

DICLOFENAC SODIUM 25 mg AND 50 mg GASTRO-RESISTANT TABLETS

Package leaflet: Information for the user

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, ask your doctor or pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Diclofenac is and what it is used for
2. What you need to know before you take Diclofenac
3. How to take Diclofenac
4. Possible side effects
5. How to store Diclofenac
6. Contents of the pack and other information

1 What Diclofenac is and what it is used for

Diclofenac is a non-steroidal anti-inflammatory (NSAID) drug.

Diclofenac 25 mg and 50 mg Gastro-resistant Tablets are used to relieve pain and inflammation in conditions such as:

- rheumatoid arthritis
- osteoarthritis
- ankylosing spondylitis (arthritis of the spine)
- low back pain
- other conditions affecting the muscles, joints, tendons and bones e.g. strains, sprains, fractures or dislocations
- acute gout
- dental and other minor surgery.

Diclofenac 25 mg Gastro-resistant Tablets may also be used to relieve juvenile chronic arthritis.

Children aged 9 years and above

Diclofenac 25 mg Gastro-resistant Tablets may be used as a short treatment for fever, caused due to infections of the ear, nose or throat.

Diclofenac 25 mg Gastro-resistant Tablets may be used alone or as an additional therapy with other pain killers to relieve pain caused due to surgery.

2 What you need to know before you take Diclofenac

Do not take Diclofenac:

- if you are allergic to diclofenac sodium or any of the other ingredients of this medicine (listed in section 6)
- if you have experienced asthma, chest pain, an itchy or runny nose, skin rashes or breathing difficulties after taking any other NSAID (Non-steroidal anti-inflammatory drugs) e.g. aspirin or ibuprofen
- if you have, or have ever had, peptic ulceration (ulcer in your stomach or duodenum)
- if you have ever experienced stomach or intestinal bleeding (black tarry stools or vomiting blood) after taking any other NSAID
- if you have severe liver, kidney or heart problems
- if you are more than 6 months pregnant or you are planning to become pregnant (see 'Pregnancy, breast-feeding and fertility')
- if you 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
- if you have or have had problems with your blood circulation (peripheral arterial disease)

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking diclofenac gastro-resistant tablets:

- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Diclofenac or other pain medications
- if you suffer from any stomach or bowel disorders such as ulcerative colitis or Crohn's disease
- if you suffer from a disease called porphyria (symptoms of porphyria are discolouration of the urine, serious skin disorders, anaemia, abdominal pains and severe mental disorders)
- if you suffer from or have in the past suffered from asthma
- if you suffer from serious illness with blistering of the skin, mouth, eyes and genitals or connective tissue disorders such as lupus
- if you notice skin rash or appearance of lesions after starting this medicine, please seek medical advice immediately
- if you suffer from runny nose, nasal polyps, chronic lung disease or chronic lung infection
- if you suffer from kidney, liver or heart problems or if you are elderly or recovering from major surgery
- if you smoke
- if you suffer from diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- if you recently had or you are going to have a surgery of the stomach or intestinal tract before using diclofenac sodium, as diclofenac sodium can sometimes worsen wound healing in your gut after surgery.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

This medicine may mask the sign and symptoms of infection.

Your doctor may decide to monitor your kidney function, liver function, blood sugar and blood cell counts whilst you are taking diclofenac sodium.

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, 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.

