PACKAGE LEAFLET : INFORMATION FOR THE USER

Diclac 25mg/ml Solution for Injection 3ml Ampoule

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

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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

- **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 NSAIDs, 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 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.

Tell your doctor if you recently had or you are going to have surgery of the stomach or intestinal tract before receiving Diclac as Diclac can sometimes worsen wound healing in your gut after surgery.

Warnings and precautions
Talk to your doctor or pharmacist before taking Diclac if:
- you are taking Diclac simultaneously with other anti-inflammatory medicines including acetylsalicyclic 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 are elderly
- you have Lupus (SLE) or any similar condition
- 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 are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
- 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 lowest dose 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)
- cardiac glycosides (for example digoxin) (used to treat 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)
- or any other NSAID or COX-2 (cyclooxygenase-2), inhibitor such as acetylsalicylic acid/aspirin or ibuprofen
- mifepristone (a medicine used to terminate pregnancy)
- 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 Diclac 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 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 1mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
- This medicine contains 120 mg benzyl alcohol in each 3 ml ampoule. Benzyl alcohol may cause allergic reactions. Caution if you have a liver or kidney disease or are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
- This medicine contains 600 mg propylene glycol in each 3 ml ampoule.

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.

Continued on the next page ››

Adults:
The recommended dose is one or two ampoules (75 mg to 150 mg) 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:
- 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)
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- injection site reactions including injection site pain, redness, swelling, hard lump, sores and bruising. This can progress to blackening and death of the skin and underlying tissues surrounding the injection site, that heal with scarring, also known as Nicolau syndrome.

Some side effects can be serious
These uncommon side effects may affect between 1 and 10 in every 1000 patients, especially when taking a high daily dose (150 mg) for a long period of time
- sudden and oppressive chest pain (signs of myocardial infarction or heart attack)
- breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (signs of cardiac failure).

These rare or very rare side effects may affect from less than 1 to 10 in every 10,000 patients
- stomach pain, indigestion, heartburn, wind, feeling sick (nausea), or being sick (vomiting)
- chest pain or tightness with shortness of breath
- vomiting of blood, bleeding from the bowel
- persistent sore throat or high temperature
- an unexpected change in the amount of urine produced and/or its appearance
- 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
- yellowing of the skin or eyes (signs of jaundice), nausea, loss of appetite, dark urine (signs of hepatitis/liver failure
- sudden difficulty of breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma or pneumonitis if fever)
- purple skin patches (signs of purpura or Henoch-Schonlein purpura if caused by an allergy)
- severe upper stomach pain (signs of pancreatitis)
- inflammation of blood vessels, inflammation of the lung, congestive heart failure or heart attack, chest pain, hypertension, blood disorders (including anaemia)
- skin rashes including Steven-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight
- kidney or severe liver disorders, presence of blood or protein in the urine
- inflammation of the tongue, inflammation of the inside of the mouth or lips, mouth ulcers, problems with your food pipe, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease)

If you experience any of these, **tell your doctor straight away**.
If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

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. raised levels 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 (there have been very rare reported cases resulting in death, particularly in the elderly)
- gastritis (inflammation, irritation, or swelling of the stomach lining)
- vomiting blood
- diarrhoea with blood in it or bleeding from the back passage
- black tarry faeces or stools
- hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness)
- drowsiness, tiredness
- skin rash and itching
- swelling of arms, hands, legs and feet (oedema)
- death of skin tissue at the injection site (necrosis)
- liver function disorders including hepatitis and jaundice.

Very rare: may affect up to 1 in 10,000 people
- tingling or numbness in the fingers, tremor, vision disorders* (signs of visual impairment, 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, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation, hair loss, abscess at the site of the injection, constipation, taste changes.

*vision disorders: If symptoms of vision disorders occur during treatment with Diclac, contact your doctor as an eye examination may be considered to exclude other causes.

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, 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 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 25 mg diclofenac sodium equivalent to a total of 75 mg in each 3 ml ampoule.
  Each ml also contains 40 mg benzyl alcohol equivalent to a total of 120 mg in each 3 ml 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 3 ml 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:
LEK Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Rowa Pharmaceuticals Ltd., Bantry, Co Cork, Ireland.

This leaflet was last revised in December 2022.

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
- Must not be given as an intravenous bolus injection
- 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.

Intramuscular use:
Recommended Dosage Schedule:
The following directions for intramuscular injection must be followed in order to avoid damage to a nerve or other tissue at the injection site.
One ampoule once (or in severe cases twice) daily intramuscularly by deep intragluteal injection into the upper outer quadrant. If two injections daily are required, it is advised the alternative buttock to be used for the second injection.
Alternatively, one ampoule of 75 mg can be combined with other pharmaceutical forms of diclofenac (e.g. tablets, suppositories) up to a maximum daily dose of 150 mg.

Renal Colic:
One 75 mg ampoule intramuscularly. A further ampoule may be administered after 30 minutes if necessary.

The recommended maximum daily dose of Diclac is 150 mg.

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 (0.5 ml 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.

Two alternative regimens are recommended:

For the *treatment* of moderate to severe post-operative pain, 75 mg should be infused continuously over a period of 30 minutes to 2 hours. If necessary, treatment may be repeated after 4-6 hours, not exceeding 150 mg within any period of 24 hours.

For the *prevention* of post-operative pain, a loading dose of 25 mg-50 mg should be infused after surgery over 15 minutes to 1 hour, followed by a continuous infusion of approx. 5 mg per hour up to a maximum daily dosage of 150 mg.

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