PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before taking DICLOFENAC 50 OETHMAAN tablets.

- Keep this leaflet. You may need to read it again.
- If you have any 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 yours.

Scheduling Status: S3

Except when intended for the emergency treatment of acute gout attacks and when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. **S2**

Proprietary name, Strength and Pharmaceutical Form:

DICLOFENAC 50 OETHMAAN: Each enteric coated tablet contains diclofenac sodium 50 mg.

1. WHAT DICLOFENAC 50 OETHMAAN CONTAINS:

Active ingredient: Diclofenac sodium

Inactive ingredients: Colloidal silicon dioxide, microcrystalline cellulose, lactose, maize starch, sodium starch glycolate, povidone K30, magnesium stearate, coating containing hydroxypropylmethyl cellulose, talc, polyethylene glycol, iron oxide red (CI number 77492), iron oxide yellow (CI number 77492), titanium dioxide (CI number 77891), methacrylic acid and ethyl acrylate copolymer, colloidal anhydrous silica, sodium bicarbonate, sodium lauryl sulfate.

2. WHAT DICLOFENAC 50 OETHMAAN IS USED FOR:

DICLOFENAC 50 OETHMAAN belongs to a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs), which are used to treat pain and inflammation.

DICLOFENAC 50 OETHMAAN is indicated for the treatment of:

- Painful musculoskeletal conditions.
- Rheumatism.
- Acute attacks of gout.
- Inflammation, pain and swelling after operations.
- Pain following dental surgery.
- Flare-up of osteoarthrosis (disease that causes painful joints).
- Symptomatic treatment of menstrual pain.
- Classical migraine headaches.

3. BEFORE YOU TAKE DICLOFENAC 50 OETHMAAN:

Do not take DICLOFENAC 50 OETHMAAN:

- If you are hypersensitive (allergic) to DICLOFENAC 50 OETHMAAN or any of the other ingredients (see “WHAT DICLOFENAC 50 OETHMAAN CONTAINS”).
- If you have ever had an allergic reaction after taking medicines to treat inflammation or pain (including aspirin, diclofenac, ibuprofen or any other NSAIDs). Reactions may include asthma, runny nose, skin rash, face swelling.
- If you suffer from a stomach or intestinal ulcer.
- If you have gastrointestinal bleeding, symptoms of which may include blood in your stools or black stools.
- If you suffer from severe kidney or liver disease.
- If you suffer from severe heart failure.
- If you suffer from asthma and have the tendency to develop asthma attacks, skin rash or cold symptoms when using aspirin of any other anti-inflammatory medication.

- If you are pregnant or breast feeding your baby (see “Pregnancy and breast-feeding”).
- Porphyria

Take special care with DICLOFENAC 50 OETHMAAN:

Tell your doctor:

- If you are taking DICLOFENAC 50 OETHMAAN simultaneously with other anti-inflammatory medicines including aspirin, corticosteroids, “blood thinners” or certain antidepressants (selective serotonin reuptake inhibitors).
- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you have ever had 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.
- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn’s disease).
- If you have or have had heart problems or high blood pressure.
- If you have liver or kidney problems.
- If you could be dehydrated (e.g. by sickness, diarrhoea, before or after major surgery).
- If you have swollen feet.
- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.

DICLOFENAC 50 OETHMAAN may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the infection more difficult to detect and to treat adequately. If you feel unwell and need to see a doctor, remember to mention that you are taking DICLOFENAC 50 OETHMAAN.

In very rare cases DICLOFENAC 50 OETHMAAN may cause severe allergic skin reactions (e.g. rash). Therefore, inform your doctor immediately if you experience such reaction.

Elderly patients may be more sensitive to the effects of DICLOFENAC 50 OETHMAAN than other adults. Therefore, they should take the minimum number of tablets that provides relief of symptoms. It is especially important for elderly patients to report undesirable effects promptly to their doctor.

Taking DICLOFENAC 50 OETHMAAN with food or drink:

These tablets should preferably be taken with food.

Pregnancy and breast-feeding:

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice. The use of DICLOFENAC 50 OETHMAAN during pregnancy and breast-feeding has not been proven.

DICLOFENAC 50 OETHMAAN may make it more difficult to become pregnant. Unless necessary, you should not take DICLOFENAC 50 OETHMAAN if you are planning to become pregnant or if you have problems to become pregnant.

