BIO-NAPROXEN

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

BIO-NAPROXEN 250 tablets
BIO-NAPROXEN 500 tablets
Naproxen
Contains sugar (lactose)
BIO-NAPROXEN 250 contains 78,40 mg and BIO-NAPROXEN 500 contains 156,80 mg lactose per tablet

Read all of this leaflet carefully before you start taking BIO-NAPROXEN
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BIO-NAPROXEN 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 BIO-NAPROXEN is and what it is used for

Naproxen, the active ingredient in BIO-NAPROXEN 250 and BIO-NAPROXEN 500, 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.

BIO-NAPROXEN 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).
BIO-NAPROXEN is also used to treat acute gout, mild to moderate pain associated painful periods, inflammation in shoulder joint (bursitis) and inflammation of a tendon (tendonitis).

2. What you need to know before you take BIO-NAPROXEN

Do not take BIO-NAPROXEN:
- If you are hypersensitive (allergic) to naproxen, naproxen sodium, aspirin, other non-steroidal anti-inflammatory agents or any of the other ingredients of BIO-NAPROXEN (listed in section 6).
- If you are hypersensitive (allergic) to aspirin, other non-steroidal anti-inflammatory medicines or any other pain relief medicines (such as ibuprofen and diclofenac). 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 BIO-NAPROXEN, 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 NSAIDs.
- 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 BIO-NAPROXEN:
If you are taking BIO-NAPROXEN 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 stomach/ gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).
- 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 BIO-NAPROXEN 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 BIO-NAPROXEN.
- you have a liver/ kidney disease or your liver/kidney is not working properly
- If you have a blood clotting disorder.
- If you are an elderly patient (as you will be more likely to experience side effects with BIO-NAPROXEN 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 BIO-NAPROXEN.
- if 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
- Naproxen tablets may hide the symptoms of an infection.
- If you need any blood or urine tests tell your doctor you are taking BIO-NAPROXEN 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 BIO-NAPROXEN can cause serious kidney problems in the unborn baby

Children
Do not give BIO-NAPROXEN to children under the age of 16 years.

Other medicines and BIO-NAPROXEN
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).
- hydantoins (e.g., phenytoin),
- sulfonamides (e.g., sulfamethoxazole)
- Sulphonylurea antidiabetics such as glimepiride or glipizide
- medicines which thin the blood, or which prevent blood clotting (e.g., heparin or warfarin)
- lithium (medicine for depression)
- diuretics (furosemide) and antihypertensive medicines (medicine used to lower blood pressure)
- probenecid for gout.
- methotrexate (medicine for the treatment of skin problems, cancer or to treat auto-immune diseases)
- cardiac glycosides (medicine used to treat heart failure and certain irregular heartbeats such as digoxin.)
- ciclosporin (medicine that suppress the immune system used after organ transplant)
- mifepristone (medicine used to end pregnancy)
- corticosteroids (such as hydrocortisone, prednisolone and dexamethasone.), if needed the doctor will reduce the dose of the steroid slowly and monitor for side effects
- other NSAIDs including cyclooxygenase-2 inhibitors (medicine such as aspirin, ibuprofen or indomethacin)
- quinolone antibiotics (such as ciprofloxacin, moxifloxacin, norfloxacin, gatifloxacin or levofloxacin to treat bacterial infections)
- anti-platelet medicines (medicine such as aspirin, clopidogrel or prasugrel)
- antidepressants that are known as selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine and paroxetine
- tacrolimus (an immunosuppressive drug used mainly in organ transplants)
- Zidovudine
- bisphosphonates
- Antacids used for heartburn or cholestyramine used to bind bile in the stomach.
- aspirin/ acetylsalicylic acid to prevent blood clots

BIO-NAPROXEN with food and alcohol
BIO-NAPROXEN should be taken with food.

Pregnancy, breastfeeding and fertility
You should not take BIO-NAPROXEN in the first 6 months of pregnancy and must not take BIO-NAPROXEN in the last 3 months of pregnancy or during labour.
Do not use BIO-NAPROXEN if you are breastfeeding your baby.
BIO-NAPROXEN 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 healthcare provider for advice before taking BIO-NAPROXEN.

