

# Diclofenac potassium 25mg & 50mg tablets

## Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

1. What Diclofenac potassium tablets are and what they are used for
2. What you need to know before you take Diclofenac potassium tablets
3. How to take Diclofenac potassium tablets
4. Possible side effects
5. How to store Diclofenac potassium tablets
6. Contents of the pack and other information

#### 1. What Diclofenac potassium tablets are and what they are used for

Diclofenac potassium belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce pain and inflammation in the following conditions:

- Sprains, strains and other injuries
- Pain and inflammation following surgery
- Gout
- Other painful conditions affecting the joints and muscles such as backache, rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and pyrophosphate arthropathy.

The tablets can also be used to relieve the symptoms associated with migraine attacks in adults.

#### 2. What you need to know before you take Diclofenac potassium tablets

##### Do not take Diclofenac potassium tablets if you:

- are **allergic** to diclofenac or any of the other ingredients of this medicine (listed in section 6), aspirin, ibuprofen or other related painkillers. Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction
- have had a **heart attack**, a **stroke**, a **mini-stroke** (TIA), **blood clots** or had a **heart bypass**

- have or have ever had a **stomach ulcer**, **perforation** or **bleeding**
- are taking other **NSAID painkillers**, or **aspirin**
- suffer from **severe kidney** or **liver failure**

- have or have had problems with your **blood circulation** (peripheral arterial disease)
- are **more than 6 months pregnant**.

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Diclofenac potassium tablets if:

- you have **asthma**, **diabetes**, **high cholesterol**, **angina**, **high blood pressure**, **liver**, **kidney** or **bowel problems**
- there is a chance you may be **pregnant**
- you are **breast-feeding**
- you **smoke**
- you suffer from any **blood clotting** disorder
- you suffer from liver **porphyria** (disorder of the red blood pigment)
- you have had or need to have **surgery**
- you are **elderly** (over 65)
- you are being treated with **diuretics** (water tablets) or **COX-2 inhibitors** such as celecoxib
- you have **Systemic Lupus Erythematosus (SLE)** or **mixed connective tissue disease**.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Medicines such as diclofenac may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, have had a previous stroke or think that you might be at risk of these conditions, you should discuss your treatment with your doctor or pharmacist.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Diclofenac potassium tablets, as Diclofenac potassium tablets can sometimes worsen wound healing in your gut after surgery.

Diclofenac may mask the signs and symptoms of infection.

Whilst you are taking these tablets, your doctor may want to give you a check-up from time to time.

##### Other medicines and Diclofenac potassium tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Especially:

- medicines to treat **diabetes**. A dose adjustment of these medicines may be necessary as blood sugar may drop too low
- **anticoagulants** (e.g. **warfarin**). These may increase the risk of bleeding
- **diuretics** (water tablets). The effect of these may be decreased. Potassium-sparing diuretics may increase the potassium levels in the blood
- **lithium** (medicine to treat depression). The blood levels of lithium may be increased if taken with Diclofenac
- **cytotoxic** medicines (e.g. **methotrexate** to treat cancers). These should not be taken less than 24 hours before or after Diclofenac potassium tablets - the blood levels of these medicines may be increased if taken with Diclofenac
- **ciclosporin**. This may harm kidney function
- **quinolones** (to treat infections, e.g. **ciprofloxacin** and **levofloxacin**). These may cause convulsions (fits)
- **steroid** tablets. These may increase the risk of bleeding in the stomach
- other **NSAIDs** (e.g. **aspirin**). These may increase the risk of side effects
- medicines to treat **high blood pressure** (ACE-inhibitors, beta blockers). The blood pressure lowering effect may be reduced
- **mifepristone** (used to induce abortion). The effect of mifepristone may be reduced by NSAIDs
- **cardiac glycosides** (e.g. digoxin) used to treat heart failure. Use with Diclofenac may worsen heart failure or increase blood levels of these medicines
- **tacrolimus** (an immunosuppressant). These may increase the risk of kidney damage
- **zidovudine** (an antiretroviral drug used to treat HIV). Taking with Diclofenac may increase the risk of blood disorders
- **phenytoin** (a medicine used to treat seizures). The blood level of this medicine may be increased if taken with Diclofenac
- **colestipol** and **cholestyramine**. These may reduce the effect of Diclofenac
- **potent CYP2C9 Inhibitors** (e.g. **sulfinpyrazone** and **voriconazole**). The blood level of Diclofenac may be increased if taken with these medicines
- **selective serotonin reuptake inhibitors** (SSRIs) (antidepressants)
- **trimethoprim** (to treat infections).

##### Laboratory tests

Frequent liver and kidney function tests and monitoring of blood counts are necessary if taken for more than a few days.

##### Pregnancy, breast-feeding and fertility

###### Pregnancy

It is not recommended that you take Diclofenac during the first 6 months of pregnancy. However, your doctor may prescribe Diclofenac for you during the first six months of pregnancy if he/she feels the benefit to you outweighs the risk. You **must not** however take Diclofenac during the last 3 months of pregnancy as damage to the foetus and reduced labour may occur.

###### Breast-feeding

You should only take Diclofenac whilst breast-feeding if advised by your doctor.

###### Female fertility

Diclofenac may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

##### Driving and using machines

Some patients may experience side effects such as dizziness, drowsiness and visual disturbances which may affect their ability to drive or operate machinery. Make sure you are not affected before driving or operating machinery.

