

Applicant: Unimed Healthcare (Pty) Ltd.

Product Name: Diclofenac Injection Unimed

Dosage form and strength: Each 3,0 ml Ampoule contains Diclofenac Sodium 75 mg Injection

Patient Information Leaflet (PIL)

for Medicines for Human Use

DICLOFENAC INJECTION UNIMED (Injection)

SCHEDULING STATUS: **S3**

DICLOFENAC INJECTION UNIMED (75 mg/3 ml) injection

Diclofenac sodium

Sugar free

Read all of this leaflet carefully before you are given DICLOFENAC INJECTION UNIMED

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- DICLOFENAC INJECTION UNIMED has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

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1. What DICLOFENAC INJECTION UNIMED is and what it is used for

DICLOFENAC INJECTION UNIMED belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

DICLOFENAC INJECTION UNIMED is used as an intramuscular injection to relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles, and tendons including:

- Rheumatoid arthritis, osteoarthritis, (pain, stiffness and swelling of the joints especially in the hands, hips and knees), ankylosing spondylitis (form of spinal arthritis) and spondylarthritis.
- Painful musculoskeletal conditions such as backache, sprains and strains, soft tissue sports injuries, dislocations and fractures.
- Conditions affecting the tendons for example, tendonitis, tenosynovitis, bursitis.
- Attacks of gout.
- Painful post-operative and post-traumatic inflammation and swelling.
- Pain associated with dental surgery.
- Menstrual pain.

2. What you need to know before you use DICLOFENAC INJECTION UNIMED

DICLOFENAC INJECTION UNIMED should not be administered to you:

- if you have stomach ulcers,
- if you are hypersensitive (allergic) to diclofenac sodium, sodium metabisulphite, or any of the other ingredients of DICLOFENAC INJECTION UNIMED (listed in section 6),
- if you are hypersensitive (allergic) to aspirin, ibuprofen or any other NSAIDs,
- if you have asthma and have previously experienced an asthma attack, runny nose or skin rash when taking aspirin or other NSAIDs,

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- if you have now, or have ever had stomach or intestinal perforation, ulcer or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in stools or black, tarry stools),
- if you have had stomach or bowel problems after you have taken other NSAIDs,
- if you have heart failure, established heart disease and/or cerebrovascular disease, e.g. if you have had a heart attack, stroke, mini-stroke 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),
- if you have inherited a disorder of the red blood pigment haemoglobin (porphyria),
- if you have kidney or liver failure,
- if you are pregnant, do not use NSAIDs at 20 weeks or later in your pregnancy because these medicines may cause problems in your unborn baby,
- if you are breastfeeding your baby,
- if the patient is a child.

Warnings and precautions

Tell your doctor or healthcare provider before being given DICLOFENAC INJECTION

UNIMED:

- You should receive the lowest effective dose of DICLOFENAC INJECTION UNIMED for the shortest duration possible time to reduce the risk of developing side effects.
- If you are taking DICLOFENAC INJECTION UNIMED for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harm to the kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

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- If you develop signs of allergic reaction, such as swelling of the face, mouth, throat or tongue, difficult breathing, a blistering skin rash, hives, itching, or chest pain which can be a sign of a potentially serious allergic reaction (Kounis syndrome). You should stop taking DICLOFENAC INJECTION UNIMED and contact your doctor or healthcare provider.
- If you have an infection since symptoms such as fever and inflammation may be masked. If you use this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- If you experience blurred or diminished vision, or changes in colour vision DICLOFENAC INJECTION UNIMED should be discontinued.
- If you have heart problems such chest pain, blood clots, or if you had a stroke or you think you might be at risk of these conditions (for example, if you have high blood pressure, high blood sugar levels, high amounts of fat in the blood or are a smoker). There is an increased risk of heart attack or stroke when you are using DICLOFENAC INJECTION UNIMED. The risk is higher if you are using high doses for a long time.
- If you, at any time while using DICLOFENAC INJECTION UNIMED, experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness or slurring of speech, contact your doctor immediately.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- If you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease (inflammatory diseases), hiatus hernia, gastro-oesophageal reflux disease (reflux of gastric contents into the oesophagus), angiodysplasia (a small vascular malformation of the gut) as these conditions may be exacerbated.