Driving and using machinery:
BIO-NAPROXEN 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 BIO-NAPROXEN 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 BIO-NAPROXEN affects them.

BIO-NAPROXEN contain lactose:
BIO-NAPROXEN contains lactose. You should not take BIO-NAPROXEN if you have a rare hereditary condition of lactose or galactose intolerance.

3. How to take BIO-NAPROXEN

Do not share medicines prescribed for you with any other person.
Always take BIO-NAPROXEN 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 BIO-NAPROXEN will last. Do not stop treatment early. If you have the impression that the effect of BIO-NAPROXEN is too strong or too weak, tell your doctor or pharmacist.
BIO-NAPROXEN should not be used in children under the age of 16 years.

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
Arthritis and ankylosing spondylitis (pain and stiffness in the neck and back): 250 mg (one tablet) to 375 mg (one and a half tablets) taken twice daily, with food.
Acute gout: An initial dose of 750 mg (three tablets) with meals, followed by 250 mg (one tablet) every 8 hours until the attack has subsided.
Muscle, joint or tendon problems and period pain: An initial dose of 500 mg (two tablets) followed by 250 mg (one tablet) every 6 to 8 hours with food.

If you take more BIO-NAPROXEN 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 BIO-NAPROXEN.
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 BIO-NAPROXEN.
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 BIO-NAPROXEN
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

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

If any of the following happens, stop taking BIO-NAPROXEN 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 ore breathing,
- rash or itching,
- fainting.
- BIO-NAPROXEN, 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. This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

These are all very serious side effects. If you have them, you may have had a serious reaction to BIO-NAPROXEN. 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).
- granulocyctopenia (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)
- damage to your liver
- 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
- 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 pain
- 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 characterised by painful, blistering skin lesions that develop on sun-exposed skin)
- Unexplained vaginal bleeding and/or heavy menstrual bleeding
- increased potassium in the blood

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 your skin becomes inflamed as a result of an allergic reaction to food, environmental allergens)
- 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

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 BIO-NAPROXEN.

5. How to store BIO-NAPROXEN

- 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 BIO-NAPROXEN contains
The active substance is naproxen.
The other ingredients are lactose, preglatinised starch, sodium starch glycolate, quinoline yellow lake 19248, polysorbate 80, povidone, purified talc, magnesium stearate and purified water.

What BIO-NAPROXEN looks like and contents of the pack
BIO-NAPROXEN 250: Round yellow biconvex tablets with score line on one side and plain on other side.
BIO-NAPROXEN 500: Yellow, capsule-shaped, biconvex tablet coded with NPX 500 on one side and break line on reverse.

BIO-NAPROXEN 250 and BIO-NAPROXEN 500 can be packed in the following containers:
White opaque, polypropylene securitainer containing 30 and 250 tablets.
Screw cap white, opaque HDPE container containing 30 and 250 tablets.
Amber PVC/PVDC blister containing 56 or 14 tablets per carton.
White, opaque, polyethylene zip lock patient ready pack (for state use only), containing 28 or 56 tablets.

Holder of Certificate of Registration
BIOTECH LABORATORIES (PTY) LTD
Ground Floor, Block K West, Central Park
400 16th Road
Randjespark
Midrand, 1685
Tel. No: (011) 848 3050

This leaflet was last revised in
29 September 2023.

Registration number
BIO-NAPROXEN 250: W/3.1/0436
BIO-NAPROXEN 500: W/3.1/0437

BIO-NAPROXEN

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:
S3

BIO-NAPROXEN 250 tablette
BIO-NAPROXEN 500 tablette
Naproksen
Bevat suiker (laktose)
BIO-NAPROXEN 250 bevat 78,40 mg en BIO-NAPROXEN 500 bevat 156,80 mg laktose per tablet
Bevat suiker (laktose)

Lees die hele pamflet noukeurig deur voordat jy begin om BIO-NAPROXEN te neem
- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy enige verdere vrae het, vra asseblief vir jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- BIO-NAPROXEN is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat BIO-NAPROXEN is en waarvoor dit gebruik word

Naproksen, die aktiewe bestanddeel in BIO-NAPROXEN 250 en BIO-NAPROXEN 500, behoort aan die groep van medisyne genaamd nie-steroïdale anti-inflammatoriese middels (NSAIDs), wat gebruik word om inflammasie en pyn in die gewrigte en spiere te verminder.