Other medicines and Diclofenac

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines— even medicines you bought yourself without a prescription. Medicines can sometimes interfere with each other. Your doctor may limit your use of a medicine or you may need to take a different medicine. It is especially important to mention any of the following:

- any other non-steroidal anti-inflammatory drug (NSAID) for pain relief such as ibuprofen, aspirin or cyclooxygenase-2 selective inhibitors. Taking two or more NSAID medicines at the same time is not recommended, but your doctor may decide that it is necessary for your treatment and the benefits you will gain outweigh the risks
- aspirin in order to prevent blood clots
- medicines for high blood pressure e.g. beta-blockers or ACE inhibitors
- medicines for high blood sugar e.g. gliclazide
- diuretics ("water tablets") e.g. spironolactone
- cardiac glycosides e.g. digoxin
- lithium (used to treat some mental problems)
- methotrexate (for some inflammatory diseases and some cancers)
- mifepristone (a medicine used to terminate pregnancy)
- corticosteroids, which are drugs given to treat a variety of conditions such as allergies and hormone imbalances e.g. prednisolone
- anti-coagulants e.g. warfarin
- immunosuppressive agents e.g. ciclosporin, tacrolimus
- quinolone antibiotics e.g. ciprofloxacin, ofloxacin
- drugs for depression called selective serotonin reuptake inhibitors (SSRIs)
- zidovudine, used to treat HIV infection
- phenytoin (used to treat fits)
- colestipol, cholestyramine (used to reduce the amount of cholesterol and certain fatty substances in your blood)
- sulfapyrazone (used to treat gout)
- voriconazole (used to treat fungal infection).

Diclofenac with food and drink

Take this medicine with or after food.

Pregnancy, breast-feeding and fertility

- Do not take diclofenac 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 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 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.
- 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.
- Diclofenac should not be taken if you are breast-feeding, therefore please talk to your doctor before taking this medicine.

Driving and using machines

- Diclofenac may cause dizziness, drowsiness, tiredness, and problems with your vision.
- DO NOT drive or operate machinery if you are affected.

Important information about some of the ingredients of Diclofenac

Diclofenac tablet contains Lactose

- Patients who are intolerant to lactose should note that Diclofenac tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Diclofenac tablets contain Sunset yellow (E110)

Sunset yellow may cause allergic reactions

Information about ingredient of Diclofenac

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

3 How to take Diclofenac

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a drink of water, but they can be taken with or without food. DO NOT chew the tablets. The tablets have been coated with a substance, which allows them to

pass through the stomach before dissolving. It is important that the coating is not damaged by chewing. The recommended dose is:

• **Adults**

75 – 150 mg a day, in divided doses. The maximum daily dose is 150 mg.

• **Elderly**

Elderly patients should take the lowest effective dose for the shortest possible time to reduce the risk of side effects.

Use in children and adolescents

• **Children 1 year old and over**

The dose depends on the child's body weight. Your doctor will calculate the appropriate dose for your child.

• **Children under 1 year old**

Diclofenac is not recommended for use in children under 1 year old.

For treatment of surgical pain and fever caused due to infections of the ear and nose in children aged 9 years (with minimum 35 kg bodyweight) or over and adolescents

- The dose depends on the bodyweight and severity of the disorder. Your doctor will decide the appropriate dose.

Diclofenac 50 mg Gastro-resistant Tablets should not be used in children under 12 years of age.

If you take more Diclofenac than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause headache, feeling sick, being sick, stomach pain, intestinal bleeding, diarrhoea, breathing problems, coma, drowsiness, dizziness, fits, ringing in the ears and fainting.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Diclofenac

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking Diclofenac

Do not suddenly stop taking your tablets as side effects may occur. If treatment is to be stopped your doctor will gradually reduce your dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

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

Serious side effects:

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital **if the following happens at any time during your treatment:**

- 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).

Rare: may affect up to 1 in 1,000 people

- A severe allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or spots, eczema, redness of the skin, scaly skin, bruise like rash, itching very low blood pressure or shock and hives)
- passing blood in your faeces (stools/motions)
- yellowing of the skin or whites of the eyes, blood problems, inflammation of liver, liver disorders
- passing black tarry stools
- vomiting any blood or dark particles that look like coffee grounds

