PATIENT INFORMATION LEAFLET FOR HUMAN USE:
AUSTELL DICLOFENAC SODIUM 25 mg/mL INJECTION

SCHEDULING STATUS

S3

AUSTELL DICLOFENAC SODIUM 25 mg/mL INJECTION

Diclofenac sodium

Sugar free

Read all of this leaflet carefully before you are given AUSTELL DICLOFENAC SODIUM 25 mg/mL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AUSTELL DICLOFENAC SODIUM 25 mg/mL** 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 AUSTELL DICLOFENAC is and what it is used for

2. What you need to know before you use AUSTELL DICLOFENAC

3. How to use AUSTELL DICLOFENAC

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1. What AUSTELL DICLOFENAC is and what it is used for

AUSTELL DICLOFENAC contains the active ingredient diclofenac sodium (75 mg/3 mL ampoule).

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

AUSTELL DICLOFENAC is used as an intramuscular injection for:

Treating inflammation of muscles, joints and tissues and pain associated with inflammation.

2. What you need to know before you use AUSTELL DICLOFENAC

AUSTELL DICLOFENAC should not be administered to you if:

- You are hypersensitive (allergic) to diclofenac sodium, aspirin, ibuprofen or any other NSAIDs or any of the other ingredients of AUSTELL DICLOFENAC (listed in section 6). 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 stools or black, tarry stools).
- You have had stomach or bowel problems after you have taken other NSAIDs.
- You have moderate or severe heart, kidney or liver failure.
- You are more than ~~6 months~~ more or less 20 weeks pregnant.
- You are breastfeeding
- You have porphyria

Warnings and precautions

Tell your doctor or healthcare provider before being given AUSTELL DICLOFENAC injection:

- You should receive the lowest dose of AUSTELL DICLOFENAC for the shortest possible time, particularly if you are underweight or elderly.
- You should be aware that medicines such as diclofenac may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.
- Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- Whilst you are taking these medicines 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 NSAIDs, 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, AUSTELL DICLOFENAC 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 receiving AUSTELL DICLOFENAC.
- AUSTELL DICLOFENAC contains the preservative, sodium metabisulphite. This can sometimes cause allergic reactions and breathing difficulties.
- AUSTELL DICLOFENAC should not be used in children.
- Patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported with AUSTELL DICLOFENAC therapy.

Children and adolescents

AUSTELL DICLOFENAC is not suitable for children and adolescents below 14 years of age.

Other medicines and AUSTELL DICLOFENAC

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Inform your doctor if you are taking any of the following medicines:

- Medicines used to treat diabetes.
- Anticoagulants (blood thinning tablets like warfarin).
- Diuretics (water tablets).
- Lithium (medicine used to treat some mental problems).
- Methotrexate (medicine used for inflammatory diseases and cancers).
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants).
- Quinolone antibiotics (for infections).
- Any other NSAIDs or COX-2 (cyclo-oxygenase-2) inhibitors, for example aspirin or ibuprofen.
- Mifepristone (a medicine used to terminate pregnancy).
- Cardiac glycosides (for example digoxin), used to treat heart problems.
- Medicines known as SSRIs used to treat depression.
- Oral steroids (an anti-inflammatory drug).
- Medicines used to treat heart conditions or high blood pressure, for example betablockers or ACE inhibitors.

These medicines should not be taken together with AUSTELL DICLOFENAC.

Pregnancy, Breastfeeding and Fertility

- Using pain-relieving and fever-reducing nonsteroidal anti-inflammatory drugs (NSAIDs) around 20 weeks or later in pregnancy may cause kidney problems in your unborn baby, which can lead to low levels of amniotic fluid that surrounds your baby. This fluid provides

a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop. Complications can occur with low levels of this fluid.

- The use of AUSTELL DICLOFENAC during the third trimester of pregnancy is contraindicated may result in closure of the foetal ductus arteriosus in utero and possible persistent pulmonary hypertension (high blood pressure) of the newborn.
- Diclofenac passes into breast milk in small amounts.
- The use of diclofenac may make it more difficult to become pregnant. You should talk to your doctor if you are having problems getting pregnant.

If you are pregnant or breastfeeding your baby while taking AUSTELL DICLOFENAC, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machines

Occasionally people have reported that diclofenac sodium injections have 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.

It is not always possible to predict to what extent AUSTELL DICLOFENAC may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which AUSTELL DICLOFENAC affects them.

AUSTELL DICLOFENAC contains propylene glycol, benzyl alcohol and sodium metabisulphite.

AUSTELL DICLOFENAC contains 600 mg propylene glycol per 3 mL ampoule which is equivalent to 200 mg/mL.

AUSTELL DICLOFENAC 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 breastfeeding 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').