BIO-NAPROXEN word gebruik om verligting te gee aan sommige van die simptome (inflammasie, swelling, styfheid en gewrigspyn) van siektes van die gewrigte soos rumatoïede artritis, osteoartritis en ankiloserende spondilitis (vorm van spinale artritis). BIO-NAPROXEN word ook gebruik vir die behandeling van akute jig, ligte tot matige pyn wat verband hou met pynlike menstruasieperiodes, inflammasie in skouergewrig (bursitis) en inflammasie van 'n ligament (tendonitis).

2. Wat jy moet weet voordat jy BIO-NAPROXEN neem

Moenie BIO-NAPROXEN neem nie:
- Indien jy hipersensitief (allergies) is vir naproksen, naproksen natrium, aspirien, ander nie-steroïdale anti-inflammatoriese middels of vir enige van die ander bestanddele van BIO-NAPROXEN is nie (gelys in afdeling 6).
- Indien jy hipersensitief (allergies) is vir aspirien, ander nie-steroïdale anti-inflammatoriese medisyne of enige ander pynstillers (soos ibuprofen en diklofenak). As hierdie medisyne jou asma, 'n loopneus, sakagtige groeisels van ontsteekte weefselvoering van jou neus of sinusse of velkorwe gegee het, kan jy ook ernstige allergiese reaksie met BIO-NAPROXEN ervaar, wat dodelik kan wees.
- Indien jy swanger is of jou baba borsvoed.
- Indien jy ernstige hartprobleme het.
- Indien jy ernstige nierprobleme het.
- Indien jy voorheen bloeding of perforasie in jou maag ervaar het terwyl jy NSAID's geneem het.
- Indien jy huidiglik of al ooit enige probleme met jou maag of derm (ingewande) gehad soos 'n ulkus of enige bloeding
- Indien jy porferie het.
- Indien jy 'n kind is jonger as 16 jaar oud.

Waarskuwings en voorsorgmaatreëls
Spesiale sorg moet geneem word met BIO-NAPROXEN:
As jy BIO-NAPROXEN vir langer as die aanbevole tyd of teen hoër as aanbevole dosisse neem, loop jy die risiko van ernstige skade. Dit sluit in ernstige skade aan die maag/derm en niere, sowel as baie lae vlakke van kalium in jou bloed. Dit kan noodlottig wees (sien afdeling 4).
- Indien jy hartprobleme het, vorige beroerte of dink dat jy die risiko loop om hierdie toestande te kry (byvoorbeeld as jy hoë bloeddruk, diabetes of hoë cholesterol het of 'n roker is), moet jy jou behandeling met jou dokter of apteker bespreek
- Medisyne soos BIO-NAPROXEN kan geassosieer word met 'n klein verhoogde risiko van hartaanval (miokardiale infarksie) of beroerte.
  Enige risiko is meer waarskynlik met hoë dosisse en langdurige behandeling.
  Moenie die aanbevole dosis of duur van behandeling oorskry nie.
- Indien jy 'n geskiedenis het van maagprobleme soos ulseratiewe kolitis of Crohn se siekte (toestande wat inflammasie van die derm, dermpyn, diarree, braking en gewigsverlies veroorsaak), sooibrand of refluks aangesien die toestand vererger kan word deur die gebruik van BIO -NAPROXEN.
- Indien jy 'n lewer/ niersiekte het of indien jou lewer/ niere nie ordentlik werk nie.
- Indien jy 'n bloedtollingsversteuring het.
- Indien jy 'n bejaarde pasiënt is (aangesien jy meer geneig sal wees om newe-effekte met BIO-NAPROXEN te ervaar, veral bloeding en perforasie van die ingewande).
- Indien jy brongiale asma, of ander asemhalingsprobleme of neuspoliepe het of gehad het
- indien jy sistemiese lupus eritematosus het
- indien jy enige veluitslag of ander teken van hipersensitiwiteit ontwikkel. Jy moet dan dadelik ophou om BIO-NAPROXEN te neem.
- indien jy griepagtige simptome ontwikkel met 'n uitslag, koors, geswelde kliere en abnormale bloedtoetsresultate (insluitend verhoogde witbloedselle (eosinofilie) en lewerensieme) (geneesmiddelreaksie met eosinofilie en sistemiese simptome (DRESS))
- indien jy beplan om swanger te word.
- indien jy dalk 'n bloedingprobleem of probleem het wat verband hou met bloedstolling
- naproksen-tablette kan die simptome van 'n infeksie verberg.
- Indien jy enige bloed- of urienetoetse benodig, vertel jou dokter dat jy BIO-NAPROXEN tablette neem. Die tablette moet dalk 48 uur voor 'n toets gestaak word, aangesien dit met die resultate kan inmeng.
- Om 'n pynstiller vir hoofpyne te dikwels of te lank te neem, kan dit vererger
- Indien jy 20 weke of langer swanger is, kan die gebruik van BIO-NAPROXEN ernstige nierprobleme by die ongebore baba veroorsaak

