PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BIO DICLOFENAC INJECTION, 25 mg/ml (injection).

Diclofenac sodium

Contains 4 % *m/v* benzyl alcohol (as preservative)

Contains sugar (mannitol 6 mg/ml)

Read all of this leaflet carefully before you are administered BIO DICLOFENAC INJECTION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BIO DICLOFENAC INJECTION 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 BIO DICLOFENAC INJECTION is and what it is used for

BIO DICLOFENAC INJECTION contains diclofenac sodium, which belongs to the group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). BIO DICLOFENAC INJECTION is used to treat mild to moderate pain, and helps to relieve symptoms of arthritis (osteoarthritis and rheumatoid arthritis), such as inflammation, swelling, stiffness, and joint pain. BIO DICLOFENAC INJECTION is used to treat

pain after an operation.

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

You should not be administered BIO DICLOFENAC INJECTION if you:

- have a known hypersensitivity to diclofenac or other NSAIDs such as aspirin or any of the other ingredients such as sodium metabisulphite in BIO DICLOFENAC INJECTION (listed in section 6)
- you are pregnant or breastfeeding
- have a stomach or intestinal ulcer
- have a history of intestinal bleeding or a perforation caused by NSAIDs (two or more distinct episodes of proven bleeding)
- have a bleeding disorder or problem
- have asthma
- have severe liver or heart failure
- suffer from porphyria
- suffer from ischaemic heart disease (narrowing of arteries of the heart and chest pain) or have a history of stroke
- BIO DICLOFENAC INJECTION should not be used in children
- are using NSAIDs or anticoagulant medication (medicine that prevents the blood from forming blood clots, including low doses of heparin)
- have a high susceptibility to bleed or confirmed or suspected bleeding in the brain
- are going to have an operation with a high risk of bleeding
- have moderate or severe renal impairment (serum creatinine > 160 µml/l)
- are dehydrated due to any cause or have a decreased volume of circulating blood in the body.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

If you are taking BIO DICLOFENAC INJECTION for longer than the recommended time or at higher than recommended doses, you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Please tell your doctor if:

- you have an allergy towards NSAIDs or sodium metabisulphite
- you have symptoms of a disease of the intestines or a history of diseases that affect the gastrointestinal tract such as Crohn's disease
- you have a stomach ulcer
- you have a liver/kidney disease or your liver/kidney is not working properly
- you have a heart disease or history of heart failure or high blood pressure being treated with or without diuretics
- you might have a bleeding problem or problem relating to blood clotting
- you develop a serious skin rash or blistering
- you develop flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- you have systemic lupus erythematosus
- you are planning to become pregnant.

Other medicines and BIO DICLOFENAC INJECTION

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

The following medicines may interact with your BIO DICLOFENAC INJECTION when you use them together and may either cause additional side effects or may not work as well:

- blood thinning medicine e.g. warfarin

- methotrexate (medicine for the treatment of cancer or to treat auto-immune diseases)
- lithium (medicine for depression)
- digoxin (medicine for the heart)
- other NSAIDs including cyclooxygenase-2 inhibitors (medicine such as aspirin, ibuprofen or indomethacin)
- ciclosporin (medicine that suppress the immune system used after organ transplant)
- antidiabetic medicines
- quinolone antibiotics (for e.g. norfloxacin, gatifloxacin or levofloxacin)
- antidepressants that are known as selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine and paroxetine
- glucocorticoids (steroids that reduce inflammation throughout the body)
- anti-platelet medicines (medicine such as aspirin, clopidogrel or prasugrel)
- diuretics and antihypertensive medicines (medicine used to lower blood pressure)
- potassium sparing diuretics (for e.g. eplerenone and spironolactone)
- tacrolimus (an immunosuppressive drug used mainly in organ transplants)
- phenytoin (medicine that is used in the treatment of epilepsy)
- colestipol and cholestyramine (used to treat cholesterol)
- cardiac glycosides (medicine used to treat heart failure and certain irregular heartbeats)
- mifepristone (medicine used to end pregnancy)
- potent CYP2C9 inhibitors (for e.g. voriconazole).

Not all medicine interactions are described in this leaflet. It is therefore very important that you tell your doctor or healthcare provider of all the other medicines you are currently taking.

BIO DICLOFENAC INJECTION with food and drink

BIO DICLOFENAC INJECTION can cause stomach irritation; it is therefore better for the injection to be

administered after meals.

Pregnancy, breastfeeding and fertility

The safety of BIO DICLOFENAC INJECTION during pregnancy and lactation has not been established.

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 healthcare provider for advice before BIO DICLOFENAC INJECTION are administered to you.

Driving and using machines

BIO DICLOFENAC INJECTION can cause headaches, dizziness, vertigo (a sensation of whirling and loss of balance), somnolence (strong desire to sleep), drowsiness (a feeling of being sleepy), fatigue (exhaustion) and problems with your ability to see. When you experience these symptoms, you should not drive or operate machines.

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

BIO DICLOFENAC INJECTION contain propylene glycol, benzyl alcohol and sodium metabisulphite

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

BIO DICLOFENAC INJECTION 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’).

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

Information about sodium content

This medicine contains less than 1mmol sodium (23 mg) per 3 ml ampoule, that is to say essentially "sodium-free".

3. How to use BIO DICLOFENAC INJECTION

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

Your doctor will prescribe the exact dose of BIO DICLOFENAC INJECTION required for your condition.

