APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

Diclofenac 50 Unicorn film-coated tablets

Diclofenac potassium

Contains sugar: lactose monohydrate (95 mg per tablet)

Read all of this leaflet carefully before you start taking Diclofenac 50 Unicorn

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Diclofenac 50 Unicorn 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 50 Unicorn is and what it is used for
2. What you need to know before you take Diclofenac 50 Unicorn
3. How to take Diclofenac 50 Unicorn
4. Possible side effects
5. How to store Diclofenac 50 Unicorn
6. Contents of the pack and other information

1. What Diclofenac 50 Unicornis and what it is used for

Diclofenac potassium, the active ingredient in Diclofenac 50 Unicorn, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Diclofenac 50 Unicorn is for the emergency treatment of short-term (acute) gout attacks, for a maximum period of 5 days.

2. What you need to know before you take Diclofenac 50 Unicorn

Do not take Diclofenac 50 Unicorn:

- if you think you may be allergic to diclofenac potassium, or any other NSAID (for example aspirin or ibuprofen) or to any of the other ingredients of Diclofenac 50 Unicorn (listed in section 6).
- 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.
- if you have now, or have ever had, a stomach (gastric) or intestinal 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).
- if you have had stomach or bowel problems after you have taken other NSAIDs.
- if you have heart, kidney or liver failure.
- if 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.
- if you have or have had problems with your blood circulation (peripheral arterial disease).
- if you are more than six months pregnant or breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Diclofenac 50 Unicorn:

- if you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease (types of inflammatory bowel diseases), hiatus hernia, gastro-

oesophageal reflux disease, and/or angiodysplasia (abnormality with the blood vessels in the gastrointestinal tract).

- if you have kidney or liver problems, or are you elderly.
- if you have a condition called porphyria.
- 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 taking these tablets.
- if you ever had asthma.
- if you are breastfeeding.
- if you have angina, blood clots, high blood pressure, abnormally high levels of fat in your blood (raised cholesterol or raised triglycerides).
- if you have heart problems, or have you had a stroke, or you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, or high cholesterol or are a smoker).
- if you have Lupus (SLE) (an autoimmune disease) or any similar condition.
- You should take the lowest dose of Diclofenac 50 Unicorn for the shortest possible time, particularly if you are underweight or elderly.
- Tell your doctor if you experience skin rash, itching, painful red areas, peeling or blistering of the skin or any other allergic reaction while taking Diclofenac 50 Unicorn. Signs of an allergic reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- There is a small increased risk of heart attack or stroke when you are taking Diclofenac 50 Unicorn. The risk is higher if you are taking high doses for a long time. Always follow the doctor’s instructions on how much to take and how long to take it for.
- If at any time while taking Diclofenac 50 Unicorn you 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.
- Whilst you are taking Diclofenac 50 Unicorn your doctor may want to give you a

check-up from time to time.

- If you have a history of stomach problems when you are taking NSAID, including Diclofenac 50 Unicorn, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, Diclofenac 50 Unicorn may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Diclofenac 50 Unicorn.
- Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Diclofenac 50 Unicorn, as Diclofenac 50 Unicorn can sometimes worsen wound healing in your gut after surgery.

Other medicines and Diclofenac 50 Unicorn

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

Diclofenac 50 Unicorn and certain other medicines may influence each other (interaction):

- Lithium (used to treat some mental problems)
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Diuretics (water tablets)
- Medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors
- Anticoagulants (blood thinning tablets like warfarin)
- Any other NSAID or COX-2 (cyclo-oxgenase-2) inhibitor, for example aspirin or ibuprofen
- Oral steroids (an anti-inflammatory drug)
- Medicines known as SSRIs used to treat depression
- Medicines to treat diabetes
- Methotrexate (for some inflammatory diseases and some cancers)

- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants) Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibiotics (for infections)
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)
- Mifepristone (a medicine used to terminate pregnancy)
- Voriconazole (a medicine used to treat fungal infections).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Diclofenac 50 Unicorn.

- If you pregnant or planning to become pregnant, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take Diclofenac 50 Unicorn during the last 3 months of pregnancy as it may affect the baby's circulation.
- If you are breastfeeding do not take Diclofenac 50 Unicorn.
- If you are you trying for a baby, do not take Diclofenac 50 Unicorn.

Driving and using machines

Diclofenac 50 Unicorn could make you feel dizzy, tired, sleepy or affect your eyesight. If you are affected in this way, you should not drive or operate machinery.

Diclofenac 50 Unicorn contains lactose

Diclofenac 50 Unicorn contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Diclofenac 50 Unicorn and sodium content

Diclofenac 50 Unicorn contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Diclofenac 50 Unicorn

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

Always take Diclofenac 50 Unicorn exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will determine what dose is appropriate for you.

Diclofenac 50 Unicorn is for oral use only.

Adults

Initial daily dose: 100 (two tablets) to 150 mg (three tablets) in two to three divided doses, with a maximum daily dose of 150 mg in divided doses.

If you have the impression that the effect of Diclofenac 50 Unicorn is too strong or too weak, tell your doctor or pharmacist.

If you take more Diclofenac 50 Unicorn than you should

If you, or anyone else, accidentally takes too much, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

If you forget to take Diclofenac 50 Unicorn

If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Diclofenac 50 Unicorn can have side effects.

Not all side effects reported for Diclofenac 50 Unicorn are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Diclofenac 50 Unicorn, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking Diclofenac 50 Unicorn 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to Diclofenac 50 Unicorn. You may need urgent medical attention or hospitalisation.

Stop taking Diclofenac 50 Unicorn and tell your doctor straight away if you notice:

- Sudden and crushing chest pain (signs of myocardial infarction or heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
- 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
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Stomach pain, indigestion, heartburn, wind, belching, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your

bowels, blood in vomit or black, tarry faeces

- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Diclofenac 50 Unicorn and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- Wheezing or shortness of breath
- Swollen face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance
- If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite
- Headache, dizziness, vertigo, nervousness
- Skin rash, spots or any other skin reactions
- If you have a blood test and levels of liver enzymes in the blood are raised.

Less frequent side effects

- Fast or irregular heartbeat (palpitations), chest pain, heart disorders, including heart attack or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day) for a long period of time

- Stomach ulcers or bleeding (there have been less frequent 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.
- Drowsiness, tiredness
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice
- Asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest)
- Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck
- Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn’s disease), inflammation of the pancreas
- Hypertension (high blood pressure), hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia)
- Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine
- Facial swelling, serious skin rashes including Stevens-Johnson syndrome and Lyell’s syndrome and other skin rashes which may be made worse by exposure to sunlight.

- Hair loss
- Impotence.

Frequency unknown side effects

- Throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances of sensation
- Medicines such as diclofenac may be associated with a small increased risk of heart attack or stroke.

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, 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 50 Unicorn.

5. How to store Diclofenac 50 Unicorn

Store all medicines out of reach of children.

Store below 30 °C in the original packaging.

Do not use after the expiry date stated on the carton.

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 50 Unicorn contains:

The active substance of Diclofenac 50 Unicorn is diclofenac potassium.

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulphate, colloidal silicon dioxide, magnesium stearate.

The Instacoat Universal Brown coating contains:

Hypromellose (E464), talc (E553b), titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172).

What Diclofenac 50 Unicorn looks like and contents of the pack

Reddish brown, round, biconvex, film–coated tablets debossed with 'DP' on one side and '50' on other side.

Contents of the pack

Blister pack of 9 (1 x 9's) film-coated tablets.

Holder of Certificate of Registration

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South Africa

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