Kinders
Moenie BIO-NAPROXEN aan kinders onder die ouderdom van 16 jaar gee nie.

Ander medisyne en BIO-NAPROXEN
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in).
- hidantoïene (bv. fenitoïen),
- sulfonamiede (bv. sulfametoksasool)
- Sulfonielureum-antidiabetiese middels soos glimepiried of glipisied
- medisyne wat die bloed verdun, of wat bloedstolling voorkom (bv. heparien of warfarien)
- litium (medisyne vir depressie)
- diuretika (furosemied) en antihipertensiewe medisyne (medisyne wat gebruik word om bloeddruk te verlaag)
- probenesied vir jig.
- metotreksaat (medisyne vir die behandeling van velprobleme, kanker of om outo-immuun siektes te behandel)
- hartglikosiede (medisyne wat gebruik word om hartversaking en sekere onreëlmatige hartklop soos digoksien te behandel.)
- siklosporien (medisyne wat die immuunstelsel onderdruk wat gebruik word na orgaanoorplanting)
- mifepristoon (medisyne wat gebruik word om swangerskap te beëindig)
- kortikosteroïede (soos hidrokortisoon, prednisoloon en deksametasoon.), indien nodig sal die dokter die dosis van die steroïde stadig verminder en vir newe-effekte monitor
- ander NSAID's insluitend siklooksigenase-2-inhibeerders (medisyne soos aspirien, ibuprofen of indometasien)
- kinoloon-antibiotika (soos siprofloksasien, moksifloksasien, norfloksasien, gatifloksasien of levofloksasien om bakteriële infeksies te behandel)
- anti-plaatjie medisyne (medisyne soos aspirien, klopidogrel of prasugrel)
- antidepressante wat bekend staan as selektiewe serotonienheropname inhibeerders (SSRI's) soos fluoksetien en paroksetien
- takrolimus ('n immuunonderdrukkende middel wat hoofsaaklik in orgaanoorplantings gebruik word)
- sidovudien
- bisfosfonate
- teensuurmiddels wat gebruik word vir sooibrand of cholestyramien wat gebruik word om gal in die maag te bind.
- aspirien/asetielsalisielsuur om bloedklonte te voorkom

BIO-NAPROXEN met kos en alkohol
BIO-NAPROXEN moet met kos geneem word.

Swangerskap, borsvoeding en vrugbaarheid
Jy moet nie BIO-NAPROXEN in die eerste 6 maande van swangerskap neem nie en moet nie BIO-NAPROXEN in die laaste 3 maande van swangerskap of tydens kraam neem nie.
Moenie BIO-NAPROXEN gebruik as jy jou baba borsvoed nie.
BIO-NAPROXEN kan dit moeiliker maak om swanger te raak.

Indien jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy BIO-NAPROXEN neem.

