PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MYLAN DICLOFENAC INJECTION (Injection)

Diclofenac, 75 mg

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

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

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

What MYLAN DICLOFENAC INJECTION is:

MYLAN DICLOFENAC INJECTION belongs to a class of medicine known as non-steroidal anti-inflammatory medicine and reduce pain and inflammation.

What this medicine is used for:

MYLAN DICLOFENAC INJECTIONS are used:

- as the initial therapy for inflammatory and degenerative rheumatic diseases;
- for painful conditions due to inflammation of non-rheumatic origin;
- to treat acute attacks of gout.

2. What you need to know before you receive MYLAN DICLOFENAC INJECTION

MYLAN DICLOFENAC INJECTION should not be administered to you if you:

- are hypersensitive (allergic) to diclofenac or any of the other ingredients of MYLAN DICLOFENAC INJECTION or to any other non-steroidal anti-inflammatory medicine;
- have a history of active gastro-intestinal bleeding or peptic ulceration;
- have severe kidney or liver problems;
- have ever had an unusual reaction to aspirin.
- are pregnant, or think they might be as safety has not been established;
- are taking high dosages of the medicine methotrexate; which is sometimes used in treating breast cancer, psoriasis and rheumatoid arthritis;
- have an established disease of the heart or blood vessels (cardiovascular disease):
    - uncontrolled high blood pressure,

    - congestive heart failure (a serious condition in which the heart doesn't pump blood as efficiently as it should),
    - established ischemic heart disease (damage or disease in the heart's major blood vessels),
    - peripheral arterial disease (a circulatory condition in which narrowed blood vessels reduce blood flow to the limbs),
    - atherosclerotic cardiovascular disease (atherosclerotic cardiovascular disease),
- have a rare liver condition called porphyria;
- suffer from asthma (shortness of breath) or any other chronic lung disease that causes difficulty in breathing;
- hay fever (seasonal allergic rhinitis).

MYLAN DICLOFENAC INJECTION should not be administered to children.

Warnings and precautions

MYLAN DICLOFENAC INJECTION should be used with caution and special care should be taken in patients who:

- have cardio-vascular disease (*see section 2 'What you need to know before you are administered MYLAN DICLOFENAC INJECTION'*);
- have blood disorders;
- have asthma or broncho-constriction;
- have impaired liver or kidney function;
- are being treated with coumarin anti-coagulants;
- are elderly;
- are underweight;
- have a past history of ulcers (stomach or intestinal);

- have gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past;
- have diseases of the bowel or inflammation of the intestinal;
- have swollen feet;
- have lupus erythematosus (an inflammatory disease caused when the immune system attacks its own tissues);
- have a high level of cholesterol;
- have suffered heavy blood loss.

Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS) has been reported in patients using NSAIDs such as MYLAN DICLOFENAC INJECTION. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis. Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophillia is often present. Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, discontinue MYLAN DICLOFENAC INJECTION and evaluate the patient immediately.

Children/ and adolescents

Do not administer MYLAN DICLOFENAC INJECTION to children (*see section 2 'What you need to know before you are adminitered MYLAN DICLOFENAC INJECTION'*).

Other medicines and MYLAN DICLOFENAC INJECTION

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

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

~~Tell your doctor or pharmacist before taking this medicine if you are already taking any of the following medicines:~~

- Blood thinners (in particular coumarin anti-coagulants).
- Methotrexate; a medicine used to treat patients with cancer
- Aspirin.
- Other non-steroidal anti-inflammatory drugs such as Ibuprofen.
- High blood pressure medication.
- Corticosteroids; medicines used to treat inflammation
- Cyclosporine; a medicine used to treat people who received skin grafts,
- Lithium; a medicine used to treat mood disorders
- Phenytoin; a medicine used to treat epilepsy.
- Tolbutamide and other medicines used to decrease blood sugar.
- Hydantoin; a medicine used to treat convulsions.
- Digoxin; a medicine used to treat cardiac arrhythmias.
- Probenecid; a medicine used to treat kidney impairment.
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants).
- Anti-depressants.
- Medicines designed to increase the amount of water and salt expelled from the body as urine.
- Medicines use to lower cholesterol.

- Mifepristone, a medicine used to bring about an abortion.
- Voriconazole a medication used to treat a number of fungal infections.

Pregnancy and breastfeeding and fertility

Do not administer MYLAN DICLOFENAC INJECTION during the first 6 months of pregnancy, except on doctor's advice and it must not be used during the last 3 months.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using MYLAN DICLOFENAC INJECTION.

