PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

MOTIFINE 75 mg capsules

Diclofenac sodium

Sugar free.

Read all of this leaflet carefully because it contains important information for you:

MOTIFINE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use MOTIFINE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MOTIFINE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet:

1. What MOTIFINE is and what it is used for

MOTIFINE belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). NSAIDs relieves pain and inflammation. MOTIFINE is used for the emergency treatment of acute gout attacks.

2. What you need to know before you TAKE MOTIFINE

Do not take MOTIFINE:

- If you are hypersensitive (allergic) to diclofenac or any of the other ingredients of MOTIFINE (listed in section 6).
- If you are hypersensitive to other anti-inflammatory medication including aspirin.
- If you have severe liver or kidney impairment.
- If you are pregnant or breastfeeding your baby (see “Pregnancy and breastfeeding”).
- If you have heart failure (when the heart is incapable to supply sufficient blood flow to meet the body's needs), established ischaemic heart disease (reduced blood supply to your heart) and/or stroke and peripheral arterial disease (narrowing of the arteries resulting in reduced blood flow to the limbs).
- If you suffer from a gastric or intestinal ulcer.
- If you have a history of gastrointestinal bleeding or perforation (PUBs) related to previous anti-inflammatory medicine use.
- If you suffer from porphyria.
- Children under the age of 12 years.

Warnings and precautions:

Side effects may be minimised by using the lowest effective dose for the shortest duration

necessary.

Talk to your doctor before taking MOTIFINE if you are also taking other non-steroidal anti-inflammatory drugs (NSAIDs), as MOTIFINE should not be used at the same time as other NSAIDs.

Your doctor should be informed if you suffer from any of the following conditions:

- High blood pressure or any other heart disease.
- Any gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia).
- If you suffer from or have a history of bronchial asthma; hay fever or other allergies, polyps in your nose, difficulty breathing (COPD), long term respiratory infections.
- SLE (Systemic Lupus Erythematosus), an inflammation of the connective tissue.
- Blood clotting problems.
- A condition called hepatic porphyria.

MOTIFINE should be discontinued immediately at the first appearance of skin rash, fever, mucosal lesions and any other sign of allergic reaction or hypersensitivity. These may be signs of a very serious condition called drug rash with eosinophilia and systemic symptoms (DRESS) (see section "Possible side effects"). You should also contact your doctor immediately.

If you suffer from impaired kidney function, heart impairment, liver dysfunction, if you are taking diuretics (water tablets), or are elderly, you are at risk of kidney failure. Your renal function should be regulatory monitored while on MOTIFINE treatment.

If stomach bleeding occurs during the treatment of MOTIFINE, the treatment should be discontinued

immediately.

A reduction in dosage may be required in elderly patients. Elderly patients have an increased frequency of adverse reactions to MOTIFINE, especially gastrointestinal bleeding and peptic ulcer bleeding (PUBs) which may be fatal.

Elderly patients are at increased risk of the serious consequences of adverse reactions. If an anti-inflammatory medicine is considered necessary, the lowest effective dose should be used and for the shortest possible duration. You should be monitored regularly for gastrointestinal bleeding during anti-inflammatory medication therapy.

Tell your doctor if you are about to have major surgery.

Because MOTIFINE is a NSAID, it can make the symptoms of an infection (such as fever, pain) less noticeable.

Medicines such as MOTIFINE 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.

If you have heart problems, previously had a stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

The use of methotrexate (used in the treatment of cancer, psoriasis and leukaemia) together with

MOTIFINE should be avoided as it can have serious effects on you.

You should stop taking MOTIFINE if you are trying to become pregnant or have difficulty conceiving, as the use thereof may impair the ability to conceive.

Children and adolescents:

MOTIFINE is not suitable for use in children under the age of 12 years.

Other medicines and MOTIFINE:

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

Concurrent use of MOTIFINE with the following medicines can have unwanted interactions:

- Inflammation reducing steroids and other anti-inflammatory medication (increase the gastrointestinal side effect of MOTIFINE).
- Aspirin will decrease the availability of MOTIFINE.
- MOTIFINE may enhance the effects of blood thinning tablets such as warfarin.
- Medicines belonging to the selective serotonin reuptake inhibitors class, e.g. citalopram, sertraline, fluoxetine.
- The use of MOTIFINE with methotrexate (used in the treatment of cancer, psoriasis and leukaemia) can lead to increased toxicity of methotrexate.
- Diuretics (triamterene); concurrent use can lead to deterioration in renal function.
- Lithium (psychotic medicines) and digoxin (heart medication); blood levels can increase.
- Mifepristone (abortion medication).
- Tacrolimus: increase the risk of kidney toxicity.

- Zidovudine, an antiretroviral medicine; increased risk of haematological toxicity.
- Ciclosporin.
- Quinolone antibiotics, e.g. ciprofloxacin, ofloxacin, levofloxacin.
- Phenytoin (anti-epileptic medicine).
- Colestipol and cholestyramine (cholesterol lowering medicines).
- Sulfinpyrazone (gout medicine) and voriconazole (anti-fungal medicine).
- Antidiabetic medicine.

