

Diclac 25mg/ml Solution for Injection 3ml Ampoule

Diclofenac Sodium

ROWEX®

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
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1 What Diclac is and what it is used for

Diclofenac sodium, the active ingredient in Diclac Solution for Injection, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Diclac Injection can either be given as an injection into the muscle, or as a slow infusion into a vein.

The intramuscular injection is used to treat a number of painful conditions including:

- acute back pain
- attacks of gout
- pain caused by gallstones or kidney stones
- pain due to osteo- and rheumatoid arthritis
- pain caused by injuries, acute trauma and fractures
- pain following surgery.

The intravenous infusion is used in hospital to prevent or treat pain following an operation.

2 What you need to know before you take Diclac

Do not take Diclac if:

- you are allergic to diclofenac sodium or any of the other ingredients of this medicine (listed in section 6)
- you have ever had an allergic reaction after taking medicines to treat pain and inflammation (NSAIDs) such as aspirin (acetylsalicylic acid), ibuprofen. Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, runny nose, skin rash or any other allergic type 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 have 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 have severe heart failure, kidney or liver problems
- you are in the last three months of pregnancy
- you are a child under 14 years of age.

Do not have Diclac if any of these apply to you. If you are not sure, talk to your doctor or pharmacist before having Diclac.

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 ulcer, 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. Diclofenac, 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.

Diclac may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the infection more

difficult to detect and to treat adequately. If you feel unwell and need to 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, particularly at high dose and in long term treatment.

Any risk is more likely with high doses and prolonged 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

This medicine is not recommended for use in children and adolescents. It must not be given to children under 14 years of age.

Other medicines and Diclac

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can interfere with your treatment. Tell your doctor if you are taking, have recently taken or might take any of the following medicines:

- lithium or selective serotonin-reuptake inhibitors (SSRI's), (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 medicines 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 organ transplants)
- 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 to treat epilepsy
- colestipol/cholestyramine (used to lower cholesterol)

Pregnancy and breast-feeding

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. You should not take Diclac during the first 6 months of pregnancy unless absolutely necessary.
- 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 or use machines. However, it may make you feel dizzy, tired or sleepy or have problems with eyesight. If you are affected in this way, you should not drive or operate machinery.

Diclac contains sodium, benzyl alcohol and propylene glycol

- This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e. essentially 'sodium-free'.
- Diclac contains benzyl alcohol (120mg/3ml). This must not be given to premature babies or neonates. It may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

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- Diclac contains propylene glycol which may cause alcohol-like symptoms.

3 How to take Diclac

Your doctor will decide when and how to treat you with Diclac. You will be given an intramuscular injection (an injection into the muscle) or an intravenous infusion (a drip into the vein).

The doctor may also prescribe another drug 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 drugs as well.

If necessary treatment can be continued with Diclac tablets or suppositories.

Adults:

The recommended dose is one or two ampoules (75 to 150mg) each day for one or two days.

Older patients

Your doctor may give you a dose that is lower than the usual adult dose if you are elderly.

Children and adolescents

This medicine is not recommended for children and adolescents. It must not be given to children under 14 years of age.

If you take more Diclac than you should

If you think you have been given too much Diclac tell your doctor or nurse straightaway. The following effects may happen: vomiting, bleeding in your stomach, diarrhoea, feeling dizzy, hearing problems or fits.

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 using Diclac and tell your doctor straightaway if you notice:

- 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).

Other side effects include:

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
- pain, swelling or reactions at the injection site

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)
- death of skin tissue at the injection site (necrosis)

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, abscess at the site of the injection.

Not known: cannot be estimated from the available data

- tissue damage at the injection site

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@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 take this medicine after the expiry date which is stated on the label and carton after EXP.

The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the ampoules in the outer carton in order to protect from light.

Do not throw away 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. Each ml of the solution contains 25mg diclofenac sodium equivalent to a total of 75mg in each 3ml ampoule. Each ml also contains 40mg benzyl alcohol equivalent to a total of 120mg in each 3ml ampoule.
- The other ingredients are acetylcysteine, propylene glycol, mannitol (E421), sodium hydroxide and water for injection.

What Diclac looks like and contents of the pack

Diclac is a clear, colourless to slightly yellow solution for injection in a 3ml colourless glass ampoule. Diclac Injections are available in packs of 10 ampoules.

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.
EVER Pharma Jena GmbH, Otto-Schott-Straße 15, D-07745 Jena, Germany.
LEK Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Rowa Pharmaceuticals Ltd., Bantry, Co Cork, Ireland.

This leaflet was last revised in August 2016.

The following information is intended for healthcare professionals only:

Instructions for use/handling:

- To be injected intramuscularly by deep intragluteal injection into the upper outer quadrant or intravenously by slow infusion
- Each ampoule is for single use only
- The solution should be used immediately after opening
- Any unused contents should be discarded
- Only clear solutions should be used. If crystals or precipitates are observed, the infusion solution should not be used.

Intravenous use:

One ampoule should be diluted before use and administered intravenously over a minimum of 30 minutes. A second dose may be administered 4-6 hours after the first infusion.

Depending on the intended duration of infusion one ampoule should be diluted in 100 to 500 mL of isotonic saline (sodium chloride 0.9% solution) or glucose 5%.

Buffer the normal saline or glucose 5% solution with sodium bicarbonate injectable solution (0.5mL of 8.4% or 1 mL of 4.2% or a corresponding volume of a different concentration), before adding the Diclac ampoule.

Incompatibilities

As a rule, Diclac solution for injection should not be mixed with other injection solutions.

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