

Boots Diclofenac Potassium 12.5 mg 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, ask your doctor or pharmacist.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 What Diclofenac Potassium is and what it is used for

Diclofenac Potassium 12.5 mg Tablets contain diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Diclofenac Potassium is a pain reliever, which also reduces inflammation (swelling) and fever.

Diclofenac Potassium provides relief from:

- backache, rheumatic pain, muscular pain, headache, dental pain and period pain.
- symptoms of colds and flu. This medicine also reduces fever.

2 Before you take

Do not take Diclofenac Potassium but see a doctor instead if you:

- are **allergic to diclofenac**, medicines containing **diclofenac potassium** or to any of the other ingredients in this medicine (see section 6)
- are allergic to **peanut** or **soya**, as this medicine contains soya
- are **allergic to aspirin, ibuprofen or other non-steroidal anti-inflammatory medicines** (NSAIDs), or you have developed signs of asthma (wheezing), runny nose, swelling of the skin or rash when taking these medicines
- have or have had **stomach or duodenal (gut) ulcers, bleeding in the stomach or intestines** (gastrointestinal bleeding) or have had **two or more** episodes of a stomach ulcer, perforation or bleeding
- have severe **heart failure, liver or kidney failure**
- use other **non-steroidal anti-inflammatory medicines** (NSAIDs), or aspirin with a daily dose above 75mg, or any medication which may cause bleeding or ulcers in the stomach
- are taking **medicines that thin the blood**, such as warfarin
- **are or may be pregnant** or are **breast feeding**.

Check with your doctor or pharmacist before taking Diclofenac Potassium if you:

- have a history of **gastrointestinal disease** e.g. ulcerative colitis, Crohn's disease
- are **elderly**
- have or have had **high blood pressure, a stroke** or any **heart, liver or kidney** problems
 - if you have kidney or liver problems you should only take Diclofenac Potassium under the supervision of your doctor, for monitoring of your kidney or liver function.
- have **asthma, diabetes, high cholesterol**

- **are a smoker**
- have **systemic lupus erythematosus** or other connective tissue disorders
- have any **blood clotting** disorders
- have **porphyria** a genetic/inherited disorder of the red blood pigment haemoglobin
- are on a **controlled potassium diet**. Each tablet contains 0.0374 mmol (1.46mg) of potassium, this should be taken into account if you are on a controlled potassium diet
- are a women trying to **become pregnant or undergoing investigation of infertility**
 - diclofenac belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that diclofenac, used occasionally, will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.

Other warnings

- 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 are elderly or frail, you have a higher risk of getting side effects**, especially of the stomach. If you experience any unusual symptoms from the stomach, you must tell your doctor about it.
- Diclofenac Potassium **may hide the symptoms of an infection**.

If symptoms persist or worsen, consult your doctor.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken, any other medicines obtained with or without a prescription. Especially:

- other non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen, COX II inhibitors and aspirin (used for pain and inflammation)
- medicines to treat high blood pressure including ACE inhibitors such as captopril, ramipril, or propranolol
- diuretics ('water tablets'), such as furosemide
- cardiac glycosides (for heart failure), such as digoxin
- lithium (used for some mental health problems)
- methotrexate (to treat some cancers)
- ciclosporin, tacrolimus (to suppress the immune system)
- mifepristone (for termination of pregnancy). Diclofenac Potassium should not be taken within 8 – 12 days of taking mifepristone
- corticosteroids (used in many different diseases), such as prednisolone
- medicines which thin the blood or which prevent blood clotting such as warfarin
- SSRI antidepressants (for depression), such as fluoxetine
- quinolone antibiotics (to treat bacterial infections), such as ciprofloxacin
- antidiabetics (to treat diabetes), such as metformin
- Zidovudine (anti-viral).

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or breast-feeding you must not take Diclofenac Potassium. Speak to your doctor or pharmacist before you use any medication.

Driving and using machines

Diclofenac Potassium does not normally cause any effects however you may experience dizziness, drowsiness, spinning sensation, difficulty in sleeping, depression or disturbed vision. If you are affected do not drive or operate machinery.

Important Information about one of the ingredients in this medicine

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

3 How to take

Swallow **whole** with water, **with or after food**. **Do not crush or chew** the tablets.

You should take the lowest dose that controls your symptoms for the shortest amount of time. This will reduce any side effects you may experience.

