PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

NAPROXEN 250 UNIMED tablets

NAPROXEN 500 UNIMED tablets

Naproxen

Each NAPROXEN 250 UNIMED tablet contains 40 mg lactose monohydrate

Each NAPROXEN 500 UNIMED tablet contains 80 mg lactose monohydrate

Read all of this leaflet carefully before you start taking NAPROXEN UNIMED

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NAPROXEN UNIMED 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 NAPROXEN UNIMED is and what it is used for

Naproxen, the active ingredient in NAPROXEN UNIMED, belongs to the group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce inflammation and pain in joints and muscles.

NAPROXEN UNIMED is used to give relieve to some of the symptoms (inflammation, swelling, stiffness and joint pain) of diseases of the joints such as rheumatoid arthritis, osteoarthritis and ankylosing spondylitis (form of spinal arthritis). NAPROXEN UNIMED is also used to treat acute gout and painful menstruation (dysmenorrhoea). NAPROXEN UNIMED is also used to treat acute musculoskeletal disorders (injuries and disorders that affect the human body's movement or musculoskeletal system (i.e. muscles, tendons, ligaments, nerves, discs, blood vessels) such as sprains and strains, direct trauma, limbrosacral pain (lower back pain), cervical spondylitis (degeneration of the bones and disks in the neck), tenosynovitis (inflammation of the tendon where muscle connects to bone) and fibrositis(inflammation of white fibrous tissue).

2. What you need to know before you take NAPROXEN UNIMED

Do not take NAPROXEN UNIMED:

- If you are hypersensitive (allergic) to naproxen, naproxen sodium, aspirin, other non-steroidal anti-inflammatory agents or any of the other ingredients of NAPROXEN UNIMED (listed in section 6).
- If you are hypersensitive (allergic) to aspirin, other non-steroidal anti-inflammatory medicines (such as ibuprofen). If these medicines have given you asthma, a runny nose, sac-like growths of inflamed tissue lining of your nose or sinuses or skin hives.
- You may also experience severe allergic reaction with NAPROXEN UNIMED, which can be fatal.
- If you are pregnant or breastfeeding your baby.
- If you have severe heart problems.
- If you have severe kidney problems.
- If you have previously experienced bleeding or perforation in your stomach while taking non-steroidal anti-inflammatory medicines.
- If you have now or have ever had any problems with your stomach or gut (intestine) like an ulcer or any bleeding.

- If you have porphyria.
- If you are a child under the age of 16 years.

Warnings and precautions

Special care should be taken with NAPROXEN UNIMED:

- If you have heart problems, previous 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
- Medicines such as NAPROXEN UNIMED 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 a history of stomach problems such as ulcerative colitis or Crohn's disease (conditions
- causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss), heart burn or reflux as the condition can be made worse by the use of NAPROXEN UNIMED.
- If you have a liver/kidney disease or your liver/kidney is not working properly.
- If you are an elderly patient (as you will be more likely to experience side effects with NAPROXEN UNIMED especially bleeding and perforation of the gut).
- If you have or have had bronchial asthma, or other breathing problems or nasal polyps.
- If you have systemic lupus erythematosus.
- If you develop any skin rash or other sign of hypersensitivity. You should then immediately stop taking NAPROXEN UNIMED.
- If f you develop 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)).
- If you are planning to become pregnant.
- If you might have a bleeding problem or problem relating to blood clotting, or you have a blood clotting disorder.
- If you develop visual disturbances, you should get an eye examination.

- If you need any blood or urine tests tell your doctor you are taking NAPROXEN UNIMED tablets. The tablets may need to be stopped 48 hours before a test, as they may interfere with the results.
- Taking a painkiller for headaches too often or for too long can make them worse.
- If you are 20 weeks or later pregnant, the use of NAPROXEN UNIMED can cause serious kidney problems in the unborn baby.
- If you are taking NOVACAM for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Children

Do not give NAPROXEN UNIMED to children under the age of 16 years.

Other medicines and NAPROXEN UNIMED

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

- hydantoins (medicines used to treat epilepsy e.g. phenytoin): effect will be stronger
- sulfonamides (like hydrochlorothiazide, acetazolamide, indapamide and sulfonamide antibiotics used to treat infections e.g. sulfamethoxazole): effect will be stronger
- sulphonylurea antidiabetics such as glimepiride or glipizide: effect might be stronger
- other NSAIDs including cyclooxygenase-2 inhibitors (medicine such as aspirin, ibuprofen or indomethacin): increased risk of side effects
- antihypertensive medicines (medicine used to lower blood pressure): the anti-hypertensive effect can be reduced
- betablockers: may increase the risk of renal impairment associated with the use of ACE inhibitors or angiotensin II receptor antagonists
- probenecid for gout: increases naproxen plasma levels
- methotrexate (medicine for the treatment of skin problems, cancer or to treat auto-immune diseases): decrease the elimination and increase toxicity
- diuretics (furosemide): the renal sodium and water excretion effect can be inhibited

