

## Package leaflet: Information for the user

### Diclofenac Potassium 12.5 mg Tablets

Diclofenac potassium

**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, please 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). NSAIDs reduce pain and inflammation.

Diclofenac Potassium Tablets relieve pain, reduce swelling and ease inflammation in:

- Rheumatoid arthritis, osteoarthritis, acute gout, low back pain, ankylosing spondylitis - Migraine
- Conditions affecting the joints and muscles such as sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations, and fractures.
- Conditions affecting the tendons for example, tendonitis, tenosynovitis, bursitis.

They are also used to treat pain and inflammation associated with orthopaedic, dental and other minor surgery.

#### 2. What you need to know before you take Diclofenac Potassium Tablets

##### Do not take Diclofenac Potassium Tablets if you:

- are **allergic** (hypersensitive) to diclofenac potassium, aspirin, ibuprofen or any other NSAID, or any of the other ingredients in the tablet (see section 6). Signs of allergic (hypersensitive) reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces), or have had two or more episodes of peptic ulcers, stomach bleeding or perforation - have had stomach or bowel problems after you have taken other NSAIDs.
- 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, severe heart or severe 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.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Diclofenac Potassium or other pain medications.

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

### Warnings and precautions

**Talk 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**.
- are breast-feeding.
- have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.
- have heart problems, or have you had a stroke, or think you might be at risk of these conditions.
- have diabetes.
- suffer from liver **porphyria** (disorder of the red blood pigment).
- have had or need to have **surgery**.
- are elderly (over 65).
- are being treated with diuretics (water tablets) or COX-2 inhibitors such as celecoxib.
- Smoke.
- have Lupus (SLE) or any similar condition.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary, particularly if you are underweight or elderly.

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 (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

If at any time while taking Diclofenac potassium 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 have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.

Diclofenac may mask the signs and symptoms of infection for example, headache and high temperature.

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. This includes 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.
- **tacrolimus** (an immunosuppressant) – these may increase the risk of kidney damage.
- **cholesterol lowering medication** (e.g. **colestipol** and **cholestyramine**) these medicines can delay or decrease the effect of diclofenac. It is recommended that diclofenac is taken at least 4 to 6 hours after taking these medicines.
- **SSRIs** (medicine to treat depression e.g. citalopram) - these may increase the risk of bleeding in the stomach
- **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** or **COX-2 (cyclo-oxygenase-2) inhibitor** (e.g. **aspirin** or **ibuprofen**) – 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.
- **phenytoin** (a medicine used to treat seizures).
- **sulfinpyrazone** (a medicine used to treat gout) or **voriconazole** (a medicine used to treat fungal infections).
- **trimethoprim** (a medicine used to prevent or treat urinary tract infections).

## Pregnancy and breastfeeding

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 any medicine.

### *Pregnancy*

- Do not take Diclofenac Tablets if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.
- You should not take Diclofenac Tablets during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor.

If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Diclofenac Tablets can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

- Are you trying for a baby? Taking Diclofenac Tablets may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

#### Other special warnings

- You should take the lowest dose of Diclofenac for the shortest possible time, particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Diclofenac. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for.
- If at any time while taking 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.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, Diclofenac may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Diclofenac
- Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Diclofenac tablets as it sometimes worsens wound healing in your gut after surgery.

#### *Breastfeeding*

You should not take diclofenac whilst breastfeeding.

#### *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.

#### **Diclofenac Potassium Tablets contain soya**

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

#### **Diclofenac Potassium Tablets contain potassium**

This medicine contains 0.0374 mmol (1.46mg) potassium per tablet. This should be taken into account if you have reduced kidney function or are on a controlled potassium diet.

#### **Other ingredients**

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

### **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:

**Adults** - 75 mg (6 tablets) to 150 mg (12 tablets) a day in two or three doses. The number of tablets you take will depend on the strength the doctor has given you.

*To treat the symptoms of migraine in adults*

50mg (4 tablets) taken when the first signs of a migraine attack appear. Another 50mg (4 tablets) taken 2 hours after the first dose if needed and then every 4 to 6 hours. You should not take more than 200mg (16 tablets) in 24 hours.