## Diclofenac potassium tablets contain lecithin soya

If you are allergic to **peanut** or **soya**, do not take this medicinal product.

### Information on sodium content

This medicine contains less than 1mmol sodium (23mg) per 25mg or 50mg tablet, that is to say essentially 'sodium-free'.

### 3. How to take Diclofenac potassium tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Diclofenac potassium tablets must not be taken long-term, blood tests should be carried out if taken for more than a few days. To minimise side effects, you should take the lowest effective dose for the shortest time necessary to relieve your symptoms. Take the tablets with or after food. Swallow the tablets whole with a drink of water. Do not crush or chew them.

The usual dose is:

#### To treat pain and inflammation

- **Adults** - 75mg to 150mg a day in two or three doses.
- **Elderly patients** – a lower dose may be used. If you are frail or have a low body weight, your doctor may ask you to go back to see them regularly for the first 4 weeks of treatment, to make sure that you are not experiencing any side effects.
- **Children aged 14 years and over** – 75mg to 100mg daily, in two or three doses.
- **Not recommended for children under 14 years old.**

#### To treat the symptoms of migraine in adults

50mg taken when the first signs of a migraine attack appear. Another 50mg taken 2 hours after the first dose if needed and then every 4 to 6 hours. You should not take more than 200mg in 24 hours.

#### These tablets are not suitable for the treatment of migraine in children.

#### If you take more Diclofenac potassium tablets than you should

Contact your doctor, nearest hospital or pharmacist if you have taken more Diclofenac potassium tablets than stated in this leaflet or more than what your doctor has prescribed.

#### If you forget to take Diclofenac potassium tablets

Do not take a double dose to make up for a forgotten dose. Continue the treatment as advised by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### Stop taking Diclofenac potassium tablets and contact a doctor straight away if you notice:

##### Uncommon (may affect up to 1 in 100 people):

- Sudden and crushing chest pain (signs of myocardial infarction or heart attack), especially if you have been taking a higher dose (150mg per day) for a long period of time.
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure).

##### Rare (may affect up to 1 in 1,000 people):

- Any sign of bleeding in the stomach or intestine (e.g. having black tarry stools or blood in your vomit). Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Diclofenac potassium tablets and followed by bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain. Gastritis (inflammation, irritation or swelling of the stomach lining).
- Stomach ulcers (there have been very rare reported cases resulting in death, particularly in the elderly).
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering. Facial swelling, serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight. Wheezing or shortness of breath (bronchospasm). Swollen face, lips, hands or fingers.
- Yellowing of your skin or the whites of your eyes.

##### Very rare (may affect up to 1 in 10,000 people):

- Sudden weakness or numbness in the face, arm or leg especially on one side of the body; sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke.
- An unexpected change in the amount of urine produced and/or its appearance.
- Inflammation of the lining of the brain (meningitis).
- Fits.
- Persistent sore throat or high temperature. If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

##### Not known (frequency cannot be estimated from the available data):

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

**Tell your doctor** if you experience any of the following:

##### Common (may affect up to 1 in 10 people):

- Stomach pain, heartburn, nausea (feeling sick), vomiting (being sick), diarrhoea, indigestion, wind, loss of appetite.
- Headache, dizziness, vertigo.
- Skin rash or spots.
- Raised levels of liver enzymes in the blood.

##### Uncommon (may affect up to 1 in 100 people):

- Fast or irregular heartbeat (palpitations), chest pain, heart disorders.

##### Rare (may affect up to 1 in 1,000 people):

- Drowsiness, tiredness.
- Skin rash and itching.
- Fluid retention, symptoms of which include swollen ankles.
- Liver function disorders, including hepatitis and jaundice, inflammation of the pancreas.
- Asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest).

##### Very rare (may affect up to 1 in 10,000 people):

- Tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, headaches together with a dislike of bright lights, fever and a stiff neck.
- Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease).
- Hypertension (high blood pressure), hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia).
- Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.
- Hair loss.
- Impotence.

##### Not known (frequency cannot be estimated from the available data):

- Throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances of sensation.

Medicines such as diclofenac may be associated with a small increased risk of heart attack or stroke.

#### Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Diclofenac potassium tablets

Keep this medicine out of the sight and reach of children.

This medicine has no special storage precautions.

Do not take this medicine after the expiry date which is stated on the carton/bottle. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Diclofenac potassium tablets contain

The active substance is Diclofenac. Each tablet contains 25mg or 50mg Diclofenac potassium. The tablets also contain silica colloidal anhydrous, sodium starch glycolate, povidone, maize starch, calcium hydrogen phosphate, magnesium stearate, polyvinyl alcohol partially hydrolysed, titanium dioxide E171, talc, lecithin soya E322, iron oxide red, iron oxide yellow and xanthan gum E415.

#### What Diclofenac potassium tablets look like and contents of the pack

The 25mg tablets are pink, circular, biconvex 6mm film-coated tablets. The 50mg tablets are reddish brown, circular, biconvex 9mm film-coated tablets.

#### Pack sizes

Blister packs: 28 film-coated tablets.

Plastic bottles: 100 and 500 film-coated tablets.

(Not all pack sizes may be available).

#### Marketing Authorisation Holder

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#### Manufacturer

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