

## Diclofenac potassium 25mg & 50mg tablets

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you have any of the side effects, or if you notice any not listed, please tell your doctor or pharmacist

**In this leaflet:**

- 1. What Diclofenac potassium tablets are and what they are used for**
- 2. 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. Further 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.

**In children aged 9 years and above:**

**25mg tablets** may be used in the short term treatment of fever related infections of the ear, nose or throat such as tonsillitis and inflammation of the ear drum. It may also be used either individually or in combination with morphine (or other opiates) for pain relief after surgery.

**2. Before you take Diclofenac potassium tablets**

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

- are **allergic** (hypersensitive) to diclofenac potassium or any of the other ingredients in the tablet (see section 6)
- have a **peptic ulcer** (ulcer in your stomach or duodenum) or **bleeding in your stomach**, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation
- have previously had a reaction (**asthma, hives** or a **cold**) caused by an allergy to salicylates (e.g. aspirin) or other non-steroidal pain killers
- suffer from **severe kidney, heart or liver failure**
- have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- have or have had problems with your blood circulation (peripheral arterial disease)
- are **pregnant**, and in the last three months (**last trimester**) of pregnancy.

**Check with your doctor or pharmacist** before taking Diclofenac potassium tablets if you:

- have a **history of gastrointestinal disease** e.g. ulcerative colitis or Crohn's disease
- have reduced **heart, kidney, or liver** function
- suffer from any **blood clotting** disorder
- have or have had **asthma**
- suffer from liver **porphyria** (disorder of the red blood pigment)
- have had or need to have **surgery**
- are **elderly** (over 65)
- if you are being treated with **diuretics** (water tablets) or **COX-2 inhibitors** such as celecoxib.

Make sure your doctor knows, before you are given diclofenac:

- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides

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.

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

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken 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 these medicines may be increased if taken with Diclofenac
- **cytotoxic** medicines (e.g. **methotrexate** to treat cancers) – 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) – 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) - combination with Diclofenac may increase the risk of blood disorders.

**Laboratory tests**

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

**Pregnancy and breastfeeding**

Ask your doctor or pharmacist for advice before taking any medicine.

*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.

### Breastfeeding

You should only use Diclofenac whilst breastfeeding 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

### 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.

### Important information about some of the ingredients

If you are allergic to **peanut** or **soya** do not take this medicine, as it contains soya. This medicine contains 0.075 mmol (2.92mg) **potassium** per 25mg tablet and 0.150 mmol (5.85mg) potassium per 50mg tablet. This should be taken into account if you have reduced kidney function or are on a controlled potassium diet.

## 3. How To Take Diclofenac potassium tablets

Always take Diclofenac potassium tablets exactly as your doctor has told you. If you are unsure check with your doctor or pharmacist. 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.

The tablets must be swallowed whole with a glass of water, **with or after food.**

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 him regularly for the first 4 weeks of treatment, to make sure that you are not experiencing any side effects.
- **Children aged 12 years and over** – 75mg to 100mg daily, in two or three doses.
- 50mg tablets only – **not recommended for children under 12 years of age.**
- 25mg tablets only - **children aged 9 years and over** - for the short term treatment of fever related infections of the ear, nose or throat and for pain relief following surgery. The dose will be calculated by your doctor.

### 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 hourly. 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, emergency room or pharmacist if you have taken more Diclofenac potassium tablets than stated in this leaflet or more than what your doctor has prescribed (and you feel unwell)

### If you forget to take Diclofenac potassium tablets

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

## 4. Possible side effects

Like all medicines, Diclofenac potassium tablets can cause side effects, although not everybody gets them.

If you suffer from any of the following at any time during your treatment, **STOP TAKING the medicine and seek immediate medical help:**

- pass blood in your faeces (stools / motions)
- pass black tarry stools
- vomit any blood or dark particles that look like coffee grounds
- **an allergic reaction** such as itching, low blood pressure, swelling of the face, lips, tongue, mouth and throat, which may cause shortness of breath or difficulty swallowing
- a form of **meningitis** (aseptic) causing a combination of symptoms such as headache, fever, stiff neck, tiredness, muscle pain, sore throat and disorientation.
- yellowing of the skin or the whites of your eyes
- stomach pain, indigestion, heartburn, wind, nausea (feeling sick), vomiting (being sick) or other abnormal stomach symptoms

### STOP TAKING the medicine and tell your doctor if you experience:

- Any type of fit or seizure
- An unexpected change in the amount of urine produced and/or its appearance

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

**Common (occurs in less than 1 in 10 people):** headache, dizziness, 'spinning' sensation, diarrhoea, loss of weight or poor appetite, abnormal liver function tests, skin rashes

**Rare (occurs in less than 1 in 1000 people):** drowsiness, tiredness, stomach ulcers or bleeding, hepatitis, itching, fluid retention (symptoms of which include swollen ankles)

**Very rare (occurs in less than 1 in 10 000 people):** 'pins and needles', tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), difficulty sleeping, nightmares, depression, irritability, anxiety, psychotic reactions, disorientation, loss of memory, numbness, sensitivity to light, taste disturbance, constipation, inflammation of the tongue, mouth ulcers, ulcers of the gullet, lower gut disorders (including inflammation of the colon causing diarrhoea and stomach pains), palpitations (fast or irregular heart beat), chest pain, high blood pressure, inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), congestive heart failure, blood disorders (including anaemia, making you tired and more prone to minor infections or bleeding), kidney or liver disorders, presence of blood or protein in the urine, skin rash, itching, skin eruptions, eczema, Erythema Multiforme (round red patches on the skin), Stevens-Johnson-Syndrome (severe skin rash with flushing, fever, blisters and ulcers), or Lyell's Syndrome (severe rash with reddening, peeling and swelling of skin that looks like severe burns), hair loss, pancreatitis (inflammation of the pancreas), worsening of ulcerative colitis or Crohn's disease, impotence (difficulty getting an erection).

Medicines such as Diclofenac potassium tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. If you have any of the side effects, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Diclofenac potassium tablets

Keep out of the reach and sight of children

This medicine has no special storage precautions. Do not use after the expiry date stated on the carton. Unused tablets should be taken back to the pharmacist for safe disposal.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Further information

### What Diclofenac potassium tablets contain

The active substance (the ingredient that makes the tablet work) is Diclofenac. Each tablet contains 25mg or 50mg Diclofenac potassium.

The tablets also contain silica colloidal anhydrous, sodium starch glycollate, povidone, maize starch, calcium hydrogen phosphate anhydrous, 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, round, unscored, biconvex 6mm film coated tablets.

The 50mg tablets are reddish brown, round, unscored, biconvex 9mm film coated tablets.

### Pack sizes

Blister packs: 28 film- coated tablets.

Plastic bottles: 100 and 500 film-coated tablets (Not all packs sizes may be available)

### Marketing Authorisation Holder

Actavis Group PTC ehf, Reykjavikurvegi 76-78, 220 Hafnarfjörður, Iceland

### Manufacturer

Actavis hf., Reykjavikurvegi 78, PO Box 420, IS-222, Hafnarfjörður, Iceland.

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