INDOMETHACIN BIOTECH 25

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

INDOMETHACIN BIOTECH 25 capsules
Indomethacin
Sugar free.

Read all of this leaflet carefully before you start taking INDOMETHACIN BIOTECH 25.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- INDOMETHACIN BIOTECH 25 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 INDOMETHACIN BIOTECH 25 is and what it is used for
2. What you need to know before you take INDOMETHACIN BIOTECH 25
3. How to take INDOMETHACIN BIOTECH 25
4. Possible side effects
5. How to store INDOMETHACIN BIOTECH 25
6. Contents of the pack and other information.

1. What INDOMETHACIN BIOTECH 25 is and what it is used for

INDOMETHACIN BIOTECH 25 contains the active ingredient indomethacin, which belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). NSAIDs are used to reduce inflammation, pain and fever.

INDOMETHACIN BIOTECH 25 is used for:

- rheumatoid arthritis (an autoimmune and inflammatory disease that may cause joint pain, inflammation, and damage throughout your body);
- osteoarthritis (degenerative joint disease, causing pain and stiffness of your joints);
- ankylosing spondylitis (pain and stiffness in your back);
- deterioration of the cartilage that serves as a cushion in the joints of your hips (degenerative joint disease of your hip);
- acute gouty arthritis (a form or arthritis in which crystals build up in your joints);
- musculoskeletal disorders (such as, bursitis, tendonitis, synovitis, tenosynovitis, capsulitis of the shoulder, sprains and strains);
- lower back pain;
- fever (in addition to your primary treatment for a short duration to assist in reducing the fever);
- pain, inflammation, swelling and difficulty opening your mouth (trismus) following dental surgical procedures;
- pain, inflammation and swelling following orthopaedic surgery or non surgical procedures (associated with repositioning bones after dislocation or fracture);
- period pain.

2. What you need to know before you take INDOMETHACIN BIOTECH 25

Do not take INDOMETHACIN BIOTECH 25:

- if you are hypersensitive (allergic) to indomethacin, aspirin or to any of the other ingredients of INDOMETHACIN BIOTECH 25 (listed in section 6);
- if you previously suffered from any of the following after taking aspirin or other NSAIDs:
  – asthma attack (wheezing, chest tightness, breathlessness);
  – skin hives (skin rash/ raised red patches on your skin with severe itching);
  – rhinitis (runny nose);
  – nasal polyps (nasal blockage due to swellings in the lining of your nose).
- if you are taking a medicine called diflunisal for pain, swelling, stiffness or joint pain;
- if you are operating machinery;
- if you suffer from any psychiatric disorder, epilepsy (fits) or you have been diagnosed with Parkinsonism (trouble moving or walking, stiffness, tremor, shakiness);
- if you suffer from severe liver and/or kidney failure;
- if you have a peptic ulcer (sore in your stomach or duodenum) or you suffer from bleeding in your stomach, or have had (history of) peptic ulcers, stomach bleeding or bursting of an ulcer (perforation) after taking NSAIDs, including INDOMETHACIN BIOTECH 25;
- if you have inflammation of your stomach and/ or intestines (gastritis, regional enteritis, ulcerative colitis) or a history of recurring ulcers (sores) in your stomach or intestines;
- if you currently have or previously had stomach and/ or intestinal lesions, including ulcers, bleeding or perforations;
- if you have previously experienced an allergic reaction (sensitivity) that caused swelling of your face and mouth (angioedema) after taking NSAIDs and/ or aspirin;
- if you are having heart surgery (for narrowed or blocked arteries), since INDOMETHACIN BIOTECH 25 should not be used to treat pain during such an operation;
- if you have a heart condition such as heart failure or ischaemic heart disease, you have suffered a stroke, or you suffer from peripheral arterial disease (a condition in which narrowed arteries reduce blood flow to your arms or legs);
- if you are pregnant or breastfeeding your baby (see Pregnancy, breast feeding and fertility).