Driving and using machinery

MYLAN DICLOFENAC INJECTION may cause dizziness, drowsiness and fatige. It is not always possible to predict to what extent MYLAN DICLOFENAC INJECTION 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 MYLAN DICLOFENAC INJECTION affects them.

MYLAN DICLOFENAC INJECTION contains benzyl alcohol

This medicine benzyl alcohol that may cause allergic reactions.

3. How MYLAN DICLOFENAC INJECTION will be administered

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

The usual dose is:

- The MYLAN DICLOFENAC INJECTION will be given to you by a healthcare professional.
- It is usually administered into the buttocks and is normally only given for one or two days before being switched to the tablets.
- This injection is not administered intravenously.

- Your doctor will tell you how long your treatment with MYLAN DICLOFENAC INJECTION will last.
- If you have the impression that the effect of MYLAN DICLOFENAC INJECTION is too strong or too weak, tell your doctor or pharmacist.
- You will not be expected to give yourself MYLAN DICLOFENAC INJECTION. It will be given to you by a person who is qualified to do so.

If you use more MYLAN DICLOFENAC INJECTION than you should

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

If you missed a dose of MYLAN DICLOFENAC INJECTION

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

4. Possible side effects

MYLAN DICLOFENAC INJECTION can have side effects.

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

If any of the following happens, stop receiving MYLAN DICLOFENAC INJECTION and consult your doctor or the emergency room of the nearest hospital immediately if you experience the following:

- Swelling of the legs or other parts of your body;

- swelling of the lips, mouth and throat;
- difficulty breathing or wheezing, chest pain;
- itchy skin rash;
- a high temperature with a sore throat and other flu-like symptoms;
- black or bloody stools;
- blood in the urine.

These are all very serious side effects. These may be signs of an allergic reaction to MYLAN DICLOFENAC INJECTION and you should contact your doctor immediately. 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:

- Confusion;
- hallucinations (experiences that appear real but are created by your mind).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Dizziness;
- skin rash and itchiness;
- headache;
- stomach pain;
- heartburn;
- nausea and vomiting;
- diarrhoea;

- flatulence (wind);
- indigestion;
- loss of appetite;
- burping
- raised levels of liver enzymes in the blood;
- if you are going for blood tests while using MYLAN DICLOFENAC INJECTION, inform the health professional of the fact that you are being treated with MYLAN DICLOFENAC INJECTION as it may influence the blood tests;
- if you were given the injection, the site of the injection may become irritated.

The following side effects have been reported less frequently:

- Trouble sleeping;
- depression;
- disorientation (an altered mental state);
- nigthmares;
- inflammation of the lining of the brain (meningitis);
- tingling or numbness in the fingers;
- taste changes;
- mood changes;
- mental disorders;
- disorientation and loss of memory;
- fits;
- headaches together with a dislike of bright lights;
- drowsiness;
- nervousness;

- irritability and agitation;
- general feeling of being unwell;
- 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 colitis or Crohn's disease);
- inflammation of the pancreas;
- disturbance in vision;
- ringing or buzzing in the ears;
- hearing loss or impairment,
- high pressure;
- inflammation of blood vessels (vasculitis);
- hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness);
- swelling of the feet or legs (signs of heart failure)
- palpitations;
- hair loss;
- impotence.

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. This includes any possible side effects not listed in this leaflet. 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/. By reporting side effects, you can help provide more information on the safety of MYLAN DICLOFENAC INJECTION.

5. How to store MYLAN DICLOFENAC INJECTION

- Store below 25 ºC.
- Store the injection ampoules in a place protected from heat or light.
- Do not refrigerate the ampoules.
- If you don't need to take this medicine anymore, take it to your doctor or nearest pharmacy to dispose of it.
- Store all medicine out of reach of children.
- Store in the original package / container.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYLAN DICLOFENAC INJECTION contains:

- Each ampoule for injection contains 75 mg diclofenac sodium with 4 % benzyl alcohol as a preservative.

What MYLAN DICLOFENAC INJECTION looks like and contents of the pack

MYLAN DICLOFENAC INJECTION: A clear, colourless to slightly amber solution in amber ampoules.

MYLAN DICLOFENAC INJECTION: Amber glass ampoules in packs of 5 or 50.

Holder of Certificate of Registration and Manufacturer

Mylan (Pty) Ltd

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Republic of South Africa

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website