Bestuur en gebruik van masjinerie:
BIO-NAPROXEN kan jou duiselig, lomerig of moeg laat voel en kan versteurde visie veroorsaak. Maak seker dat jy nie geraak word voordat jy bestuur of masjinerie gebruik nie.
Dit is nie altyd moontlik om te voorspel tot watter mate BIO-NAPROXEN met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak voordat hulle bewus is van die mate waarin BIO-NAPROXEN hulle affekteer nie.

BIO-NAPROXEN bevat laktose:
BIO-NAPROXEN bevat laktose. Jy moet nie BIO-NAPROXEN neem as jy 'n seldsame oorerflike toestand van laktose of galaktose-onverdraagsaamheid het nie.

3. Hoe om BIO-NAPROXEN te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem BIO-NAPROXEN altyd presies soos jou dokter of apteker vir jou gesê het. Gaan praat met jou dokter of apteker as jy nie seker is nie.
Jou dokter sal jou vertel hoe lank jou behandeling met BIO-NAPROXEN sal duur.
Moenie die behandeling vroegtydig stop nie. Indien jy die indruk het dat die effek van BIO-NAPROXEN te sterk of te swak is, vertel jou dokter of apteker.
BIO-NAPROXEN moet nie by kinders onder die ouderdom van 16 jaar gebruik word nie.

Sluk die tablet met 'n bietjie water, met of na eet.
Jy moet die laagste moontlike dosis neem vir die kortste moontlike duur van behandeling.

Volwassenes
Artritis en ankiloserende spondilitis (pyn en styfheid in die nek en rug): 250 mg (een tablet) tot 375 mg (een en 'n halwe tablette) twee keer per dag geneem, saam met kos.
Akute jig: 'n Aanvangsdosis van 750 mg (drie tablette) met etes, gevolg deur 250 mg (een tablet) elke 8 uur totdat die aanval bedaar het.
Spier-, gewrig- of ligamentprobleme en menstruasiepyn: 'n Aanvangsdosis van 500 mg (twee tablette) gevolg deur 250 mg (een tablet) elke 6 tot 8 uur met kos.

Indien jy meer BIO-NAPROXEN neem as wat jy moet:
Simptome
Simptome van oordosis is hoofpyn, voel of siek wees, sooibrand, diarree, disoriëntasie, bloeding van die maag of ingewande, bewusteloosheid, lomerigheid, duiseligheid, gesuis of gons in die ore, floute, aanvalle en opwinding.

Behandeling
Pasiënte moet simptomaties behandel word.
Geaktiveerde houtskool moet binne een uur na die inname van 'n potensieel toksiese hoeveelheid BIO-NAPROXEN gegee word.
Goeie uriene-uitset moet verseker word.
Nier- en lewerfunksie moet noukeurig gemonitor word.
Pasiënte moet vir ten minste vier uur na die inname van 'n potensieel toksiese hoeveelhede BIO-NAPROXEN gekontroleer word.
Gereelde of langdurige stuiptrekkings moet met intraveneuse diasepam behandel word.

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om BIO-NAPROXEN te neem
Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

