

## CONSUMER MEDICINE INFORMATION



## DICLOFENAC POTASSIUM 25

Diclofenac Potassium 25 mg

### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Pharmacy Health Diclofenac Potassium 25.

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

**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 taking 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.

### WHAT PHARMACY HEALTH DICLOFENAC POTASSIUM 25 IS USED FOR

Pharmacy Health Diclofenac Potassium 25 belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Pharmacy Health Diclofenac Potassium 25 relieves pain and reduces inflammation (swelling and redness).

It can be used for short-term treatment of following conditions:

- The relief of migraine headaches. It may also relieve accompanying symptoms, such as nausea and vomiting, which you sometimes experience when you have a migraine.
- The relief of menstrual cramps (period pain).
- The short-term treatment (up to 1 week) of painful conditions where swelling is a problem such as back or joint pain, dental pain, muscle strains or sprains and tendonitis (e.g. tennis elbow).

Pharmacy Health Diclofenac Potassium 25 can relieve the symptoms of pain and inflammation, but it will not cure your condition.

### BEFORE YOU TAKE PHARMACY HEALTH DICLOFENAC POTASSIUM 25

***When you must not take it***

**Do not take Pharmacy Health Diclofenac Potassium 25 if you are allergic (hypersensitive) to:**

- diclofenac, the active ingredient in Pharmacy Health Diclofenac Potassium 25 or any of the ingredients listed at the end of this leaflet
- other medicines containing diclofenac
- aspirin
- any other anti- inflammatory medicines

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or anti-inflammatory medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting.

**If you are allergic to aspirin or anti-inflammatory medicines and take Pharmacy Health Diclofenac Potassium 25, these symptoms may be severe.**

**If you get an allergic reaction, stop taking and see your doctor immediately.**

**Do not use this product if you:**

- currently have a stomach or intestinal ulcer, or other stomach disorder
- have bleeding from the stomach or bowel (symptoms of which may include blood in your stools or black stools)
- have impaired kidney or severe liver disease
- have heart failure

**Do not give this medicine to a child under 12 years of age.** There is not enough information on the use of Pharmacy Health Diclofenac Potassium 25 in children under that age.

**Tell your doctor or pharmacist if any of the above apply because Pharmacy Health Diclofenac Potassium 25 is not suitable for you in these circumstances.**

**Do not take Pharmacy Health Diclofenac Potassium 25 during the last 3 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 take Pharmacy Health Diclofenac Potassium 25 after the expiry date printed on the pack.**

**Do not take Pharmacy Health Diclofenac Potassium 25 if the foil seal over the tablets has been broken or shows signs of tampering.**

In that case, return it to your pharmacist.

***Before you start to take it***

**Tell your pharmacist or doctor if you are allergic to any other medicines, including aspirin or other NSAID medicines, foods, preservatives or dyes.**

They will want to know if you are prone to allergies.

**Talk to your doctor before taking Pharmacy Health Diclofenac Potassium 25 if you have:**

- asthma or any other chronic lung disease that causes difficulty in breathing

**Talk to your doctor or pharmacist before taking Pharmacy Health Diclofenac Potassium 25 if you have or have had 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 or peripheral arterial disease) or history of blood vessel disease
- significant risk factors for heart disease, such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes or if you smoke
- history of ulcers (stomach or intestinal)

- gastrointestinal problems such as stomach ulcer, bleeding or black stools (vomiting blood or bleeding from the back passage)
- stomach discomfort or heartburn after taking pain relievers or anti-inflammatory medicines
- diseases of the bowel or inflammation of the intestinal tract (Crohn’s disease) or colon (ulcerative colitis)
- liver or kidney problems
- a rare liver condition called hepatic porphyria
- bleeding disorder or other blood disorders such as anaemia
- diabetes
- dehydration (e.g. by sickness, diarrhoea, before or after recent major surgery)
- swollen feet

**Do not exceed the recommended dose.**

Treatment with anti-inflammatory medicines, such as diclofenac, may be associated with an increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. If you have existing heart disease or risk factors for heart disease, you may be at greater risk.