- cardiac glycosides (medicine used to treat heart failure and certain irregular heartbeats such as digoxin): may exacerbate cardiac failure
- ciclosporin (medicine that suppress the immune system used after organ transplant): increased risk of nephrotoxicity (rapid deterioration in the kidney function due to toxic effect of medications)
- mifepristone (medicine used to end pregnancy): NSAIDs can reduce the effect of the mifepristone
- corticosteroids (such as hydrocortisone, prednisolone and dexamethasone): increased risk of gastrointestinal ulceration or bleeding
- other NSAIDs including cyclooxygenase-2 inhibitors (medicine such as aspirin, ibuprofen or indomethacin): increase risk of side effects
- aspirin/acetylsalicylic acid to prevent blood clots: inhibits platelet activity
- medicines which thin the blood, or which prevent blood clotting (e.g. heparin or warfarin): may enhance the effect
- quinolone antibiotics (such as ciprofloxacin, moxifloxacin, norfloxacin, gatifloxacin or levofloxacin to treat bacterial infections): increase risk of convulsions (seizures)
- anti-platelet medicines (medicine such as clopidogrel or prasugrel): increased risk of gastrointestinal bleeding
- antidepressants that are known as selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine and paroxetine: increased risk of gastrointestinal bleeding
- tacrolimus (an immunosuppressive medicine used mainly in organ transplants): increased risk of nephrotoxicity (rapid deterioration in the kidney function due to toxic effect of medications)
- zidovudine (medicine used to treat AIDS/HIV infections): increased risk of haematological toxicity
- bisphosphonates (medicines that prevent the loss of bone density, used to treat osteoporosis): increase the risk of gastric mucosal damage
- antacids used for heartburn or cholestyramine used to bind bile in the stomach: can delay the absorption of NAPROXEN UNIMED. NAPROXEN UNIMED should be taken at least one hour before or four to six hours 372 after cholestyramine.
- lithium (medicine for depression): increases in plasma lithium concentrations

NAPROXEN UNIMED with food and alcohol

NAPROXEN UNIMED should be taken with food.

Pregnancy, breastfeeding and fertility

You should not take NAPROXEN UNIMED while pregnant.

Do not use NAPROXEN UNIMED if you are breastfeeding your baby.

NAPROXEN UNIMED may make it more difficult to become pregnant.

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 health care provider for advice before taking NAPROXEN UNIMED.

Driving and using machinery

NAPROXEN UNIMED may make you feel dizzy, drowsy or tired and may cause blurred vision. Make sure you are not affected before you drive or operate machinery.

It is not always possible to predict to what extent NAPROXEN UNIMED 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 NAPROXEN UNIMED affects them.

NAPROXEN UNIMED contain lactose

NAPROXEN UNIMED contains lactose. You should not take NAPROXEN UNIMED if you have a rare hereditary condition of lactose or galactose intolerance.

3. How to take NAPROXEN UNIMED

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

Always take NAPROXEN UNIMED exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with NAPROXEN UNIMED will last. Do not stop treatment early. If you have the impression that the effect of NAPROXEN UNIMED is too strong or too weak, tell your doctor or pharmacist.

Swallow the tablet with a little water, with or after food.

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

Adults:

For rheumatoid arthritis, osteoarthrosis and ankylosing spondylitis, the starting dose and usual maintenance dose is in the range of 500 mg to 1000 mg per day taken in two doses at twelve-hour intervals.

In the following cases a dose of 750 mg to 1000 mg per day for the acute phase is recommended:

a) in patients reporting severe night-time pain and/or morning stiffness;

b) in patients being switched to NAPROXEN UNIMED from a high dose of another antirheumatic compound and,

c) in osteoarthrosis where pain is the predominant symptom.

For the patient who requires 750 mg per day whose night-time pain and/or morning stiffness are most troublesome, 500 mg should be taken upon retiring and 250 mg upon awakening. For the patient whose day-time pain and reduced mobility are most troublesome, 500 mg should be taken upon awakening and 250 mg upon retiring.

In acute gout, the recommended dosage is 750 mg at once, then 250 mg every eight hours until the attack has passed.

For the treatment of acute musculo-skeletal disorders, the recommended dosage is 250 mg twice or thrice daily, most patients will require only 7 days treatment, but some patients may require up to 14 days.

In dysmenorrhoea, the recommended regime is 500 mg initially, followed by 250 mg every six to eight hours.

Children:

For juvenile arthritis in children over 5 years of age the usual dosage is 10 mg per kg body- mass per day in two doses at twelve-hour intervals.

