1.5.5 Clinical Professional Information and Patient Information Leaflet

amendments/updates

1.5.5.2 Annotated Patient Information Leaflet (clean)

The information in this patient information leaflet has been taken from the package insert.

Please read this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

This medicine 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

SCHEDULING STATUS: S3

PROPRIETARY NAME AND DOSAGE FORM:

MYLAN DICLOFENAC 25 (Tablets)

MYLAN DICLOFENAC 50 (Tablets)

MYLAN DICLOFENAC INJECTION (Injection)

COMPOSITION OF THE MEDICINE, THAT IS, WHAT THIS MEDICINE CONTAINS:

Each tablet contains 25 milligrams, or 50 milligrams of diclofenac sodium. Each ampoule for injection contains 75 mg diclofenac sodium with 4 % benzyl alcohol as a preservative.

The inactive ingredient in the tablets are microcrystalline cellulose, sodium starch glycolate, lactose monohydrate (sugar), maize starch, magnesium stearate, purified talc, cellulose acetate phthalate and opadry yellow.

INDICATIONS AND USE, THAT IS, WHAT THIS MEDICINE IS USED FOR:

DICLOFENAC belongs to a class of medicine known as non-steroidal anti-inflammatory medicine.

DICLOFENAC tablets are used for the treatment of:

- pain and inflammation in rheumatoid arthritis, osteo-arthritis and ankylosing spondylitis (chronic inflammation of the spine and sacroiliac joints).
- pain and inflammation after trauma or an operation.
- symptoms of painful menstrual periods.

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.

BEFORE TAKING THIS MEDICINE:

Please read this leaflet before you take your DICLOFENAC. It gives you important information about your tablets. Please keep this leaflet safe. You may want to read it again. If you have any questions or if you are not sure about anything, ask your doctor or pharmacist.

Do not take this medicine if you:

- 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.
- have ever had an allergic reaction to DICLOFENAC or to any other non-steroidal anti-inflammatory medicine.
- are allergic to any of the ingredients of DICLOFENAC.

DICLOFENAC should also not be in used in patients who:

- 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.

DICLOFENAC should be used with caution in patients who:

- have cardio-vascular disease.
- have blood disorders.
- have asthma or broncho-constriction.
- have impaired liver or kidney function.
- are being treated with coumarin anti-coagulants.
- are elderly.

DICLOFENAC reaction with Eosinophillia (a condition of having an increased numbers of white blood cells in the blood) and Systemic Symptoms (DRESS) has been reported in patients. Some of these reactions have been fatal or life-threatening. DRESS typically, although not exclusively, has symptoms such as fever, rash, lymphadenopathy (enlarged lymph nodes), and/or facial swelling. Other symptoms may include hepatitis (inflammation of the liver), nephritis (inflammation of the kidneys), haematological abnormalities (abnormalities in the blood), myocarditis (an inflammation of the heart muscle), or myositis (inflammation of the muscles that you use to move your body). Because this disorder is changeable, other organs not noted here may be involved. It is important to note that early signs of hypersensitivity, such as fever or lymphadenopathy (enlarged lymph nodes), may be present even though rash is not noticeable. If such signs or symptoms are present, discontinue DICLOFENAC and consult your doctor, pharmacist or other health care professional for advice.

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; a medicine 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.

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

HOW TO TAKE THIS MEDICINE:

The tablets must be swallowed with water, with or directly after a meal.

DICLOFENAC 25 mg and 50 mg Tablets:

Treatment of adults:

Your treatment will normally be one (25 mg or 50 mg) tablet three times per day, depending on the severity of your condition.

Treatment of children:

Your treatment will be determined based on your body mass, 2 mg per kilogram body mass daily will normally be prescribed.

DICLOFENAC Injection:

The Diclofenac injection will be given to you by a health 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.

In the event of an over-dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital of poison control centre. Show the pack to the doctor.

Do not share medicines prescribed for you with others.

SIDE EFFECTS:

Most people take this medicine without many side effects, but all medicine can cause some side effects.

Stop taking DICLOFENAC 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
- itchy skin rash
- a high temperature with a sore throat and other flu-like symptoms
- black or bloody stools
- blood in the urine

These may be signs of an allergic reaction to DICLOFENAC and you should contact your doctor immediately.

Other side effects that may occur:

Contact your doctor if they continue or become troublesome:

- dizziness
- skin rash and itchiness
- headache
- stomach pain
- heartburn
- nausea and vomiting
- diarrhoea
- swelling
- trouble sleeping
- drowsiness
- nervousness
- depression
- irritability and agitation
- general feeling of being unwell
- disturbance in vision
- ringing or buzzing in the ears
- palpitations
- if you were given the injection, the site of the injection may become irritated

- if you are going for blood tests while taking DICLOFENAC, inform the health professional of the fact that you are being treated with DICLOFENAC as it may influence the blood tests.

- DICLOFENAC reaction with Eosinophillia, a condition of having an increased numbers of white blood cells in the blood and Systemic Symptoms (DRESS) which can cause symptoms such as fever, rash, lymphadenopathy (enlarged lymph nodes), and/or facial swelling. Other symptoms may include hepatitis (inflammation of the liver), nephritis (inflammation of the kidneys), haematological abnormalities (abnormalities in the blood), myocarditis (an inflammation of the heart muscle), or myositis (inflammation of the muscles that you use to move your body) [see 'Do not take this medicine').

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION

- Store your tablets in a dry place below 25 ºC.
- Store the injection ampoules in a place protected from heat or light. Do not refrigerate the ampoules.
- Do not take the tablets after the expiry date printed on the packet.
- 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
- These tablets are for you. Please do not give them to anyone else, even if they have the same symptoms as you.

PRESENTATION

Tablets:

25 mg tablets: Blister Packs or Securitainers of 100 or 500 tablets.

50 mg tablets: Blister pack of 21 tablets or Securitainers with 500 tablets.

Injections: Amber glass ampoules in packs of 5 or 50.

IDENTIFICATION OF THE MEDICINE:

Tablets:

25 mg tablets: Yellowish-mustard enteric-coated tablet.

50 mg tablets: Light brown enteric-coated tablet.

Injection: A clear, colourless to slightly amber solution in amber ampoules.

REGISTRATION NUMBERS:

MYLAN DICLOFENAC 25 mg tablets: Y/3.1/148

MYLAN DICLOFENAC 50 mg: tablets: Y/3.1/149

MYLAN DICLOFENAC Injection: Z/3.1/265

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Mylan (Pty) Ltd

4 Brewery Street

Isando

1600

Republic of South Africa

THE DATE OF PUBLICATION OF THE PATIENT INFORMATION

LEAFLET: To be allocated.