Taking MOTIFINE with food or drink:

These capsules should preferably be taken with or after food.

Pregnancy and breastfeeding:

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 taking MOTIFINE.

Women who are pregnant or who are breastfeeding their babies, must not take MOTIFINE.

Driving and using machines:

Patients who experience dizziness, drowsiness, fatigue and visual disturbances, vertigo, somnolence or other central nervous system disturbances while taking MOTIFINE, should refrain from driving a vehicle or operating machinery.

3. How to take MOTIFINE

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

Always take MOTIFINE exactly described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

You should use the lowest effective dose for the shortest possible duration of treatment.

The capsules should be swallowed whole with a liberal quantity of liquid.

Adults

One capsule daily. Dose may be increased to two capsules daily if necessary, with a maximum daily dose of 150 mg. The first dose should be taken in the morning with breakfast and the second if required 8 – 12 hours later. The maximum treatment period of 3 days should not be exceeded.

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

If you take more MOTIFINE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Symptoms of an overdose can include: headache, nausea (feeling sick), vomiting, abdominal pain, stomach or intestinal bleeding, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting, or occasionally convulsions (seizures, uncontrolled fits).

If you forget to take MOTIFINE:

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

4. Possible side effects

MOTIFINE can have side effects. Not all side effects reported for MOTIFINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOTIFINE, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking MOTIFINE 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.
- Blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)
- Drug rash with eosinophilia and systemic symptoms (DRESS), which include symptoms such as fever, skin rash, swelling of your lymph nodes and/or face, kidney and liver injury.

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

- Sudden and crushing chest pain (signs of myocardial infarction, heart attack or Kounis syndrome).
- Heart disorders, including heart attack or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day) for a long period of time.

- Fast or irregular heartbeat (palpitations).
- Sudden weakness or numbness in the face, arm or leg especially on one side of the body, sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke.
- High blood pressure (hypertension), low blood pressure, symptoms of which may include faintness, giddiness or light headedness (hypotension).
- Lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease).
- Inflammation of the pancreas (pancreatitis).
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick) as you may be experiencing ischemic colitis.
- Diarrhoea containing blood or rectal bleeding (haemorrhagic diarrhoea).
- Any sign of ulcers or bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit (haematemesis) or black, tarry faeces (melaena), vomiting of blood.
- Liver disorders (yellowing of the skin or eyes).
- Kidney problems (water retention, problems urinating i.e passing water) presence of blood or protein in the urine, an unexpected change in the amount of urine produced and/or its appearance.
- Breathlessness, coughing and a tightness across the chest (asthma).
- Inflammation of the lung (pneumonitis).
- Inflammation of blood vessels (vasculitis).
- Inflammation of the lining of the brain with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation (meningitis).

- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with MOTIFINE and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain.
- If you notice that 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.

Tell your doctor if you notice any of the following:

Frequent side effects

- Flatulence, constipation, inflammation of the lining of the stomach.
- Headache, dizziness, vertigo, nervousness.

Less frequent side effects

- Disturbance of taste, vision, hearing or sensation.
- Anxiety, confusion, depression or trembling.
- Hair loss (temporary).
- Blood disorders (your blood may not clot easily, or bruises may appear).
- Increased sensitivity to sunlight (i.e. burn more easily or exposure to light causes itching.
- If you have hallucinations (seeing or hearing something that does not exist).

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. You can also report side effects to SAHPRA via the "**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 MOTIFINE.

5. How to store MOTIFINE

- Store at or below 25 °C. Protect from moisture
- The capsules should be stored in the blister strips until required for use
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the capsules 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)

6. Contents of the pack and other information

What MOTIFINE contains

The active ingredient is diclofenac sodium.

Each capsule contains 75 mg diclofenac sodium (25 mg as enteric coated pellets and 50 mg as sustained release pellets).

The other ingredients are:

Enteric coated pellets: colloidal anhydrous silica, methacrylic acid copolymer type C, microcrystalline cellulose, povidone K25, propylene glycol, talc.

Sustained release pellets: colloidal anhydrous silica, microcrystalline cellulose, poly (ethyl acrylate, methyl methacrylate, trimethylamonio, ethyl methacrylate chloride), povidone K25, triethylcitrate, talc.

Capsule shell: gelatine. indigocarmine E132, titanium dioxide E171.

Capsule body: gelatine, ink: containing shellac, soy lecithin, antifoam DC1510, titanium dioxide E171.

What MOTIFINE looks like and contents of the pack

Hard gelatine capsules (size 2) with light blue opaque cap and colourless transparent body marked in white print “D75M”.

The capsules are blister packed in white opaque PVC/PVDC and silver aluminium foil and packed into outer cardboard cartons. Pack size: 6 capsules.

Holder of certificate of registration and manufacturer

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