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

- a serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
- ringing in the ears, hearing impairment
- blood disorders such as anaemia, reduction in the number of white blood cells, which may be characterised by fever or chills, sore throat, ulcers in your mouth or throat and infection
- a severe blistering rash in which the surface layers of the skin may peel off (Lyell's syndrome)
- symptoms which include stiff neck, headache, feeling and being sick, fever or disorientation, particularly in patients with systemic lupus erythematosus (SLE) or connective tissue disorders, signs of serious inflammation of the linings of the brain (Aseptic meningitis),
- palpitations, chest pain and heart failure (myocardial infarction), stroke
- severe liver disorders including acute liver failure.
- kidney failure, blood in the urine, increased amount of protein in the urine, severe kidney disorders
- inflammation of the pancreas (pancreatitis), which causes severe pain in the abdomen and back.

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.
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- mild cramping and tenderness of the abdomen, starting shortly after the start of the

treatment with diclofenac and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain.

Other side effects

The following side effects have also been reported. If you feel unwell with any of these side effects tell you doctor:

Common: may affect up to 1 in 10 people

- headache, dizziness, spinning
- feeling sick, being sick, nausea, vomiting, loose stools, abdominal pain, indigestion or heartburn
- wind, loss of appetite
- abnormal liver function tests

Rare: may affect up to 1 in 1,000 people

- drowsiness, tiredness
- inflammation of the lining of the stomach, vomiting blood, ulcers.
- nettle rash
- hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness)
- fluid retention resulting in swelling of the ankles or feet.

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

- abnormal sensation of skin (e.g. tingling, numbness), memory impairment, fits, anxiety, shaking, taste disorders, stroke
- depression, difficulty in sleeping, nightmares, irritability and psychological problems
- visual disturbances, blurred vision and double vision
- loss of hair, sensitivity to light
- high blood pressure and inflammation of blood vessels, often with skin rash
- inflammation of lungs, symptoms you may feel are like fever, shortness of breath, chills etc
- inflammation of colon causes abdominal pain or diarrhoea, aggravation of existing digestive problems such as colitis and Crohn's disease, constipation, inflammation or ulceration of the mouth e.g. mouth ulcers and cold sores, inflammation of the tongue.
- throat lesions, damage of colon, narrowing of the intestine.

Not known: frequency cannot be estimated from the available data

- optic nerve inflammation, sensation disorders
- difficulty in getting and maintaining an erection.

Reporting of 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 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

Keep this medicine out of the sight and reach of children.

The tablets should be stored below 25°C, in a dry place in the original package or container supplied. Keep the container tightly closed. Do not transfer them to another container. Do not use this medicine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Diclofenac Gastro-resistant Tablets contain:

- The active ingredient is diclofenac sodium, 25 mg or 50 mg
- The other ingredients are lactose monohydrate, maize starch, povidone (E1201), sodium starch glycolate (Type A), colloidal anhydrous silica and magnesium stearate (E572). The gastro-resistant coating contains hydroxypropyl methylcellulose (E464), citric acid monohydrate (E330), methacrylic acid copolymer, purified talc (E553b), polyethylene glycol (E1520) and the colours are titanium dioxide (E171), sunset yellow (E110) and iron oxide yellow (E172). The 50 mg tablets also contain iron oxide red (E172). The 25 mg tablets also contain quinoline yellow (E104). The black printing ink contains shellac, iron oxide black (E172) and propylene glycol (E1520).

What Diclofenac Gastro-resistant Tablets look like and contents of the pack:

- The 25 mg tablets are yellow, round, biconvex, bevel-edged, gastro-resistant tablets. They are printed '25' over '0518' and plain on the reverse.
 - The 50 mg tablets are tan, round, biconvex, bevel-edged, gastro-resistant tablets. They are printed '50' over '0519' and plain on the reverse.
 - The product is available in pack sizes of 10, 20, 28, 30, 50, 56, 60, 84, 100, 250, 500, and 1000 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Company Responsible for Manufacture:

TEVA Pharmaceutical Works Private Limited Company, Pallagi street 13 Debrecen, H-4042, Hungary.

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