Driving and using machinery:

In rare cases patients using DICLOFENAC 50 OETHMAAN may experience side effects such as vision disorders, dizziness or drowsiness. If you notice such effects, you should not drive, use machines or carry out other activities that need careful attention**.**

Using other medicines with DICLOFENAC 50 OETHMAAN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of DICLOFENAC 50 OETHMAAN with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

Concurrent use of DICLOFENAC 50 OETHMAAN with the following agents can have unwanted interactions:

- Methotrexate, used in the treatment of cancer, psoriasis and leukaemia.
- Lithium (psychotic agent) and digoxin (heart medication).
- Glucocorticoids (medicines used to provide relief for inflamed areas of the body) and other anti-inflammatory medication such as aspirin or ibuprofen.
- Medicines used to treat diabetes, except insulin.
- Blood thinning tablets, e.g. warfarin.

- Cyclosporin (a medicine primarily used in patients who have received organ transplants).
- Quinolone antibiotics, e.g. ciprofloxacin, ofloxacin, levofloxacin.
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure and heart failure).
- Diuretics.
- Selective serotonin reuptake inhibitors (antidepressants).

4. HOW TO USE DICLOFENAC 50 OETHMAAN:

Always take DICLOFENAC 50 OETHMAAN exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of DICLOFENAC 50 OETHMAAN is too strong or too weak, talk to your doctor or pharmacist.

These tablets should not be crushed, chewed or broken.

Adults:

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

Milder cases: 75 to 100 mg daily in divided doses.

Menstrual pain: 50 to 150 mg daily in divided doses. Dosage should be individually determined. Treatment should be initiated at onset of symptoms and continued for a few days, depending on the intensity of pain.

Classical migraine: 50 mg taken at first signs of an impending attack. If pain relief is not sufficient within 2 hours after the first dose, a second dose of 50 mg may be taken. A third dose may be taken after 4 to 6 hours if necessary but the total daily dose of 150 mg must not be exceeded

The use of DICLOFENAC 50 OETHMAAN in migraine attacks has not been established in children.

If you take more DICLOFENAC 50 OETHMAAN than you should:

In the event of overdosage, consult your doctor or seek help at the nearest hospital or poison control centre.

Treatment is symptomatic and supportive, especially for high blood pressure, renal failure, convulsions, stomach

irritation and shortness of breath.

If you forget to take DICLOFENAC 50 OETHMAAN:

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

5. POSSIBLE SIDE EFFECTS:

DICLOFENAC 50 OETHMAAN can have side effects. 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.

The following side effects occur rarely or very rarely. However, if it occurs, stop taking this medicine and tell your doctor straight away.

- Unusual bleeding or bruising.
- High fever or persistent sore throat.
- Allergic reaction with swelling of the face, lips, mouth, tongue or throat often associated with rash and itching, which may cause difficulty to swallow, hypotension (low blood pressure) and fainting. Wheezing and feeling of tightness in the chest (signs of asthma).
- Chest pain (signs of heart attack).
- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, paralysis.
- Stiff neck.
- Convulsions.
- High blood pressure.
- Red or purple skin, skin rash with blisters, blistering of lips, eyes and mouth, skin inflammation with flaking or peeling.
- Severe stomach pain, bloody or black stools, vomiting blood.
- Yellowing of the skin or eyes.
- Blood in urine, severe decreased urine output.

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.

Common: Headache, diarrhoea, dizziness, heartburn, indigestion, abdominal pain, flatulence, loss of appetite, skin rash, vomiting, nausea.

Rare: Drowsiness, stomach pain, swelling of arms, hands, legs and feet (oedema).

Very rare: Disorientation, difficulty sleeping, psychotic disorder, tingling or numbness of hands or feet, memory impairment, anxiety, trembling, taste disorders, vision or hearing disorders, constipation, irritability, mouth sores, ulcer of the oesophagus, palpitation, hair 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.

6. STORING AND DISPOSING OF DICLOFENAC 50 OETHMAAN:

Store below 25 ºC. Protect from moisture. Keep the blister in the carton until required for use. Keep the containers tightly closed.

KEEP OUT OF REACH OF CHILDREN.

Do not use the tablets after the expiry date printed on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF DICLOFENAC 50 OETHMAAN:

DICLOFENAC 50 OETHMAAN:

Packs of 21, 30 or 100 tablets in amber glass bottles.

Packs of 21, 30, 100 or 500 tablets in securitainers.

Blisters packs of 9, 15, 20, 21, 28, 30, 100 or 500 tablets.

Sealed aluminium bags with 15, 21, 30 or 100 tablets.

8. IDENTIFICATION OF DICLOFENAC 50 OETHMAAN:

DICLOFENAC 50 OETHMAAN: Light brown, round, slightly biconvex, enteric-coated tablet.

9. REGISTRATION NUMBER:

DICLOFENAC 50 OETHMAAN: V/3.1/137

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION

Oethmaan Biosims (Pty) Ltd

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11. DATE OF PUBLICATION:

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