Adults and children aged 14 years and over:

Initially take two tablets (25mg) then if needed, one or two tablets (12.5mg or 25mg) every 4 – 6 hours.

Leave at least 4 – 6 hours between doses and do not take more than the maximum dose of six tablets (75mg) in any 24 hour period.

Diclofenac Potassium should not be used for longer than 3 days. If symptoms persist or worsen consult your doctor.

If you take more Diclofenac Potassium than you should

It is important not to take too many tablets. Contact your doctor, pharmacist or nearest hospital casualty department **immediately** if you have taken more tablets than you should.

Symptoms of an overdose are feeling or being sick, stomach pain or bleeding, diarrhoea, ringing in the ears, headache.

If you forget to take the tablets

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Then go on as before. Never double up on the next dose to make up for the one missed.

4 Possible side effects

Like all medicines, Diclofenac Potassium can cause side-effects, although not everybody gets them. If any of the side effects get worse, or if you notice any not listed in this leaflet, please tell your doctor or pharmacist. Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.yellowcard.gov.uk, or you can call Freephone 0808 100 3352 (available between 10am – 2pm Monday to Friday) or fill in a paper form available from your local pharmacy.

Stop taking Diclofenac Potassium and contact your doctor or pharmacist immediately if you develop:

- An **allergic reaction**: skin reactions such as rash, itching, pale or red irregular raised patches with severe itching (hives), disorder characterised by blood spots, bruising and discolouring to skin (purpura), swelling of the face, lips, tongue or throat. Development or worsening of asthma, difficulty breathing or narrowing of the airways.
- **Severe rash** involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), circular, irregular red patches on the skin of the hands and arms (erythema multiforme) and severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson Syndrome).
- **Dark blood-stained stools, vomiting blood, indigestion, heartburn, abdominal pain** (signs of ulceration, bleeding and perforation of the stomach and intestines).
- **Blistering of mucous membranes** e.g. eye, mouth or anus.
- **Aseptic meningitis** (stiff neck, headache, feeling or being sick, fever, disorientation).

Tell your doctor or pharmacist if you notice any of the following side effects:

- **Common** (less than 1 in 10 users): headache, dizziness, a spinning sensation, feeling or being sick, diarrhoea, wind.
- **Rare** (less than 1 in 1000 users): inflammation of the stomach lining (gastritis), water retention, abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin or whites of the eyes (jaundice).

- **Very rare** (less than 1 in 10,000 users): constipation, mouth ulcers, worsening of colitis and Crohn's disease, inflammation of the pancreas causing pain and tenderness in the abdomen and back (pancreatitis), kidney inflammation or failure, increased protein in urine and fluid retention (nephrotic syndrome), blood in the urine, high blood pressure or heart failure, inflammation of the optic nerve, disturbed vision, tingling or "pins and needles", depression, confusion, ringing in the ears, sensing things that are not there, feeling of general discomfort and illness, tiredness, drowsiness, sensitivity to light, reduced sexual potency in men. Changes in the numbers or types of blood cells causing increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion, or abnormal paleness of the skin.

Medicines such as Diclofenac Potassium may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke (see page 1 'Other warnings').

If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

5 How to store

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package.

Do not use Diclofenac Potassium after the expiry date stated on the carton. The expiry date refers to the last day of that month.

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 12.5 mg Tablets contain

- The active substance (the ingredient that makes the medicine work) is diclofenac potassium. Each tablet contains 12.5mg of the active substance.
- The other ingredients are silica colloidal anhydrous, sodium starch glycollate, povidone, starch maize, calcium hydrogen phosphate anhydrous, magnesium stearate, polyvinyl alcohol partially hydrolysed, titanium dioxide (E171), talc, lecithin soya (E322), xanthan gum (E415).

What Diclofenac Potassium 12.5 mg Tablets look like and contents of the pack

The tablets are white round, unscored biconvex film coated tablet.

Pack size: 18 tablets

Marketing Authorisation Holder

Actavis Group PTC ehf,
Reykjavíkurvegi 76-78,
220 Hafnarfjörður,
Iceland.

Manufacturer

Wasdell Packaging Ltd
Units 6,7,8 Euro Way,
Blagrove, Swindon,
SN5 8YW, United Kingdom.

Distributor

The Boots Company PLC
Nottingham NG2 3AA

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