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

3. How to use AUSTELL DICLOFENAC

Do not share medicines prescribed for you with any other person.
Always use AUSTELL DICLOFENAC exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults

AUSTELL DICLOFENAC is given by deep intra-muscular injection into the gluteal muscle in a dose of 75 mg once daily or, if required in severe conditions, 75 mg twice daily.
AUSTELL DICLOFENAC should not be given as an intravascular injection.
The maximum total daily dose of AUSTELL DICLOFENAC by any route is 150 mg.

Your doctor will tell you how long your treatment with AUSTELL DICLOFENAC will last. If you have the impression that the effect of AUSTELL DICLOFENAC is too strong or too weak, tell your doctor or pharmacist.

AUSTELL DICLOFENAC 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 tissues at the injection site. After inserting the needle the plunger should be pulled back to avoid inadvertent intra-arterial injection.

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

If you receive more AUSTELL DICLOFENAC than you should

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

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

General symptoms of nausea, vomiting, headache, drowsiness, blurred vision and dizziness have been reported. There have been isolated case reports of more serious toxicity, including seizures, hypotension, apnoea, coma, and renal failure, although usually after ingestion of substantial quantities.

Treatment is entirely supportive. Gastric lavage and activated charcoal may be of benefit within 1 hour of ingestion.

Forced diuresis, haemodialysis, or haemoperfusion are unlikely to be of any benefit, although haemodialysis may be required if oliguric renal failure develops.

There is no specific antidote.

If you forget to use AUSTELL DICLOFENAC

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

4. Possible side effects

AUSTELL DICLOFENAC can have side effects.

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

If any of the following happens, stop using AUSTELL DICLOFENAC 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,
- Stomach pain, indigestion, heartburn, wind, 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,
- Allergic reactions which can include bruising, painful red areas, peeling or blistering, wheezing or shortness of breath (bronchospasm),
- 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,
- You are bruising more easily than usual or have frequent sore throats or infections.

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

The side effects listed below have also been reported.

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,
- Skin rash or spots,
- Raised levels of liver enzymes in the blood,
- Vision disturbed/blurred, diplopia (double vision).

Less frequent side effects:

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly),
- Disorientation, depression, insomnia (struggle to sleep), nightmare, irritability, psychotic disorder,
- Drowsiness, tiredness, paraesthesia (needles and pins), memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular haemorrhage,
- Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness) or hypertension (high blood pressure),
- Skin rash and itching,
- Fluid retention, symptoms of which include swollen ankles,
- Liver function disorders, including hepatitis and jaundice,
- Impaired hearing,

- Asthma or breathing problems,
- Haematuria (blood in urine), proteinuria (protein in urine) and renal function disorders,
- Impotence.

Side effects with frequency unknown:

- Injection site necrosis,
- Confusion, hallucinations, disturbances of sensation, malaise (feeling unwell),
- Optic neuritis (inflammation of the nerves of the eye causing pain/vision disturbances),
- Chest pain signalling acute coronary artery syndrome associated with allergic reaction also called Kounis syndrome,
- Ischaemic colitis (inflammatory bowel disease).
- 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)),

Effects on the nervous system:

Tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental disorders, confusion, hallucinations, malaise, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, taste changes, lower gut disorders (including inflammation of the colon).

Effects on the heart, chest or blood:

Palpitations (fast or irregular heartbeat), chest pain, hypertension (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), congestive heart failure, blood disorders (including anaemia).

Effects on the liver or kidneys:

Kidney or liver disorders, presence of blood or protein in the urine.

Effects on skin or hair:

Serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight. Also refer to the DRESS syndrome above.

Hair loss.

Other Effects:

Inflammation of the pancreas, impotence.

Medicines containing diclofenac, such as AUSTELL DICLOFENAC, may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Do not be alarmed by this list - most people have an injection of AUSTELL DICLOFENAC without any problems.

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 AUSTELL DICLOFENAC**.**

5. How to store AUSTELL DICLOFENAC

Store all medicines out of reach of children.

Store below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Keep ampoules in the carton/polystyrene container until required for use.

Store in original package.

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

Your doctor, pharmacist or healthcare professional knows how to store AUSTELL DICLOFENAC.

The doctor or nurse who is administering AUSTELL DICLOFENAC to you, will make sure that the medicine is not used after the expiry date printed on the vial.

They will also visually inspect the solution before giving it to you. Only clear solution without particles will be used.

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 AUSTELL DICLOFENAC contains

The active ingredient in AUSTELL DICLOFENAC is diclofenac sodium.

Each injection ampoule contains 75 mg of the diclofenac sodium in solution.

The other ingredients are propylene glycol, benzyl alcohol, sodium metabisulphite, mannitol, sodium hydroxide, water for injection, 4 % *w/v* sodium hydroxide solution.

What AUSTELL DICLOFENAC looks like and contents of the pack

Clear and colourless ampoules of 10 x 3 mL and 50 x 3 mL.

A clear colourless solution free from any particulate matter.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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