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 4).
• have a peptic ulcer, in your stomach (gastric) or small intestine (duodenal) bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach 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 severe kidney, heart or liver failure
• have established heart disease and 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 e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or an operation
• 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 kidney, heart or liver function
• suffer from any blood clotting disorder
• have had asthma
• 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
• have Systemic Lupus Erythematosus (SLE) and mixed connective tissue disease

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.

Meditations such as diclofenac may be associated with a small increased risk of side effects including heart attack and stroke, bleeding in the stomach, stomach bleeding or perforation. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. If you have had 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. If you are taking these tablets, your doctor may want to give you a checkup 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
• blood (medicine to treat depression) – the blood levels of these medicines may be increased if taken with Diclofenac
• cytotoxic medicines (e.g. methotrexate to treat cancer) – should not be taken less than 24 hours before or after Diclofenac 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 levoflloxacin) – these may cause convulsions (fits)
• other NSAIDs – these may increase the risk of bleeding in the stomach or intestines (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
• methylprideine (used to induce abortion) – effect of methylpridine may be reduced by NSAIDs
• cardiac glycosides (e.g. digitoxin) used to treat heart failure. Use with Diclofenac may worsen heart failure or increase blood levels of these medicines.
• ciclosporin (an immunosuppressant) – these may increase the risk of kidney damage
• sildenafil (an antifluviral 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
• cyclosporin – these may increase the effect of Diclofenac
• CYP2C9 inhibitors (e.g. sulfonylureas and voriconazole) – the blood level of Diclofenac may be increased if taken with these medicines
• selective serotonin reuptake inhibitors (SSRIs) – these may increase the risk of bleeding in the stomach
• lithium – (medicine to treat depression) the blood levels of these medicines may be increased if taken with Diclofenac
• methotrexate (a medicine used to treat cancers) – effects of methotrexate may be increased if taken with Diclofenac
• oral anticoagulants - these may increase the risk of bleeding
• ACE inhibitors (e.g. enalapril) – effect of mifepristone (used to induce abortion) – effect of mifepristone may be reduced by NSAIDs
• cyclosporin – these may increase the risk of side effects

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 in the last 3 months of pregnancy as damage to the fetus and reduced labour may occur.
Breafly:
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

Driving and using machines:
Some patients may experience side effects such as dizziness, drowsiness and visual disturbance 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 this contains soya, this medicine contains:
- 0.075 mmol (2.92mg) potassium as potassium carbonate
- 0.150 mmol (5.85mg) potassium as potassium anhydrous

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 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 tablets when the first signs of a migraine attack appear.
Another 50mg tablets after 2 hours if the first dose needed and then every 4 hours. Do 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 need:
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 doses.
Continue your 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, STOP TAKING the medicine and seek immediate medical advice:
- pass blood in your faeces (stools / motions)
- pass blood in your faeces:
  - vomit any blood or dark particles that look like coffee grounds
  - have an unusual cough, such as: thickening of blood
  - swelling of the face, lips, tongue, mouth and throat, which may cause death
- a form of meningeitis (affecting a combination of symptoms such as headache, fever, stiff neck, tiredness, muscle pain and vomiting)
- swelling of the skin or the whites of your eyes
- develop shingles (a burning sensation, heat, redness, pain, skin erosion, fluid filled blisters)
- any type of fits or seizure
- condition started in the amount of urine produced and/or its appearance
- 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 (frequency not known, cannot be estimated from the available data).

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

Common (affects up to 1 in 10 people):
- headache, dizziness, ‘spinning’ sensation, feeling or being sick, diarrhoea, pain or swelling of your stomach or abdomen, indigestion, heartburn, wind, loss of weight or poor appetite, abnormal liver function tests, skin rashes

Rare (may affect up to 1 in 1,000 people):
- allergic reactions, tiredness, difficulty breathing, inflammation of the stomach, stomach ulcers or bleeding, vomiting blood, blood in the faeces, headache, yellowing of the skin or whites of your eyes, rash or raised lumps on your skin, swelling (symptoms of which may include swollen ankles), drowsiness

Very rare (may affect up to 1 in 10,000 people):
palpitations (fast or irregular heart beat)
chest pain, high or low blood pressure, inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), congestive heart failure, blood disorders (including anaemia, malaria, you have tried and are prone to minor infections or bleeding), kidney or liver disorder or failure, presence of blood or protein in the urine, skin rash, itching in skin eruptions, eczema, dermatitis, 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 redness, peeling and swelling of skin that looks like severe burns), hair loss, pancreatitis (inflammation of the pancreas), weaselling of ulcerative colitis or Crohn's disease, impotence (difficulty getting an erection) angio-neurotic oedema (swelling of the skin). Please refer to the leaflet for more.

Unknown (frequency cannot be estimated from the data):
anaemia (can lead to low 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 via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

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 medicine 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:
- aminophylline (aseptic) causing a combination of symptoms such as headache, fever and stiff neck
- active substance
-辅料

What Diclofenac potassium tablets look like and what they are used for:
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 size:
Blister packs: 28 film-coated tablets.
Manufacturers:
Actavis hf., Reykjavikurvegi 78, PO Box 420, IS-222, 220 Hafnarfjördur, Iceland

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