It is generally important to take the lowest dose of Pharmacy Health Diclofenac Potassium 25 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 pharmacist or doctor if you have an infection in the present time.**

If you take Pharmacy Health Diclofenac Potassium 25 while you have an infection, some of the signs of the infection may be hidden (pain, fever, swelling, redness). The tablets may hide some of the signs of an infection. You may think, mistakenly, that you are better or that the infection is not serious.

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

Unless your doctor has told you to, do not use Pharmacy Health Diclofenac Potassium 25 during the first 6 months of pregnancy. Do not use at all during the last 3 months of pregnancy.

**Tell your pharmacist or doctor if you are breastfeeding.**

Unless a doctor has told you to, do not use Pharmacy Health Diclofenac Potassium 25 tablet during breastfeeding.

***Taking other medicines***

**Tell your pharmacist or 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
- lithium or selective serotonin reuptake inhibitors (SSRIs), medicines used to treat depression
- digoxin, a medicine used to treat heart problems
- ACE inhibitors or beta-blockers, medicines used to treat high blood pressure or heart conditions, glaucoma and migraine
- diuretics, also called fluid or water tablets, used to increase the amount of urine
- medicines used to treat diabetes, except insulin
- Prednisone, cortisone, or other corticosteroids, medicines used to provide relief for inflamed areas of the body
- Warfarin, other blood thinners or anticoagulants, medicines used to prevent blood clotting
- methotrexate, a medicine used to treat arthritis and some cancers

- cyclosporin or tacrolimus, medicines in patients who have received organ transplants
- trimethoprim, a medicine used to prevent or treat urinary tract infection
- quinolone antibacterials, medicines used to treat infections
- Glucocorticoid, medicines used to treat arthritis
- sulfipyrazone, a medicine used to treat gout
- voriconazole, a medicine used to treat fungal infections
- phenytoin, a medicine used to treat seizures

These medicines may be affected by Pharmacy Health Diclofenac Potassium 25 tablet or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medications.

Your pharmacist and doctor have more information on medicines to be careful with or to avoid while taking Pharmacy Health Diclofenac Potassium 25.

### HOW TO TAKE IT

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

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

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

***How much to take***

**Ask your pharmacist or doctor if you are unsure of the correct dose for you.**

They will tell you exactly how much to take. Follow the instructions they give you.

**Do not take more than the recommended dose.**

Take the lowest dose of Pharmacy Health Diclofenac Potassium 25 that relieves your pain and/or swelling.

**Stop taking as soon as your symptoms are relieved. Do not take for longer than a few days at a time.**

**For adults and children aged 12 years and over:**

Take 2 tablets initially, then 1 tablet every 8 hours as necessary.

***How to take it***

Swallow the tablet with a glass of water.

***When to take it***

**Take the tablets on an empty stomach (at least half an hour before food or two hours after food).**

They will work more quickly if you take them on an empty stomach.

**If they upset your stomach, take the tablets with food.** They will still work if you have to take them with food to prevent stomach upset.

***How long to take it***

**Do not take Pharmacy Health Diclofenac Potassium 25 tablets for more than a few days at a time, unless a doctor has told you to.**

It is usually taken for a short time only.

**If symptoms persist or worsen, see your pharmacist or doctor to ensure that they are not due to a serious illness.**

The use of Pharmacy Health Diclofenac Potassium 25 could mask potentially serious infections.

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

**Immediately telephone your doctor or Poisons Information Centre (Australia 131 126, New Zealand: 0800 764 766), or go to Accidents and Emergency at your nearest hospital if you think you or anyone else may have taken too much Pharmacy Health Diclofenac Potassium 25 tablets.**

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

You may need urgent medical attention.

### WHILE YOU ARE TAKING PHARMACY HEALTH DICLOFENAC POTASSIUM 25 TABLETS

***Things you must do***

**If you become pregnant while taking Pharmacy Health Diclofenac Potassium 25 tablets, tell your pharmacist or doctor immediately.**

They can discuss with you the risks of using it while you are pregnant. If, at any time while taking Pharmacy Health Diclofenac Potassium 25 tablets 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.

**If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking Pharmacy Health Diclofenac Potassium 25 tablets.**

**If you are going to have surgery, tell the surgeon and the anaesthetist that you are taking Pharmacy Health Diclofenac Potassium 25 tablets.**

Anti-inflammatory medicines can slow down blood clotting and affect kidney function.