The safety of INDOMETHACIN BIOTECH 25 in children has not been established.

Warnings and precautions:

INDOMETHACIN BIOTECH 25 may lead to serious heart and/or blood vessel problems, stomach and/or intestinal problems, or skin reactions which may lead to death. If you are using INDOMETHACIN BIOTECH 25 for longer than the recommended time or at higher than recommended doses, you are at risk of serious harm. These inclde serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4)

Take special care with INDOMETHACIN BIOTECH 25:

- use the lowest effective dose for the shortest period necessary to control symptoms, as this may help to reduce side effects;
- if you are taking other NSAIDs, including cyclooxygenase-2 selective inhibitors (used to treat pain and inflammation);
- if you have any heart, liver or kidney problems. Your liver and/ or kidney function should be closely monitored by your doctor;
- if you have a bleeding disorder;
- if you have high blood pressure, as INDOMETHACIN BIOTECH 25 may cause fluid retention and swelling, and worsen the condition;
- if you have any risk factors for heart disease, such as high blood pressure, high cholesterol levels, diabetes (high blood sugar levels) or if you are a smoker;
- if you are taking a diuretic (water tablet) (used reduce water retention in your body);
- if you have an infection, as INDOMETHACIN BIOTECH 25 may mask the signs and symptoms of an infection (e.g. fever);
- if you experience any difficulties with your eyes while taking INDOMETHACIN BIOTECH 25. If you have rheumatoid arthritis your doctor may want to examine your eyes at intervals during your treatment with INDOMETHACIN BIOTECH 25. You should see your doctor if you notice any change in your vision;
- if you are an elderly patient, you may be more likely to experience the side effects of INDOMETHACIN BIOTECH 25;
- if you suffer from asthma;
- if you develop a fever, severe skin rash or skin reaction, swollen glands, blistering of the skin, mouth or eyes, scaling of the skin, or any unusual reaction such as facial swelling when starting treatment with INDOMETHACIN BIOTECH 25, stop taking INDOMETHACIN BIOTECH 25 and tell your doctor immediately. These serious events may occur without warning and may be fatal. They include DRESS (drug reaction with eosinophilia and systemic symptoms), exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN);
- if you experience any symptoms of either stomach ulcer or bleeding while taking INDOMETHACIN BIOTECH 25, stop taking INDOMETHACIN BIOTECH 25 and consult your doctor immediately;
- if you are taking other medicines which could increase your risk for ulcers or bleeding, such as corticosteroids (used to treat inflamed areas of your body), anticoagulants or antiplatelet medicines (used to thin your blood), such as warfarin and aspirin, and selective serotonin reuptake inhibitors (SSRIs) (used to treat depression);
- if you suffer from systemic lupus erythematosus (SLE), an autoimmune disorder, or mixed connective tissue disorders;
- if you have a blood clotting disorder (bleeding disorder);
- if you just had an operation as INDOMETHACIN BIOTECH 25 can increase your bleeding time;
- do not use INDOMETHACIN BIOTECH 25 as a substitute for aspirin as a preventative treatment for heart disease;
- if you experience headaches, dizziness or light-headedness while taking INDOMETHACIN BIOTECH 25, you may need to reduce the dose and if your headache continues despite the dose reduction, stop taking INDOMETHACIN BIOTECH 25;
- if you have been taking INDOMETHACIN BIOTECH 25 for a long time and have frequent headaches, you should stop taking INDOMETHACIN BIOTECH 25 and tell your doctor;
- if you experience high levels of potassium in your blood (hyperkalaemia), anaemia or any liver problems while taking INDOMETHACIN BIOTECH 25;

You should be regularly monitored by your doctor for any unwanted effects of your stomach or intestine, especially if you have been taking INDOMETHACIN BIOTECH 25 for a long time.

Children:

The safe use of INDOMETHACIN BIOTECH 25 in children has not been established.
Children should not take INDOMETHACIN BIOTECH 25.