Always use BIO DICLOFENAC INJECTION exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with BIO DICLOFENAC INJECTION will last.

If you have the impression that the effect of BIO DICLOFENAC INJECTION is too strong or too weak, tell your doctor or pharmacist.

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

BIO DICLOFENAC INJECTION should not be given for more than 2 days.

BIO DICLOFENAC INJECTION is for intramuscular injection only. Use the lowest effective dose for the shortest possible duration of treatment.

The usual daily dose of BIO DICLOFENAC INJECTION is 75 mg once or twice daily.

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

If you have received more BIO DICLOFENAC INJECTION than you should have

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

In the event of an overdosage you will experience symptoms such as swelling face, ankles or hands, confusion and nervousness. The treatment will usually be symptomatic and supportive.

If you missed a dose of BIO DICLOFENAC INJECTION

Do not receive a double dose to make up for forgotten individual doses. Continue to receive the next dosage at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

4. Possible side effects

BIO DICLOFENAC INJECTION can have side effects.

Not all side effects reported for BIO DICLOFENAC INJECTION are included in this leaflet. Should your general health worsen while BIO DICLOFENAC INJECTION is being administered to you, please consult your healthcare provider for advice.

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

- fainting; fast or irregular heartbeat; fast or irregular breathing; large hive-like swellings; mouth, lips or tongue swelling; puffiness of swelling of the eyelids or around the eyes; wheezing or tightness in the chest; angioneurotic oedema (condition characterised by rapid swelling of the dermis, subcutaneous tissue, mucosa and submucosal tissues).
- BIO-DICLOFENAC INJECTION, 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. This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIO DICLOFENAC INJECTION. 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:

Frequent:

- abdominal or stomach pain, cramping or burning; nausea.

Less frequent:

- 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)
- chest pain; unusual bruising or bleeding
- spitting up blood
- dizziness
- bloody or black, tarry stools
- loss of balance and coordination
- difficulty speaking
- numbness or paralysis in the face, leg or arm (mostly only one side of the body)
- blurred or darkened vision
- liver disorder or liver necrosis (usually characterised by abdominal pain)
- impotence (inability to sustain an erection).

Frequency not known:

- confusion, hallucinations (when you see, hear, smell, taste or feel things that don't exist)
- malaise (a general feeling of discomfort)
- vision loss in one eye
- pain around the eye (worsened by movement)
- inability to see colours

- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))

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

Tell your doctor if you notice any of the following:

Frequent:

- severe headache, especially in the mornings
- nervousness
- wind, heartburn
- loss of appetite, belching, local irritation
- raised levels of liver enzymes in the blood
- feeling off balance
- injection site reactions, symptoms include redness, swelling, change in the skin colour, inflammation, pain, and hypersensitivity

Less frequent:

- blood disorders
- bladder pain; bleeding from cuts or scratches that lasts longer than usual
- bloody or cloudy urine or any problem with urination
- disturbances in vision
- yellow eyes or skin
- gastritis (inflammation of the lining of the stomach)
- 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, anxiety
- sleeplessness, nightmares, mood changes, depression

- 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 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)
- fluid retention, symptoms of which include swollen ankles
- liver function disorders, including hepatitis and jaundice, liver failure
- kidney or severe liver disorders including liver failure, presence of blood or protein in the urine, all or part of the kidney die
- collection of symptoms due to kidney damage, collection of different signs and symptoms that occur as a result of inflammation in the kidneys.
- facial swelling, serious skin rashes including Stevens-Johnson syndrome Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight
- hair loss
- asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest)
- inflammation of the lung (pneumonitis)

Frequency unknown

- injection site necrosis (dead skin and tissue around the injection site)
- coincidental occurrence of acute coronary syndromes during an allergic reaction with cardiac anaphylaxis
- inflammation of the optic nerve

Other side effects may occur that usually do not need medical attention. These side effects may go away when your body adjusts to the medicine.

Frequent:

- Diarrhoea or constipation; stomach pain; dizziness; heartburn; light-headedness; nervousness; vomiting; reaction and pain where the injection was administered.

Less frequent:

- Constipation; irritability; unexplained weight loss; sensitivity of the skin to sunlight; depression and nightmares.

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 BIO DICLOFENAC INJECTION.

5. How to store BIO DICLOFENAC INJECTION

Store at or below 25 °C. Protect from heat and light.

Do not remove ampoules from outer carton until required for use.

Store all medicines out of reach of children.

Do not use BIO DICLOFENAC INJECTION after the expiry date stated on the container.

Do not use BIO DICLOFENAC INJECTION 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 BIO DICLOFENAC INJECTION contains

The active substance in BIO DICLOFENAC INJECTION is diclofenac sodium 25 mg/ml.

The other inactive ingredients are the benzyl alcohol as preservative, mannitol, propylene glycol, and the

antioxidant sodium metabisulphite.

Contains sugar (mannitol).

What BIO DICLOFENAC INJECTION looks like and contents of the pack

A clear, colourless to slightly yellow solution free from foreign particles.

5 x 3 ml clear colourless glass, labelled ampoules in a carton box.

10 x 3 ml clear colourless glass, labelled ampoules in a carton box.

100 x 3 ml clear colourless glass, labelled ampoules in a carton box.

All pack sizes may not necessarily be marketed at one time.

Holder of Certificate of Registration

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