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- If you have or have had an ulcer in the stomach or intestines, especially if this has been complicated by perforation or accompanied by bleeding, you should look out for any unusual symptoms in the abdomen and report them at once to your doctor. If bleeding or ulceration of the digestive tract occurs, the treatment has to be stopped.
- If you are taking corticosteroids (such as prednisone or hydrocortisone), anticoagulants (such as warfarin), selective serotonin-reuptake inhibitors (SSRIs) (such as citalopram, fluoxetine, sertraline), anti-platelet medicines (such as acetylsalicylic acid), or methotrexate.
- If you recently had or you are going to have a surgery of the stomach or intestinal tract, as DICLOFENAC INJECTION UNIMED can sometimes delay wound healing in your gut after surgery.
- If you have serious skin reactions, including shedding of scaly dead skin, extremely serious allergic skin reactions, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) and toxic skin degeneration. DICLOFENAC INJECTION UNIMED should be discontinued immediately at the first appearance of skin rash, fever, mucosal lesions, or any other sign of hypersensitivity (such as Stevens Johnson's syndrome, Toxic Epidermal Necrosis, Drug Reaction with Eosinophilia and Systemic Symptoms). You should also contact your doctor as soon as possible.
- If you are pregnant or plan to become pregnant. Using DICLOFENAC INJECTION UNIMED at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to use DICLOFENAC INJECTION UNIMED for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take DICLOFENAC INJECTION UNIMED around 30 weeks of pregnancy or later.
- If you ever had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract.

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- If you have kidney or liver problems, or if you are elderly.
- If you suffer from any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while you are being given DICLOFENAC INJECTION UNIMED.
- If you suffer from anaemia which may occur as a result of water retention or other blood disorders.
- If you have Systemic Lupus Erythematosus (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition.
- The use of DICLOFENAC INJECTION UNIMED may affect a woman's ability to have a baby.

Children

DICLOFENAC INJECTION UNIMED is not suitable for use in children.

Other medicines and DICLOFENAC INJECTION UNIMED

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Inform your doctor if you are taking the following medicines:

- Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen.
- Corticosteroids (an anti-inflammatory medicine).
- Lithium (a medicine used to treat depression).
- Digoxin (cardiac glycoside) used to treat heart problems.
- Diuretics (water tablets).

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- Medicines used to treat heart conditions or high blood pressure, for example beta blockers or ACE inhibitors.
- Ciclosporin and tacrolimus (medicines used to treat some inflammatory diseases and after transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- Anti-platelets and anticoagulants (blood thinning tablets), such as heparin or warfarin.
- Selective serotonin reuptake inhibitors (SSRIs) (used to treat depression).
- Medicines used to treat diabetes.
- Methotrexate (a medicine used for the treatment of some inflammatory diseases and some cancers).
- Pemetrexed (a chemotherapy medicines used to treat some forms of cancer).
- Deferasirox (a medicine used in patients having long term blood transfusions).
- Quinolone antibiotics (a medicine for infections).
- Phenytoin (a medicine used to treat seizures).
- Colestipol/cholestyramine (a medicine used to lower cholesterol).
- Voriconazole (a medicine used to treat fungal infections).
- Sulfinpyrazone or probenecid (medicines used to treat gout).
- Mifepristone (a medicine used to terminate pregnancy).
- Hydantoin (a medicine used to treat different types of seizures).

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DICLOFENAC INJECTION UNIMED.

Pregnancy

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DICLOFENAC INJECTION UNIMED may harm your unborn baby and may cause problems during delivery. At around 20 weeks or later in pregnancy DICLOFENAC INJECTION UNIMED may cause kidney problems in your unborn baby, which may lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn baby's lungs and muscles to develop. Complications can occur with low levels of this fluid. The use of DICLOFENAC INJECTION UNIMED during the third trimester of pregnancy is contraindicated as it may result in closure of the foetal ductus arteriosus (blood vessel) in utero.