Other medicines and INDOMETHACIN BIOTECH 25:

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

Tell your doctor if you are taking any of the following:

- other nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin, diflunisal and cyclooxygenase-2 selective inhibitors (used to treat pain and inflammation). Diflunisal should not be taken with INDOMETHACIN BIOTECH 25 (see Do not take INDOMETHACIN BIOTECH 25);
- antacids (used to neutralise the acid in your stomach to relieve heartburn, indigestion or an upset stomach);
- anticoagulants (used to prevent blood clots), such as warfarin;
- antidepressants (used to treat depression), such as SSRIs;
- antidiabetic medicine (used to treat high blood sugar levels), such as sulfonylureas;
- antihypertensive medicines (used to treat high blood pressure), such as diuretics or water tablets (e.g. furosemide and triamterene), angiotensin-converting enzyme (ACE) inhibitors, angiotensin-II antagonists, alpha-blockers or beta-blockers. INDOMETHACIN BIOTECH 25 and triamterene should not be taken together;
- antiplatelet medicines (used to thin your blood);
- antipsychotics (used to treat mental health conditions), such as haloperidol;
- antivirals (used to treat viral infections such as HIV), including zidovudine and ritonavir;
- cardiac glycosides (used to treat heart failure and a fast heartbeat), such as digoxin;
- calcineurin inhibitors or immunosuppresive medicines (used to prevent organ rejection after a transplant), such as ciclosporin or tacrolimus;
- phenylpropanolamine (used in cold and flu medicine to provide relief for a blocked nose);
- corticosteroids (used to treat inflamed areas of your body);
- cytotoxic medicines (used to treat certain types of cancer or autoimmune disorders), including methotrexate;
- desmopressin (used to treat night-time bedwetting, central diabetes insipidus, and increased thirst and urination caused by head surgery or head trauma);
- lithium (used to treat mood disorders);
- mifepristone (used to cause an abortion during the early part of a pregnancy);
- muscle relaxants (used to relieve muscle spasms), such as baclofen;
- pentoxifylline (used to improve blood flow);
- probenecid (used to treat gout);
- quinolone antibiotics (used to treat certain bacterial infections);
- salicylates, including aspirin (used to treat pain, fever and inflammation);
- tiludronic acid (used to treat Paget's disease (broken and deformed bones and pain in the affected area));
- if you are having blood tests done, as it can result in false-negative results.

INDOMETHACIN BIOTECH 25 with food and drink:

It is recommended that INDOMETHACIN BIOTECH 25 be taken with food, milk or an antacid to reduce potential side effects.

Pregnancy, breastfeeding and fertility:

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 INDOMETHACIN BIOTECH 25.
Do not take INDOMETHACIN BIOTECH 25 if you are pregnant or breastfeeding your baby (see Do not take INDOMETHACIN BIOTECH 25).
Taking INDOMETHACIN BIOTECH 25 may make it more difficult for you to become pregnant.

Driving and using machines:

INDOMETHACIN BIOTECH 25 may cause dizziness, drowsiness, visual disturbances and headaches, and affect your ability to drive a vehicle or use machinery. You should not take INDOMETHACIN BIOTECH 25 if you operate machinery.
It is not always possible to predict to what extent INDOMETHACIN BIOTECH 25 may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which INDOMETHACIN BIOTECH 25 affects you.

3. How to take INDOMETHACIN BIOTECH 25

Do not share medicines prescribed for you with any other person.
Always take INDOMETHACIN BIOTECH 25 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Use the lowest effective dose for the shortest possible duration necessary to control symptoms, as this may help to reduce side effects.
The dose depends on the medical condition which is being treated. Your doctor will let you know how much you should take.
Your doctor will tell you how long your treatment with INDOMETHACIN BIOTECH 25 will last. Do not stop treatment early because your doctor will monitor your recovery and advise you when to stop treatment.
If you have the impression that the effect of INDOMETHACIN BIOTECH 25 is too strong or too weak, or after several days you do not feel any improvement in your condition, tell your doctor or pharmacist.