4. Moontlike newe-effekte

Nie alle newe-effekte wat vir BIO-NAPROXEN aangemeld is word in hierdie pamflet bevat nie. Sou jou algemene gesondheid versleg of indien jy enige ongewensde effekte ervaar terwyl jy BIO-NAPROXEN neem, raadpleeg asseblief jou gesondheid-sorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om BIO-NAPROXEN te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat moeilike sluk of moeilike asemhaling mag veroorsaak,
- uitslag of jeuk,
- floute.
- BIO-NAPROXEN, veral wanneer dit teen hoër as aanbevole dosisse geneem word of vir 'n lang tydperk, kan skade aan jou niere veroorsaak en dit beïnvloed om sure behoorlik uit jou bloed in die uriene te verwyder (renale tubulêre asidose). Dit kan ook baie lae vlakke van kalium in jou bloed veroorsaak.
  Hierdie is 'n baie ernstige toestand en sal onmiddellike behandeling vereis. Tekens en simptome sluit spierswakheid en lighoofdigheid in.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, het jy dalk 'n ernstige reaksie op BIO-NAPROXEN gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
- hemolitiese anemie (rooibloedselle word vinniger vernietig as wat dit gemaak kan word).
- granulosiktopenie (lae aantal granulosiete, 'n tipe witbloedsel).
- trombositopenie (bloedplaatjietekort wat bloeding in weefsels en stadige bloedstolling na besering veroorsaak).
- agranulositose (agranulosiettekort (tipe witbloedsel)).
- leukopenie ('n vermindering in die aantal wit selle in die bloed, tipies van verskeie siektes.)
- neutropenie (abnormale aantal neutrofiele in die bloed)
- eosinofilie ('n toename in die aantal eosinofiele in die bloed, wat voorkom in reaksie op sommige allergene, dwelms en parasiete, en in sommige tipes leukemie).
- anemieë ('n toestand waarin daar 'n tekort aan rooiselle of hemoglobien in die bloed is, wat bleekheid en moegheid tot gevolg het)
- aplastiese anemie (tekort aan alle soorte bloedselle wat veroorsaak word deur mislukking van beenmurgontwikkeling)
- skade aan jou lewer
- hiperkalemie (hoë kaliumvlakke in jou bloed)
- stuiptrekkings/ aanvalle
- aseptiese meningitis (ontsteking/inflammasie van die voerings van die brein)
- verergering van Parkinson se siekte
- hartkloppings (vinnige, sterk en onreëlmatige hartklop)
- hartversaking (Swelling van jou hande, voete of bene (edeem), dit kan borspyn, moegheid, kortasemheid insluit)
- angioneurotiese edeem
- kongestiewe hartversaking (chroniese progressiewe toestand wat die pompkrag van jou hartspier beïnvloed)
- perikarditis (ontsteking van die perikardium, 'n sakagtige struktuur met twee dun lae weefsel wat die hart omring)
- inflammasie van die bloedvate (vaskulitis)
- hoë bloeddruk (hipertensie)
- hartaanval of beroerte as gevolg van bloedklont wat 'n slagaar blokkeer (arteriële trombotiese gebeure, bv. miokardiale infarksie of beroerte)
- verergerde asma
- hoë aantal eosinofiele (tipe witbloedsel) (eosinofiele)
- inflammasie van die wande van die alveoli in die longe (pneumonitis)
- moeilike asemhaling (dispnee)
- spasma van die brongiale gladdespier (brongospasma)
- oortollige vloeistof in die longe (pulmonêre edeem)
- letsel in die voering (mukosa) van die spysverteringskanaal, tipies in die maag of duodenum, wat veroorsaak word deur die spysverteringsaksie van pepsien en maagsuur (peptiese ulkusse)
- gate wat in jou maag of ingewande vorm (perforasie) wat lei tot bloeding in die spysverteringskanaal
- verergering van ulseratiewe kolitis of Crohn se siekte, wat lei tot pyn, diarree, braking en gewigsverlies.
- Inflammasie van die lewer (hepatitis)
- seldsame, ernstige versteuring van die vel en slymvliese. Dit is gewoonlik 'n reaksie op medikasie wat begin met griepagtige simptome, gevolg deur 'n pynlike uitslag wat versprei en blase (Stevens Johnsons se sindroom)
- potensieel lewensgevaarlike dermatologiese versteuring wat gekenmerk word deur wydverspreide eriteem, nekrose en bullose loslating van die epidermis en slymvliese (toksiese epidermale nekrose).
- velafwykings wat veroorsaak dat die vel baie broos word. Enige trauma of wrywing aan die vel kan pynlike blase veroorsaak (epidermolysis bullosa)
- inflammasie van die klein filters in jou niere (glomerulêre nefritis)
- nierversteuring waarin die spasies tussen die nierbuisies geswel word (interstisiële nefritis)
- niersiekte, veral wanneer gekenmerk deur edeem en die verlies van proteïen uit die plasma in die uriene as gevolg van verhoogde glomerulêre deurlaatbaarheid (nefritiese sindroom)
- versteuring van die niere waarin die hele of 'n gedeelte van die nierpapille sterf. Die nierpapille is die areas waar die openinge van die versamelbuise die nier binnegaan en waar uriene in die ureter vloei (renale papillêre nekrose)
- Inkorting van nierfunksies, niersiekte en nierversaking

