

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diclac 50mg Gastro-resistant tablets

Diclofenac Sodium

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.
- 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 Diclac is and what it is used for
2. What you need to know before you take Diclac
3. How to take Diclac
4. Possible side effects
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1 What Diclac is and what it is used for

Diclac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to treat pain and inflammation. Diclac relieves symptoms of inflammation, such as swelling and pain and also reduces fever. It has no effect on the cause of inflammation or fever. Diclac can be used to treat the following conditions:

- inflammatory conditions such as rheumatoid arthritis, osteoarthritis
- acute musculoskeletal disorders such as frozen shoulder or tendinitis
- other painful conditions such as fractures, low back pain, sprains, strains, dislocations, orthopaedic or dental surgery
- pain and swelling after surgery
- painful menstrual periods
- attacks of gout
- painful ear, nose and throat infections.

2 What you need to know before you take Diclac

•Some people MUST NOT use Diclac. Talk to your doctor if:

- you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Diclac. (These are listed at the end of the leaflet.) Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash, or any other type of allergic reaction. .
- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the gut (digestive tract). This can include blood in vomit, bleeding when emptying bowels, fresh blood in stools or black tarry stools. This may have been when you used an NSAID before.
- you suffer from severe kidney or liver disease
- you suffer from severe heart failure

- you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages in blood vessels to the heart or brain or an operation to clear or bypass blockages
- you have or have had problems with your blood circulation (peripheral arterial disease)
- you are in the last three months of pregnancy.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Diclac, as Diclac can sometimes worsen wound healing in your gut after surgery. If any of these apply to you, tell your doctor and do not take Diclac. Your doctor will decide whether this medicine is suitable for you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Diclac if:

- you are taking Diclac simultaneously with other anti-inflammatory medicines including acetylsalicylic acid/aspirin, anti-coagulants or SSRIs
- you have ever had gastro-intestinal problems such as stomach ulcers, bleeding or black stools or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past
- you suffer from asthma, hay fever, nasal polyps, chronic obstructive pulmonary diseases (COPD) or often get chest infections
- you have any allergies
- you have an inflammatory bowel disease, such as ulcerative colitis (colon inflammation) or Crohn's (intestinal tract inflammation)
- you have a bleeding disorder, or any other blood problems, including the rare liver condition called porphyria
- you have, or have ever had a heart problem or high blood pressure
- you have swollen feet
- you have any liver or kidney problems
- you think you are dehydrated, perhaps due to diarrhoea or sickness, or in association with surgery.

If any of these apply to you, tell your doctor before taking Diclac. Diclac, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash). Therefore, inform your doctor immediately if you experience such reactions.

Make sure your doctor knows, before you are given Diclac

- 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.

Diclofenac may reduce or mask symptoms of an infection such as headache or high temperature. This could make the infection more difficult to detect and treat. If you feel unwell and see a doctor remember to mention that you are taking Diclac.

Medicines such as Diclac 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 any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor the function of your liver, kidney or your blood count. Your

doctor will take these blood tests into consideration to decide if Diclac needs to be discontinued or if the dose needs to be changed.

Elderly or underweight

Elderly patients may be more sensitive to the effects of Diclac than other adults. Follow your doctor's instructions carefully and take the minimum number of tablets that provides relief of symptoms. It is especially important for elderly patients to report undesirable effects to their doctor especially stomach problems.

Children and adolescents

The 50 mg strength of Diclac is not recommended for use in children and adolescents below 14 years. Please refer to section 3 for information regarding the specific dosage.

Other medicines and Diclac

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is important because some medicines should not be taken together with Diclac. It is particularly important to tell your doctor if you are taking any of the following medicines:

- lithium or selective serotonin-reuptake inhibitors (SSRIs, medicines used to treat some types of depression)
- digoxin (a medicine used for heart problems)
- diuretics (medicines used to increase the amount of urine)
- ACE inhibitors or beta-blockers (classes of medicine used to treat high blood pressure or heart failure)
- other anti-inflammatory medicines such as acetylsalicylic acid/aspirin or ibuprofen
- corticosteroids (medicines used to provide relief for inflamed areas of the body)
- anti-coagulants (medicines used to prevent blood-clotting)
- medicines used to treat diabetes, except insulin
- methotrexate (a medicine used to treat some kinds of cancer or arthritis)
- ciclosporin, tacrolimus (a medicine primarily used in patients who have received organtransplants)
- trimethoprim (a medicine used to prevent or treat urinary tract infections)
- quinolone antibiotics (for infections)
- potent CYP2C9 inhibitors such as voriconazole (a medicine used to treat serious fungal infections)
- phenytoin (a medicine used to treat epilepsy)
- colestipol/cholestyramine (used to lower cholesterol).

Pregnancy and breast-feeding and fertility

Please tell your doctor or pharmacist if you are pregnant or think you might be pregnant.

- Diclac may make it more difficult to become pregnant. You should not take tablets unless absolutely necessary if you are planning to become pregnant or if you have difficulty in becoming pregnant.
- Do not take Diclac in the last three months of pregnancy as it could harm your unborn child or cause problems during 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 Diclac 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.
- Do not breast-feed if you are taking Diclac, because small amounts can pass into breast milk and may harm your baby.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask

your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Usually Diclac does not affect your ability to drive and use machines. However, it may make you feel dizzy, tired, sleepy or have problems with your eyesight. If any of these affect you, do not drive or use machines and contact your doctor immediately.