Breastfeeding

You should not use DICLOFENAC INJECTION UNIMED if you are breastfeeding your baby.

Fertility

Using DICLOFENAC INJECTION UNIMED may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

Driving and using machines

DICLOFENAC INJECTION UNIMED may cause drowsiness, dizziness and visual disturbances which may affect your ability to perform skilled tasks. If you are affected, you should not drive or operate machinery.

It is not always possible to predict to what extent DICLOFENAC INJECTION UNIMED may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DICLOFENAC INJECTION UNIMED affects you (see section 4).

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DICLOFENAC INJECTION UNIMED contains propylene glycol, benzyl alcohol and sodium metabisulphite.

DICLOFENAC INJECTION UNIMED contains 600 mg propylene glycol per 3 ml ampoule which is equivalent to 200 mg/ml.

DICLOFENAC INJECTION UNIMED contains 120 mg benzyl alcohol per 3 ml ampoule which is equivalent to 40 mg/ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have 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”).

DICLOFENAC INJECTION UNIMED contains the antioxidant, sodium metabisulphite. This can sometimes cause allergic reactions and breathing difficulties.

3. How to use DICLOFENAC INJECTION UNIMED

Do not share medicines prescribed for you with any other person.

Always use DICLOFENAC INJECTION UNIMED exactly as directed in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use the lowest effective dose for the shortest possible duration of treatment.

The usual dose is:

Adults

The dosage is generally one DICLOFENAC INJECTION UNIMED ampoule daily.

DICLOFENAC INJECTION UNIMED should not be mixed with other injection solutions.

By way of exception, in severe cases, two injections separated by an interval of a few hours

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can be given per day (one into each buttock).

DICLOFENAC INJECTION UNIMED should not be given for more than two days.

Your doctor will tell you how long your treatment with DICLOFENAC

INJECTION UNIMED will last. If you have the impression that the effect of DICLOFENAC

INJECTION UNIMED is too strong or too weak, tell your doctor or pharmacist.

DICLOFENAC INJECTION UNIMED will be given to you as an intramuscular injection.

The directions for intramuscular injection must be followed in order to avoid damage to a nerve or other tissue at the injection site. After inserting the needle the plunger should be pulled back to avoid inadvertent intra- arterial injection.

DICLOFENAC INJECTION UNIMED is not intended for the intravenous route of administration.

DICLOFENAC INJECTION UNIMED is given by deep intragluteal injection into the upper outer quadrant.

You will not be expected to give yourself DICLOFENAC INJECTION UNIMED. It will be given to you by a person who is qualified to do so.

Children

DICLOFENAC INJECTION UNIMED is not suitable for use in children.

If you receive more DICLOFENAC INJECTION UNIMED than you should

Since a healthcare provider will administer DICLOFENAC INJECTION UNIMED, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

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If the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Symptoms of an overdose can include vomiting, abdominal pain, stomach or intestinal bleeding, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting, or occasionally convulsions (seizures, uncontrolled fits).

If you forget to use DICLOFENAC INJECTION UNIMED

Since a healthcare provider will administer DICLOFENAC INJECTION UNIMED, it is unlikely that the dose will be missed.

4. Possible side effects

DICLOFENAC INJECTION UNIMED can have side effects.

Not all side effects reported for DICLOFENAC INJECTION UNIMED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DICLOFENAC INJECTION UNIMED, please consult your healthcare provider for advice.

If any of the following happens, stop using DICLOFENAC INJECTION UNIMED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or toxic epidermal

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necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to DICLOFENAC INJECTION UNIMED. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- sudden and crushing chest pain (signs of myocardial infarction or heart attack),
- heart disorders or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been using a higher dose (150 mg per day) for a long period of time,
- fast or irregular heartbeat (palpitations),
- sudden weakness or numbness in the face, arm or leg especially on one side of the body, sudden loss or disturbance of vision, sudden difficulty in speaking or ability to understand speech, sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke,
- high blood pressure (hypertension), low blood pressure, symptoms of which may include faintness, giddiness or light headedness (hypotension),
- lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease),
- inflammation of the pancreas (pancreatitis),
- stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick) as you may be experiencing ischemic colitis,
- diarrhoea with blood in it or bleeding from the back passage (haemorrhagic diarrhoea),