NAPROXEN UNIMED is not recommended for use in other indications in children under sixteen years of age.

If you take more NAPROXEN UNIMED than you should

Symptoms

Symptoms of overdose are headache, feeling or being sick, heartburn, diarrhoea, disorientation, bleeding of the stomach or intestines, unconsciousness, drowsiness, dizziness, ringing or buzzing in the ears, fainting, fits and excitation.

Treatment

Patients should be treated symptomatically.

Activated charcoal should be given within one hour after taking a potentially toxic amount of NAPROXEN UNIMED.

Gastric lavage should be considered within one hour after taking a potentially life-threatening overdose of NAPROXEN UNIMED.

Good urine output should be ensured.

Renal and liver function should be closely monitored.

Patients should be checked for at least four hours after taking a potentially toxic amounts of NAPROXEN UNIMED.

Frequent or prolonged convulsions should be treated with intravenous diazepam.

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

If you forget to take NAPROXEN UNIMED

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

NAPROXEN UNIMED can have side effects.

Not all side effects reported for NAPROXEN UNIMED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NAPROXEN UNIMED, please consult your health care provider for advice.

If any of the following happens, stop taking NAPROXEN UNIMED 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.

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

- haemolytic anaemia (red blood cells are destroyed faster than they can be made).
- granulocytopenia (low number of granulocytes, a type of white blood cells).
- thrombocytopenia (blood platelets deficiency that causes bleeding into tissues and slow blood clotting after injury).
- agranulocytosis (agranulocytes deficiency (type of white blood cells)).
- leukopenia (a reduction in the number of white cells in the blood, typical of various diseases.)
- neutropenia (abnormal number of neutrophils in the blood)
- eosinophilia (an increase in the number of eosinophils in the blood, occurring in response to some allergens, drugs, and parasites, and in some types of leukaemia).
- anaemias (a condition in which there is a deficiency of red cells or of haemoglobin in the blood, resulting in pallor and weariness)
- aplastic anaemia (deficiency of all types of blood cell caused by failure of bone marrow development)
- hyperkalaemia (high potassium levels in your blood)
- convulsions
- aseptic meningitis (inflammation of the linings of the brain)
- worsen of Parkinson’s disease
- palpitations (rapid, strong and irregular heartbeat)

- cardiac failure (Swelling of your hands, feet or legs (oedema), this may include chest pain, tiredness, shortness of breath)
- angioneurotic oedema
- congestive heart failure (chronic progressive condition that affects the pumping power of your heart muscle)
- pericarditis (inflammation of the pericardium, a sac-like structure with two thin layers of tissue that surround the heart)
- inflammation of the blood vessels (vasculitis)
- high blood pressure (hypertension)
- heart attack or stroke due to blood clot that blocks an artery (arterial thrombotic events e.g. myocardial infarction or stroke)
- asthma worsened
- high number of eosinophils (type of white blood cells) (eosinophilic)
- inflammation of the walls of the alveoli in the lungs (pneumonitis)
- difficulty in breathing (dyspnoea)
- spasm of the bronchial smooth muscle (bronchospasm)
- excess fluid in the lungs (pulmonary oedema)
- lesion in the lining (mucosa) of the digestive tract, typically in the stomach or duodenum, caused by the digestive action of pepsin and stomach acid (peptic ulcers)
- holes forming in your stomach or gut (perforation) that leads to bleeding in the gastrointestinal tract.
- worsening of ulcerative colitis or Crohn’s disease, leading to pain, diarrhoea, vomiting and weight loss.
- inflammation of the liver (hepatitis)
- rare, serious disorder of the skin and mucous membranes. It's usually a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters (stevens Johnsons syndrome)
- potentially life-threatening dermatologic disorder characterized by widespread erythema, necrosis, and bullous detachment of the epidermis and mucous membranes (toxic epidermal necrosis)
- skin disorders that cause the skin to become very fragile. Any trauma or friction to the skin can cause painful blisters (epidermolysis bullosa)

- inflammation of the tiny filters in your kidneys (glomerular nephritis)
- kidney disorder in which the spaces between the kidney tubules become swollen (interstitial nephritis)
- kidney disease, especially when characterized by oedema and the loss of protein from the plasma into the urine due to increased glomerular permeability (nephritic syndrome)
- disorder of the kidneys in which all or part of the renal papillae die. The renal papillae are the areas where the openings of the collecting ducts enter the kidney and where urine flows into the ureter (renal papillary necrosis)
- Impairment of renal functions, renal disease and renal failure

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:

- confusion
- dizziness
- drowsiness
- headache
- light-headedness
- visual disturbances
- changes to your hearing, which can include ringing in the ears (tinnitus)
- swelling caused by the accumulation of fluid in a part of the body (oedema)
- ecchymoses (a discoloration of the skin resulting from bleeding underneath, typically caused by bruising)
- severe itching of the skin (pruritis)
- a rash of purple spots on the skin caused by internal bleeding from small blood vessels (purpura)
- skin eruptions
- sweating
- extreme tiredness (fatigue)

Less frequent side effects:

- depression

- has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life (cognitive dysfunction)
- trouble falling or staying asleep (insomnia)
- loss of concentration
- abnormal dreams
- hearing impairment
- inflammation of the pancreas (pancreatitis)
- yellowing of the skin and white of the eyes, pale coloured stools (jaundice)
- muscle weakness
- blood in the urine (haematuria)
- skin immune reaction that an infection or medication can trigger (erythema multiforme)
- a rash of round, red welts on the skin that itch intensely, sometimes with dangerous swelling, caused by an allergic reaction, typically to specific foods (urticaria)
- partial or complete absence of hair from areas of the body where it normally grows (alopecia)
- photosensitivity reaction including cases of porphyria cutanea tarda (a rare disorder characterized by painful, blistering skin lesions that develop on sun-exposed skin)
- unexplained vaginal bleeding and/or heavy menstrual bleeding

Side effects with unknown frequency:

- laryngeal oedema (abnormal accumulation of fluid in tissues of any part of the larynx)
- serum sickness-like reaction (an acute inflammatory condition affecting children and adults characterised by the development of erythematous skin lesions and joint swelling with or without fever)
- lymphadenopathy (a disease affecting the lymph nodes)
- aspirin hypersensitivity (harmful reaction to aspirin. Reactions include breathing, nasal/sinus and skin problems)
- hallucinations
- malaise (a general feeling of discomfort and illness)
- nervousness
- headache

- vertigo (loss of balance)
- abnormal feeling of pins and needles (paraesthesia)
- blurred vision
- corneal opacity (eye problems that can lead to scarring or clouding of the cornea, which decreases vision)
- papillitis (inflammation and deterioration of the portion of the optic nerve known as the optic disk)
- retrobulbar (abscess behind the eyeball)
- swelling and inflammation to the optic nerve (optical neuritis)
- increased pressure in or around the brain causes the part of the optic nerve inside the eye to swell (papilloedema)
- inflammation of the mucous membrane of the nose (rhinitis)
- haemoptysis (the coughing up of blood)
- feel a need to drink something (thirst)
- nausea
- vomiting
- diarrhoea
- accumulation of gas (flatulence)
- constipation
- difficulty in digesting of food with symptoms tant my include pain or discomfort, bloating, feeling of fullness (dyspepsia)
- abdominal pain
- dark sticky faeces containing partly digested blood (melaena)
- vomiting of blood (haematemesis)
- painful sores in the mouth (ulcerative stomatitis)
- colitis (inflammation of the lining of the colon)
- inflammation of the lining of the stomach (gastritis)
- oesophagitis (inflammation of the oesophagus)
- non-peptic gastrointestinal ulceration
- abdominal discomfort
- abnormal liver functions

- erythema nodosum (skin inflammation that is located in a part of the fatty layer of skin)
- fixed drug eruption (is an eruption that is characterized by its round shape)
- inflammatory disorder that appears as purplish, flat-topped bumps when it affects the skin (lichen planus)
- pustular reaction (when environmental allergens) your skin become inflamed as a result of an allergic reaction to food
- Systemic lupus erythematosus (SLE) (long-term condition that can cause inflammation in the skin, organs, and in various other places in the body)
- swelling beneath your skin (angio-oedema)
- redness and peeling of the skin over large areas of the body (exfoliative and bullous dermatoses)
- 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))
- increased potassium in the blood
- increase in creatinine in the blood and fluid retention
- woman who had unsuccessfully tried to conceive a baby for over a year (impaired female fertility)
- swelling of the lower legs and hands (mild peripheral oedema)
- fever

NAPROXEN UNIMED, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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, 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 NAPROXEN UNIMED.

5. How to store NAPROXEN UNIMED

- Store all medicines out of reach of children
- Store at or below 25 °C
- Protect from light
- Store in the original container.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NAPROXEN UNIMED contains

The active substance is naproxen.

The other ingredients are lactose monohydrate, starch, sodium starch glycolate, pregelatinised starch, purified talc, magnesium stearate, quinolone yellow and purified water.

What NAPROXEN UNIMED looks like and contents of the pack

NAPROXEN 250 UNIMED: Yellow, flat bevel-edged, scored tablets.

NAPROXEN 500 UNIMED: Yellow, biconvex scored tablets.

NAPROXEN 250 UNIMED: Securitainers containing 30, 100, 250 and 500 tablets.

NAPROXEN 500 UNIMED: Securitainers containing 10, 30, 100, 250 and 500 tablets.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

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