin and/or eyes, dark urine, pale faeces (signs of liver problems)
- serious skin reactions such as painful red areas, large blisters, peeling skin, bleeding lips, eyes, mouth, nose or genitals
- sudden and severe headache, and/or nausea, stiff neck, dizziness, numbness, problems speaking, paralysis, convulsions (fits) (possible signs of stroke or brain problem)
- kidney problems indicated by a change in the colour or amount of urine passed, a need to urinate more often, burning feeling when urinating, blood in the urine
- fainting
- convulsions (fits)
- chest pain (possible sign of a heart attack), difficulty breathing, weakness, slurring of speech (possible sign of a stroke).

Other side effects not listed above may occur in some patients.

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## Storage and disposal

### *Storage*

**Keep your medicine in its original packaging until it is time to take them.**

If you take the tablets out of their original bottle they may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay below 25°C.**

**Do not store your 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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

### *Ingredients*

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

In addition the tablets contain the following inactive ingredients:

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

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

### *Australian Registration Numbers*

- **APO-Diclofenac 25 mg tablets:**  
Blister packs of 50 tablets.  
AUST R 160729.
- **APO-Diclofenac 50 mg tablets:**  
Blister packs of 50 tablets.  
AUST R 160730.

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

### *Sponsor*

#### **Apotex Pty Ltd**

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