Diclac contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Diclac contains sodium

This medicinal product contains less than 1mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3 How to take Diclac

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

You should take Diclac by mouth. Swallow the tablets whole with a drink and before a meal or on an empty stomach. Do not crush, chew or suck the tablets.

The doctor may also prescribe another medicine to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other medicines as well.

Adults

The recommended daily dose is 75-150 mg in two or three divided doses. The maximum daily dose should not exceed 150 mg.

Children and adolescents:

Your child's doctor will work out the dose that is suitable for your child. They will tell you how many tablets to give them and how often. The 50 mg strength is not recommended for use in children and adolescents below 14 years. Doses vary with age, but the recommended dose is between 0.5 mg and 2 mg for each kg of body weight. The doctor may raise this if required. This is taken every day in 2 or 3 divided doses.

The maximum daily dose should not exceed 150 mg.

Elderly

Older people tend to be more at risk of the side effects of NSAIDs, so it is particularly important that older people take the lowest possible dose of diclofenac which is effective.

If you take more Diclac than you should

If you have accidentally taken too much Diclac, tell your doctor or go straight to the nearest hospital. If possible take your tablets with you, so that the doctor can see what you have been taking. The following side effects may happen: vomiting, bleeding in your stomach, diarrhoea, feeling dizzy, ringing in the ears or fits.

If you forget to take Diclac

If you forget to take a dose, take it as soon as you remember, then go on as before. If it is nearly time for your next dose, you should simply take the next dose at the usual time and forget about the one you missed. Do not take more than the total daily dose in 24 hours.

Do not take a double dose to make up for a forgotten dose.

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

4 Possible side effects

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

Some side effects can be serious. Stop taking Diclac and tell your doctor straight away or go to the emergency department at your nearest hospital if any of the following happens:

- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- chest pain or tightness with shortness of breath
- breathlessness, difficulty of breathing when lying down, swelling of the feet or legs
- vomiting of blood, bleeding from the bowel
- sudden slurred speech, facial drooping, weakness, disorientation, or speech problems
- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, wheezing or shortness of breath ('bronchospasm'), swollen face, lips, hands or fingers, hypotension (low blood pressure) and fainting
- mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Diclac 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).

The following rare or very rare side effects (may affect between 1 and 10 in 10,000 patients) have also been reported in patients taking Diclac

- stomach pain, indigestion, heartburn, wind, feeling sick (nausea), or being sick (vomiting)
- any sign of bleeding in your stomach or intestine, for example, when emptying your bowels, blood in vomit, or black tarry faeces
- yellowing of your skin or the whites of your eyes
- pain in your abdomen and lower back, with feeling or being sick or loss of appetite (possible signs of pancreatitis)
- persistent sore throat or high temperature
- an unexpected change in the amount of urine produced and/or its appearance
- bruising more easily than usual
- frequent sore throats or infections
- fits, headaches together with a dislike of bright lights, fever and a stiff neck
- headache and dizziness (signs of high blood pressure, hypertension)
- serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome
- sudden severe headache, nausea, dizziness, numbness, inability or difficulty to speak, paralysis (possible signs of stroke).

If you experience any of these, tell your doctor straight away.

Other side effects:

Common: may affect up to 1 in 10 people

- headache, dizziness, vertigo
- nausea, vomiting, diarrhoea, indigestion, abdominal pain, wind, loss of appetite
- change in liver function (e.g. level of transaminases)
- skin rash.

Uncommon: may affect up to 1 in 100 people

- palpitations.

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

- stomach ulcers or bleeding
- drowsiness, tiredness
- skin rash and itching
- swelling of arms, hands, legs and feet (oedema).

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

- tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, ringing in the ears, sleeplessness, nightmares, mood changes, depression, anxiety, mental health disorders, disorientation and memory loss
- constipation, inflammation of the tongue, taste changes, mouth ulcers, problems with your food pipe, lower gut disorders (including inflammation of the colon)
- inflammation of blood vessels, inflammation of the lung, congestive heart failure, blood disorders (including anaemia)
- kidney or liver disorders, presence of blood or protein in the urine
- skin rashes which may be made worse by exposure to sunlight, hair loss.

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 HPRA Pharmacovigilance, website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Diclac

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

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store Diclac in the original package.

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 Diclac contains

- The active substance is diclofenac sodium.
Diclac 50 mg: Each tablet contains 50 mg diclofenac sodium.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, calcium hydrogen phosphate dihydrate, maize starch, sodium starch glycollate (type A), colloidal anhydrous silica, magnesium stearate.
- Film coating:
Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30%, triethyl citrate, talc, titanium dioxide (E172), yellow ferric oxide (E172).

What Diclac looks like and contents of the pack

Diclac 50 mg Gastro-resistant Tablets are yellow-brown, round, film-coated gastro-resistant tablets.

They are blister packed and are available in packs of 10, 20 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers:

Marketing Authorisation Holder:

Rowex Ltd, Bantry, Co Cork, Ireland.

Manufacturers:

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

Rowa Pharmaceuticals Ltd., Bantry, Co Cork, Ireland.

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