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- any sign of ulcers or bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit (haematemesis) or black, tarry faeces (melaena),
- kidney disorders including kidney failure, kidney pain or inflammation of the kidneys,
- liver disorders including liver failure or inflammation of the liver,
- presence of blood or protein in the urine,
- an unexpected change in the amount of urine produced and/or its appearance,
- yellowing of your skin or the whites of your eyes (jaundice),
- wheezing or shortness of breath (bronchospasm),
- breathlessness, coughing and a tightness across the chest (asthma),
- inflammation of the lung (pneumonitis),
- inflammation of blood vessels (vasculitis),
- inflammation of the lining of the brain with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation (meningitis),
- mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with DICLOFENAC INJECTION UNIMED and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain,
- if you notice that you are bruising more easily than usual or have frequent sore throats or infections,
- convulsions (fitting),
- 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

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Frequent side effects:

- stomach pain, heartburn, nausea, vomiting, diarrhoea, constipation, indigestion, wind, loss of appetite,
- inflammation, irritation or swelling of the stomach lining (gastritis),
- mouth ulcers with swelling and redness inside the mouth or individual painful sores,
- skin rash and spots,
- headache, dizziness,
- a feeling of whirling or spinning (vertigo),
- raised levels of liver enzymes in the blood,
- anorexia (eating disorder),
- discomfort of the limbs,
- injection site reactions, symptoms include redness, swelling, change in the skin colour, inflammation, pain, and hypersensitivity.

Less frequent side effects:

- tiredness, excess sleepiness (somnolence),
- fluid retention, symptoms of which include swollen ankles (oedema),
- visual disturbances such as blurred or double vision,
- hearing disorders, tinnitus (ringing in the ears),
- sleeplessness, nightmares, depression, anxiety, irritability, mental disorders,
- disorientation, loss of memory, fits, tremor,
- tingling or numbness in the fingers,
- taste changes,
- inflammation of the tongue (glossitis), inflammation of the inside of the mouth or lips (stomatitis),

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- blood disorders (including anaemia),
- photosensitivity (increased sensitivity to sunlight),
- hair loss,
- loss of male sexual ability (impotence),
- tissue damage at the injection site.

Side effects with an unknown frequency:

- inflammation of the nerves in the eye (optic neuritis), other ocular reactions,
- drowsiness, nervousness, agitation,
- confusion, hallucinations, malaise (general feeling of discomfort)

DICLOFENAC INJECTION UNIMED, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DICLOFENAC INJECTION UNIMED.

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5. How to store DICLOFENAC INJECTION UNIMED

- Store at or below 25 ° C. Protect from light.
- Do not freeze.
- Store all medicines out of reach of children.
- Store in the original package.
- Do not use after the expiry date stated on the label.
- Do not use DICLOFENAC INJECTION UNIMED if you notice any foreign particles in the solution.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DICLOFENAC INJECTION UNIMED contains:

- The active substance is diclofenac sodium. Each 3 ml ampoule contains Diclofenac sodium 75 mg.
- The other ingredients are benzyl alcohol 4 % *m/v* as preservative, disodium edetate, 5 % *v/v* hydrochloric acid solution (for pH adjustment), propylene glycol, 5 % *w/v* sodium hydroxide solution (for pH adjustment), sodium metabisulphite 0,1 % *m/v* as an antioxidant, water for injection.

What DICLOFENAC INJECTION UNIMED looks like and contents of the pack

Ampoules 75 mg / 3 ml: Clear, colourless to pale yellow solution free from fibers and particulate matter.

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3 ml colourless and transparent USP type I glass ampoule, packed in pack sizes of 10 x 3 ml or 50 x 3 ml ampoules.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

Corner Birch Road and Bluegum Avenue,

Anchorville,

Lenasia,

1827,

South Africa

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