Hierdie is alles ernstige newe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- verwarring
- duiseligheid
- lomerigheid
- hoofpyn
- lighoofdigheid
- visuele versteurings
- veranderinge aan jou gehoor, wat gelui in die ore (tinnitus) kan insluit.
- swelling wat veroorsaak word deur die ophoping van vloeistof in 'n deel van die liggaam
- ekhimose ('n verkleuring van die vel as gevolg van bloeding onder, tipies veroorsaak deur kneusing)
- erge jeuk van die vel (pruritis)
- 'n uitslag van pers kolle op die vel veroorsaak deur interne bloeding van klein bloedvate (purpura)
- veluitbarstings
- sweet
- uitermatige moegheid

Minder gereelde newe-effekte:
- depressie
- sukkel om te onthou, nuwe dinge te leer, te konsentreer of besluite te neem wat hul alledaagse lewe beïnvloed (kognitiewe disfunksie)
- probleme om te raak of aan die slaap te bly (slapeloosheid)
- verlies aan konsentrasie
- abnormale drome
- gehoorversteuring
- inflammasie van die pankreas (pankreatitis)
- vergeling van die vel en die wit van die oë, bleekkleurige stoelgange (geelsug).
- spierpyn
- spierswakheid
- Bloed in die uriene (hematurie)
- vel immuunreaksie wat 'n infeksie of medikasie kan veroorsaak (erythema multiforme)
- 'n uitslag van ronde, rooi kolle op die vel wat intens jeuk, soms met gevaarlike swelling, veroorsaak deur 'n allergiese reaksie, tipies op spesifieke kosse (urtikaria)
- gedeeltelike of volledige afwesigheid van hare van areas van die liggaam waar dit normaalweg groei (alopesie)
- fotosensitiwiteitsreaksie insluitend gevalle van porphyria cutanea tarda ('n seldsame afwyking wat gekenmerk word deur pynlike, blase of velletsels wat op son-blootgestelde vel ontwikkel)
- Onverklaarbare vaginale bloeding en/of swaar menstruele bloeding
- verhoogde kalium in die bloed

