Diclofenac potassium 25mg & 50mg Tablets

PATIENT INFORMATION LEAFLET

Diclofenac potassium tablets 25mg & 50mg Tablets

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

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 psoriatic arthritis.

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

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 in your stomach (gastritis) or small intestine (duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation
- have had history of gastro-intestinal bleeding or perforation, relating to previous NSAID therapy
- 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 liver disease
- suffer from any other liver disorder (disorder of the red blood pigment) or a genetic disorder
- have previously had a reaction (e.g. anaphylaxis) to diclofenac potassium
- have a history of gastro-intestinal bleeding or perforation
- have had 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 close or bypass blockages
- 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 had heart, kidney, or liver function
- suffer from any blood clotting disorder
- have had heart attacks
- suffer from low blood pressure (hypotension) or anemia
- have had heart, kidney, or liver function
- have had kidney disease
- have been given a medicine to treat depression (SSRIs)
- have had blood circulation problems (peripheral arterial disease)
- are pregnant, and in the last three months (last trimester) of pregnancy.

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.

3. How to take Diclofenac potassium tablets

4. Possible side effects

5. How to store Diclofenac potassium tablets

6. Further information

Diclofenac may mask the signs and symptoms of infection.

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.

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.

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
- corticosteroids (e.g. methylprednisolone to treat cancer) – 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
- milrinone (used to reduce abnormal heart rhythms) – the effect of milrinone 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
- tiazidines (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
- phenytoin (a medicine used to treat seizures) – the blood level of this medicine may be increased if taken with Diclofenac
- celecoxib and diclofenac - these may reduce the effect of Diclofenac
- patient CYP2C9 Inhibitors in 4 sulfonpyrazone and roxanolamine – the blood level of Diclofenac may be increased if taken with these medicines
- selective serotonin reuptake inhibitors (SSRIs)
- trinitroglycerine

Laboratory tests

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

Diclofenac Potassium 25mg & 50mg Tablets PIL - UK

Approved for print/post

Item number: BBBA2023

Dimensions: 170 x 320

Min Body Text Size: 4pt

Supplier: Specialcar

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Version 2

01.11.2017

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

Common (affects up to 1 in 10 people):
- headache, dizziness, ringing in the ears, difficulty sleeping, nightmares, depression, irritability, anxiety, psychotic reactions, disorientation, loss of memory, seizures, acute meningoencephalitis, difficulty to light, taste changes, constipation, inflammation of the tongue, mouth ulcers, ulcers of the gut, blurred vision, reduction of inflammation of the colon causing diarrhoea and stomach pain, palpitations (fast or irregular heart beat), chest pain, high or low blood pressure, inflammation of blood vessels (blisters), inflammation of the lung (pneumonitis), congestive facial tans, blood disorders (including anaemia, making you tired and more prone to minor infections or bleeding, kidney or liver failure or failure of blood or protein in the urine, skin rash, itching, skin eruptions, eczema, dermatitis, Erythema Multiforme (round red patches on the skin), Stevens-Johnson Syndrome (severe rash with blisters and ulcers), Lyell's Syndrome (severe skin rash with flushing, fever, blisters and ulcers), or jaundice. Some patients may experience side effects such as dizziness, drowsiness and visual disturbances which may affect their ability to drive or operate machinery if you are not affected before driving or operating machinery.

Some patients may experience side effects such as:
- vomiting (being sick) or other abnormal stomach symptoms such as headache, fever, stiff neck, tiredness, muscle pain, sore throat and disorientation
- an allergic reaction
- an unexpected change in the amount of urine produced and/or its appearance
- a form of pancreatitis (inflammation of the pancreas), worsening of ulcerative colitis or Crohn's disease, impotence (difficulty getting an erection), angina or a sudden deterioration in the skin.

Unknown (frequency cannot be estimated from the data):
- neutropenia (a loss to resistance to infections), confusion, hallucinations, disturbances of sensation, generally feeling unwell, sudden loss of vision.

Medicines such as Diclofenac potassium tablets may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke (very rare).

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 to the National Reporting Service. Visit website 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 out of the sight and reach 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 into sinks, sewers or household waste. Ask your pharmacist how to safely 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 talc, microcrystalline cellulose, polyethylene glycol, magnesium stearate, polyvinylpyrrolidone, sodium starch glycolate, povidone, maize starch, calcium hydrogen phosphate, magnesium stearate, povidone, iron oxide yellow, magnesium stearate, talc, iron oxide red, starch, hypromellose and magnesium stearate. Diclofenac is a type of medicine called a non-steroidal anti-inflammatory drug (NSAID) which helps to reduce pain, swelling and redness caused by inflammation. Diclofenac tablets contain Diclofenac in 25mg and 50mg film-coated tablets.

What Diclofenac potassium tablets look like and contents of the pack

The 25mg tablets are pink, round, uncoated, binoxene 6mm film coated tablets. The 50mg tablets are reddish brown, round, uncoated, binoxene 9mm film coated tablets.

Pack size

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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This leaflet was last updated in May 2018.