**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.

#### **Use in children and adolescents**

**Children over 14 years of age** - 75mg to 100mg daily, in two or three doses.

**Diclofenac potassium Tablets are not recommended for children under the age of 14. They are not recommended for the treatment of migraine in children of any age.**

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

#### **If you take more Diclofenac Potassium Tablets than you should**

If you, or anyone else, accidentally takes too much, for example, if you have taken more Diclofenac Potassium Tablets than stated in this leaflet or more than what your doctor has prescribed – contact your doctor, casualty department or pharmacist immediately. If you are then required to visit your doctor, casualty department or pharmacist – Take your medicine pack with you so that people can see what you have taken.

Symptoms of overdose can include, but are not limited to, headache, nausea (feeling sick), vomiting (being sick), stomach pain, bleeding in the stomach or intestine, diarrhoea, dizziness, disorientation, excitation, coma, drowsiness, tinnitus (ringing in the ears), fainting or convulsions. In the case of significant poisoning acute kidney failure and liver damage are possible.

#### **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. Do not double up on the next dose to make up for the one missed.

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 tell your doctor straight away if you notice:**

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick).

- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit dark particles that look like coffee grounds or black, tarry faeces.
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering.
- Wheezing or shortness of breath (bronchospasm).
- Swollen face, lips, hands or fingers.
- Yellowing of your skin or the whites of your eyes.
- Persistent sore throat or high temperature.
- An unexpected change in the amount of urine produced and/or its appearance.
- Any type of fit or seizure.
- A form of meningitis (aseptic) causing a combination of symptoms such as headache, fever, stiff neck, tiredness, muscle pain, sore throat and disorientation.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Diclofenac Potassium Tablets and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
- 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.
- Sudden and crushing chest pain (signs of myocardial infarction or heart attack)
- A serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, and itching (Generalised bullous fixed drug eruption).

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell our doctor.

The side effects listed below have also been reported.

**Common: may affect up to 1 in 10 people**

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

**Uncommon: may affect up to 1 in 100 people**

- Palpitations (fast or irregular heart beat).
- Chest pain.
- Heart attack or breathlessness.
- Heart failure.
- Difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day) for a long period of time.

**Rare: may affect up to 1 in 1000 people**

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly).
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhoea with blood in it or bleeding from the back passage
- Black, tarry faeces or stools
- Drowsiness, tiredness.
- Low blood pressure, symptoms of which may include faintness, giddiness or light headedness.

- Skin rash and itching.
- Fluid retention, symptoms of which include swollen ankles.
- Liver function disorders, including hepatitis and jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems which would lead to tiredness, loss of appetite, stomach pain, joint pain).
- Asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest).

**Very rare: may affect up to 1 in 10, 000 people**

Effects on the nervous system:

Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), difficulty sleeping, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation of taste.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, taste changes, 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), inflammation of the pancreas.

Effects on the heart, chest or blood:

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) causing fever, difficulty breathing and cough, blood disorders (including anaemia).

Effects on the liver or kidneys:

Kidney or liver disorders including kidney failure and liver failure, presence of blood or protein in the urine.

Effects on skin or hair:

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. Hair loss.

Effects on the reproductive system:

Impotence.

**Other effects that have also been reported include:**

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

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

- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.

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

**Reporting of 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

Yellow Card Scheme

Tel: Freephone 0808 100 3352

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.

Do not store above 25 °C

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

Unused tablets should be taken back to the pharmacist for safe disposal.

Do not throw away any medicines 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. Contents of the pack and other information**

**What Diclofenac potassium tablets contain**

- The active substance (the ingredient that makes the tablet work) is diclofenac. Each tablet contains 12.5mg 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 and Xanthan gum E415.

**What Diclofenac Potassium Tablets looks like and contents of the pack**

The tablets are white, round, unscored, biconvex 5mm film coated tablets, with 'I' marked on one side

Pack sizes

Pack sizes 7, 10, 14, 28, 30, 50, 56, 98 and 100 film coated tablets.

(Not all packs sizes may be available)

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