Newe-effekte met 'n onbekende frekwensie:
- laringeale edeem (abnormale ophoping van vloeistof in weefsels van enige deel van die larinks)
- serumsiekte-agtige reaksie ('n akute inflammatoriese toestand wat kinders en volwassenes affekteer wat gekenmerk word deur die ontwikkeling van eritematiese velletsels en gewrigsswelling met of sonder koors)
- limfadenopatie ('n siekte wat die limfknope aantas)
- aspirien hipersensitiwiteit (skadelike reaksie op aspirien. Reaksies sluit in asemhaling, neus-/ sinus- en velprobleme)
- hallusinasies
- malaise ('n algemene gevoel van ongemak en siekte)
- senuweeagtigheid
- hoofpyn
- vertigo (verlies van balaans)
- abnormale gevoel van naalde en spelde (parestesie)
- versteurde visie
- korneale ondeursigtigheid (oogprobleme wat kan lei tot littekens of troebeling van die kornea, wat visie verminder)
- papillitis (ontsteking en agteruitgang van die gedeelte van die optiese senuwee bekend as die optiese skyf)
- retrobulbaar (abses agter die oogbal)
- swelling en inflammasie van die optiese senuwee (optiese neuritis)
- verhoogde druk in en rondom die brein veroorsaak dat die deel van die optiese senuwee binne die oog swel (papilloedeem)
- inflammasie van die slymvlies van die neus (rinitis)
- hemoptise (die ophoes van bloed)
- 'n behoefte om iets te drink (dors)
- naarheid
- braking
- diarree
- opeenhoping van gas (winderigheid)
- hardlywigheid
- probleme om kos te verteer met simptome soos pyn of ongemak, opgeblasenheid, gevoel van volheid (dispepsie)
- maagpyn
- donker, taai ontlasting wat gedeeltelik verteerde bloed (melaena) bevat
- braking van bloed (hematemese)
- pynlike sere in die mond (ulseratiewe stomatitis)
- kolitis (inflammasie van die voering van die kolon)
- inflammasie van die voering van die maag (gastritis)
- esofagitis (inflammasie van die slukderm)
- nie-peptiese gastroïntestinale ulserasie
- maag ongemak
- abnormale lewerfunskies
- erythema nodosum (velontsteking wat in 'n deel van die vetterige vellaag geleë is)
- vaste geneesmiddeluitbarsting (is 'n uitbarsting wat gekenmerk word deur sy ronde vorm)
- inflammatoriese afwyking wat as perserige, plat bulte voorkom wanneer dit die vel aantas (lichen planus)
- pustulêre reaksie (wanneer jou vel ontsteek word as gevolg van 'n allergiese reaksie op voedsel, omgewingsallergene)
- Systemiese lupus erythematosus (SLE) (langtermyn toestand wat inflammasie in die vel, organe en op verskeie ander plekke in die liggaam kan veroorsaak)
- swelling onder jou vel (angioedeem)
- rooiheid en afskilfering van die vel oor groot areas van die liggaam (afskilferende en bulagtige dermatose)
- griepagtige simptome met 'n uitslag, koors, gewelde kliere en abnormale bloed-toetsuitslae (insluitend verhoogde witbloedselle (eosinofilie) en lewerensieme) (geneesmiddelreaksie met eosinofilie en sistemiese simptome (DRESS))
- verhoogde kalium in die bloed
- verhoging in kreatinien in die bloed en vloeistofretensie
- vrouens wat vir meer as 'n jaar onsuksesvol probeer het om 'n swanger te word (verswakte vroulike vrugbaarheid)
- swelling van die laer bene en hande (ligte perifere edeem)
- koors

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA aanmeld deur die vorm **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van BIO-NAPROXEN te verskaf.

5. Hoe om BIO-NAPROXEN te bewaar

- Bewaar alle medisyne buite bereik van kinders
- Bewaar teen of benede 25 °C
- Beskerm teen lig
- Bewaar in die oorspronlike houer.
- Gee alle ongebruikte medisyne terug aan jou apteker
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat BIO-NAPROXEN bevat
Die aktiewe bestanddeel is naproksen.
Die ander bestanddele is laktose, voorgeglatiniseerde stysel, natriumstyselglikolaat, kinoliengeel lake 19248, polisorbaat 80, povidoon, gesuiwerde talk, magnesium-stearaat en gesuiwerde water.

Hoe BIO-NAPROXEN lyk en die inhoud van die pak
BIO-NAPROXEN 250: Ronde, geel, bikonvekse tablette met 'n breeklyn aan die een kant en ongedruk aan die ander kant.
BIO-NAPROXEN 500: Geel, kapsuulvormige, bikonvekse tablet met NPX 500 aan die een kant gedruk en 'n breeklyn aan die ander kant.

BIO-NAPROXEN 250 en BIO-NAPROXEN 500 kan in die volgende houers verpak word:
Wit ondeursigtige, polipropileen sekuriteitshouer wat 30 en 250 tablette bevat.
Skroefdop wit, ondeursigtige HDPE-houer wat 30 en 250 tablette bevat.
Amber PVC/ PVDCstulpverpakking wat 56 of 14 tablette per karton bevat.
Wit, ondeursigtige, poliëtileen ritssluiting pasiëntgereed pak (slegs vir staatsgebruik), wat 28 of 56 tablette bevat.

Houer van die Sertifikaat van Registrasie
BIOTECH LABORATORIES (EDMS) BPK
Grondvloer, Blok K Wes, Central Park
16de Weg 400
Randjespark
Midrand, 1685
Tel. Nr: (011) 848 3050

Hierdie pamflet is laas hersien
29 September 2023.

Registrasienommer
BIO-NAPROXEN 250: W/3.1/0436
BIO-NAPROXEN 500: W/3.1/0437