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. 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
5. How to store Diclac
6. Contents of the pack and other information

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
- acute attacks of gout
- renal colic (pain caused by 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.

Elderly:
Elderly patients may be more sensitive to the effects of Diclac than other adults. Therefore they should follow the doctor’s instructions particularly carefully and take the lowest dose for their condition. It is especially important for elderly patients to report undesirable effects promptly to their doctor.

Children/Adolescents:
Diclac is not suitable for children and adolescents (below 18 years of age).

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 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
- you have or have had problems with your blood circulation (peripheral arterial disease)

Some people must not have this injection. Talk to your doctor if:
- you think you may be allergic to diclofenac sodium, aspirin (acetylsalicylic acid), 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, 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 digestive tract (This can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces).
- you have had stomach or bowel problems after you have taken other NSAIDs
- you have moderate or severe heart failure, kidney or liver diseases
- you are more than six months pregnant

Warnings and precautions
Talk to your doctor or pharmacist before taking Diclac if:
- you suffer from any bowel disorders including ulcerative colitis or Crohn's disease
- you have kidney or liver problems, or if you are elderly
- you suffer from any blood or bleeding disorder
- you have a condition called porphyria
- you ever had asthma
- you are breast-feeding
- you have Lupus (SLE) or any similar condition
- you are suffering from dehydration
- you suffered any heavy loss of blood recently

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.

In very rare cases 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.

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.

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 acetysalicylic 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 (a medicine primarily used in patients who have received organ transplants)
- some medicines used against infection (aminoglycosides, quinolone antibacterials)
- potent CYP2C9 inhibitors such as voriconazole (a medicine used to treat serious fungal infections)
- phenytoin, a medicine to treat epilepsy

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

**Pregnancy and breast-feeding**
Ask your doctor or pharmacist for advice before taking any medicine.
You should not take Diclac while pregnant unless absolutely necessary.
• Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not have Diclac during the last 3 months of pregnancy as it may harm your unborn child or cause problems at delivery.
• Having Diclac may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.
You should tell your doctor if you are breastfeeding, because you should not breast-feed if you are taking Diclac as it might be harmful to your infant.

**Driving and using machines**
Very occasionally people have reported that diclofenac has made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

**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).

It is important that you take the lowest dose that controls your pain. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose. Diclac Injection should not be given for more than 2 days. If necessary treatment can be continued with Diclac tablets or suppositories.

**Adults:**
The usual dose is one ampoule once or for in severe cases twice, daily intramuscularly by deep gluteal injection into the upper outer quadrant for one or two days. When more than one injection is required, it is advised the alternate buttock be used for the second injection.

**Renal colic:** One ampoule intramuscularly. A further ampoule may be administered after 30 minutes if necessary.

The recommended maximum daily dose is 150mg. Do not exceed the recommended dose or duration of treatment. Once opened any unused solution should be discarded.

A doctor, nurse or pharmacist will prepare the injection for you. If you have had an operation and are in hospital the ampoule content may be diluted and put into a drip bag before being given to you.
A maximum of two doses may be given intravenously. A nurse or doctor will usually then give you the injection or infusion. You would not usually have to give the injection to yourself.

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 you take more Diclac than you should**

If you think you have been given too much Diclac tell your doctor or nurse straightaway

If you accidentally take more than the prescribed dose or in the event of an overdose, seek medical advice immediately. Contact your doctor or nearest hospital casualty department and if possible take the injections with you.

**If you forget to take Diclac**

Get your injection as soon as you remember, then proceed as before. 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 rare or very rare side effects could be serious**

- unusual bleeding or bruising
- high fever or persistant sore throat
- allergic reaction with swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing, often associated with rash and itching, hypotension (low blood pressure), fainting, wheezing and feelings of tightness in the chest (signs of asthma)
- chest pain (signs of heart attack)
- sudden and severe headache, nausea, dizziness, numbness, inability or difficulty in speaking, paralysis (signs of cerebral attack)
- stiff neck (signs of viral meningitis)
- convulsions
- hypertension (high blood pressure)
- red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering of the lips, eyes and mouth, skin inflammation with flaking or peeling
- severe stomach pain, bloody or black stools, vomiting blood
- yellowing of the skin or eyes (signs of hepatitis)
- blood in the urine, excess protein in the urine, severely decreased urinary output (signs of kidney disorders)
- inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis)

**If you experience any of these tell your doctor straightaway**

**Other side effects include:**

Common: may affect up to 1 in 10 people

- headache, dizziness
- nausea, vomiting, diarrhoea, indigestion, abdominal pain, flatulence (wind), loss of appetite
- change in liver function (e.g. level of transaminases)
- skin rash
- vertigo
Rare: may affect up to 1 in 1,000 people
- drowsiness
- stomach pains
- swelling of arms, hands, legs and feet (oedema)

Very rare: may affect up to 1 in 10,000 people
- disorientation, depression, anxiety, difficulty sleeping, nightmares, irritability, psychotic disorder
- tingling or numbness of the hands or feet, memory impairment, convulsion, trembling, fits
- problems with taste, vision, hearing (ringing in the ears) and balance
- ulcer of the oesophagus (the tube that carries food from the throat to the stomach)
- palpitations
- hair loss, redness, swelling and blistering of the skin (due to increased sensitivity to the sun)
- high blood pressure, vasculitis
- constipation or other bowel problems including colitis (symptoms include persistent diarrhoea) or worsening of existing inflammatory bowel disorders
- sore mouth, sore tongue, sore gullet
- unusual skin sensitivity to sunlight, resulting in red or purple, swollen, blistered skin
- kidney problems, including blood or protein in urine, decreased urine output
- severe rapidly progressing liver failure
- inflammation of the lungs which causes breathlessness and chest pain (pneumonitis)

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland
Tel: +353 1 6764971
Fax: +353 16762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

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

**This leaflet was last revised in 03/2014**

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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.