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 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 psoriatic arthropathy.

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 (gastric) or small intestine (duodenal) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation
- have had a previous peptic ulcer
- have a history of gastrointestinal disease
- are over 65
- 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 significant blockages
- have a history of arterial disease
- have had a heart attack, stroke or mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass significant blockages
- have ever 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 gastro-intestinal bleeding or perforation, relating to previous NSAID therapy
- have previously had a reaction (asthma, hives or a rash) caused by an allergy to salicylates (e.g. aspirin) or other non-steroidal pain killers
- suffer from severe kidney, heart or liver failure
- have had a stroke or heart attack or for 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 had blood problems with your blood circulation (peripheral arterial disease)
- are pregnant, and in the last three months (last trimester) of pregnancy.

3. How to take Diclofenac potassium tablets

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.

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
- cytoxic medicines (e.g. methotrexate 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)
- steroidal 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 inhibitor, beta blocker) – the blood pressure lowering effect may be reduced
- milrinone (used to reduce induction) – 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
- 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
- ciclosporin (a medicine used to treat severe, advanced organ rejection) – the blood level of this medicine may be increased if taken with Diclofenac
- cefadroxil and cefazolin – these may reduce the effect of Diclofenac
- potent CYP3A4 inhibitors in 5 sulfonamides and verapamil – the blood level of Diclofenac may be increased if taken with these medicines
- selective serotonin reuptake inhibitors (SSRIs)
- trimethoprim

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

PATIENT INFORMATION LEAFLET

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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 and taken for more than a few days. To minimise side-effects, you should take the lowest effective dose for the shortest period 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 100mg daily, in two or more divided 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 him 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 tablets taken when the first signs of a migraine attack appear. Another 50mg tablet may be used 2 hours after the first dose if required, and then every 4 to 6 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 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 a forgotten dose. Continue the treatment as advised by your doctor.

4. Possible side effects

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

If you suffer from any of the following at any time during your treatment with Diclofenac potassium tablets:

- possible swelling of your face (nasal / mouth)
- 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 lips, tongue, mouth and throat, which may cause shortness of breath or difficulty swallowing
- a form of meningitis (septic), causing a combination of symptoms such as a headache, fever, feeling cold or feverish, muscle pain, sore throat and diarrheaa
- 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
- any type of diarrhoea
- an unexpected change in the amount of urine produced and/or its appearance
- raised lumps on your skin, fluid retention (symptoms of which include raised veins under the skin, swelling of the body, tiredness)
- rash, skin, or mouth ulcers
- severe skin reactions, such as Stevens-Johnson-Syndrome (severe skin rash with flushing, fever, blistering and ulceration), urticaria (hives), bull’s eye rash (red circular rash in the shape of your fingers or toes), angioneurotic oedema (swelling of the skin).

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 report 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 using the Yellow Card Scheme at www.mhra.gov.uk/yelcard.

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

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 glycolate, magnesium stearate, polyvinyl alcohol partially hydrolysed, titanium dioxide E171, ferric oxide yellow E172, 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, bicarbonate 6mm film coated tablets. The 50mg tablets are reddish brown, round, unscored, bicarbonate 9mm film coated tablets.

Pack size

Blistar pack 24 film-coated tablets

Pack size

Blistar pack 24 film-coated tablets

Manufacturing Authorisation Holder

Accord Healthcare Limited, Sparkie View, 319 Pinner Road North Harrow, Middlesex, HA1 1HD, United Kingdom

Supplier

Specifar L.A.

1, 28 Octoberisou, 125 51 Ag. Varanis, Athens, Greece

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