**If you get an infection while taking Pharmacy Health Diclofenac Potassium 25 tablets, 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.

**Tell all of the doctors, dentists and pharmacists that are treating you that you are taking Pharmacy Health Diclofenac Potassium 25 tablets.**

***Things you must not do***

**Do not take any of the following medicines while you are taking Pharmacy Health Diclofenac Potassium 25 tablets without first telling your doctor or pharmacist:**

- aspirin or other salicylates
- other forms of Diclofenac Potassium 25
- any other anti-inflammatory medicine

**Do not use Pharmacy Health Diclofenac Potassium 25 tablets to treat any other complaints unless your pharmacist or doctor tells you to.**

**Do not give your medicine to anyone else, even if they seem to 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 Pharmacy Health Diclofenac Potassium 25 tablets affects you.**

As with other anti-inflammatory medicines, Pharmacy Health Diclofenac Potassium 25 tablets may cause dizziness, drowsiness, spinning sensation (vertigo) or blurred vision in some people. If you have any of these symptoms, do not drive or carry out other activities that need careful attention.

**Be careful if you are older than 65 years of age.**

Older people may be more sensitive to the effects of Pharmacy Health Diclofenac Potassium 25 tablets than other adults. Take the lowest number of tablets that provides relief of symptoms, and report side effects promptly to your doctor or pharmacist.

***Side effects***

**Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Pharmacy Health Diclofenac Potassium 25 tablets.**

This medicine helps most people, but it may have unwanted side effects in a few people. 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 get an allergic reaction, stop taking and see your doctor immediately.

**If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your pharmacist or doctor.**

As people get 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 pharmacist or doctor to answer any questions you may have.**

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

- stomach upset including nausea (feeling sick), vomiting, heartburn, 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 heartbeat, also called palpitations
- unusual weight gain or mild swelling
- symptoms of sunburn (such as redness, itching, swelling, blistering of the lips, eyes, mouth and/or skin) that happen more quickly than normal
- vision disorders (e.g. blurred or double vision)
- buzzing or ringing in the ears, difficulty hearing
- hypertension (high blood pressure)
- hair loss or thinning.

**Tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:**

- red or purple skin (possibly 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)
- sudden or severe itching, 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, coughing, sudden difficulty in 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 possible effects of the brain, such as sudden and severe headache, stiff neck (signs of viral meningitis), severe nausea, dizziness, numbness, difficulty speaking, paralysis (signs of cerebral attack), convulsion (fits)
- a 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).

These are very serious side effects. Some of these side effects are signs of a serious allergic reaction. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

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

Other side effects not listed above may happen in some people.

### AFTER USING IT

***Storage***

**Keep your tablets in the original packaging until it is time to take them.**

**Store the tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store Pharmacy Health Diclofenac Potassium 25 tablets or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window-sills.**

Heat and dampness can destroy some medicines. **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 pharmacist or doctor tells you to stop taking Pharmacy Health Diclofenac Potassium 25 tablets or the tablets have passed the expiry date, ask your pharmacist what to do with any medicine that are left over.**

Return any unused medicine to your pharmacist for safe disposal.

### PRODUCT DESCRIPTION

***What it looks like***

Pharmacy Health Diclofenac Potassium 25 tablets are pink coloured, round, biconvex, film coated tablets plain on both sides. It is available in blister packs of 30 tablets.

***Ingredients***

Pharmacy Health Diclofenac Potassium 25 tablets contains Diclofenac Potassium 25 as the active ingredient.

Each Pharmacy Health Diclofenac Potassium 25 tablets contains 25 mg of diclofenac potassium.

The other ingredients are: pregelatinised maize starch, calcium hydrogen phosphate, silicon dioxide, sodium starch glycolate type A, povidone, microcrystalline cellulose, magnesium stearate and Opadry amb complete film coating system 80W68912 pink Pl No: 114342.

Pharmacy Health Diclofenac Potassium 25 tablets also contains soy beans derived ingredients.

### SUPPLIER

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**Australian Registration Number**  
AUST R 329409

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