If you take more INDOMETHACIN BIOTECH 25 than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Your doctor will monitor your symptoms and treat you according to your condition.

If you forget to take INDOMETHACIN BIOTECH 25:

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, continue to take the next dose at the usual time. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking INDOMETHACIN BIOTECH 25:

You should take INDOMETHACIN BIOTECH 25 for as long as your doctor tells you to. You should not stop taking it without your doctor's advice.

4. Possible side effects

INDOMETHACIN BIOTECH 25 can have side effects.
Not all side effects reported for INDOMETHACIN BIOTECH 25 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INDOMETHACIN BIOTECH 25, please consult your healthcare provider for advice.

If any of the following happens, stop taking INDOMETHACIN BIOTECH 25 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS);
- eruption of lesions on the skin known as erythema multiforme;
- fever, flu-like symptoms, a painful red rash (may include purplish spots) that spreads, and blisters follows where the top part of the skin dies and peels off known as toxic epidermal necrolysis (TEN);
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to INDOMETHACIN BIOTECH 25. You may need urgent medical attention or hospitalisation.

If any of the following happens, stop taking INDOMETHACIN BIOTECH 25 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- necrotising fasciitis (NF) is a rare but fatal rapidly progressive soft tissue infection, which is characterised by widespread necrosis of the superficial fascia and the subcutaneous fat;
- signs of recurrent infections, such as fever or sore throat (blood cancers (diagnosed by tests done by your doctor));
- blood disorders that can cause unexplained bruising or bleeding, including pinpoint bleeds or nose bleeds;
- seizures/ fits;
- coma;
- aseptic meningitis, especially in patients with existing autoimmune disorders, such as systemic lupus erythematosus or mixed connective tissue disease (symptoms include stiff neck, headache, nausea, vomiting, fever or disorientation);
- heart attack;
- stroke (loss of movement or sensation in one side of your body, difficulty speaking or moving);
- changes in the way your heart beats, beating faster than normal or skipping a beat;
- heart failure or chest pain;
- thrombophlebitis (inflammatory process that causes a blood clot to form in your veins causing warmth, pain, swelling and redness in the area affected);
- difficulty breathing, shortness of breath, asthma;
- pulmonary eosinophilia (PE) (the infiltration of eosinophils into the lung compartments constituting airways, interstitium, and alveoli, increased eosinophils in the lungs presents with chest pain, dry cough, fever);
- stomach ulcer, perforation or bleeding (pain of your stomach area, nausea, vomiting, unexplained weight loss, dark stools, bloody vomit);
- melaena refers to dark tarry stools that is usually an indication of bleeding in the digestive tract;
- exacerbation of colitis and Crohn's disease;
- haematemesis (vomiting of blood);
- yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems, including jaundice or hepatitis;
- blockage of flow of bile from the liver (cholestasis) with symptoms such as severe pain in the stomach and back;
- changes in blood and liver enzymes when test are done;
- kidney problems, blood in your urine, kidney failure, frequent urination or high levels of urea in your blood indicating the kidneys are not working well.
- INDOMETHACIN BIOTECH 25, especially when used 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 Warnings and precautions). 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 INDOMETHACIN BIOTECH 25. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- confusion, feeling anxious, inability to sleep, a state in which one's thoughts and feelings seem unreal or not to belong to oneself;
- mental disorders and aggravation of these disorders;
- psychotic episodes;
- headache, dizziness, light-headedness;
- inflammation of the nerve in your eye;
- ringing of your ears (tinnitus);
- redness of your skin;
- inflammation of your blood vessels;
- photosensitivity (sensitivity of your skin to light).

Side effects occurring less frequently:

- high blood sugar levels (increased thirst and urination), or excess sugar in your urine;
- high levels of potassium in your blood (chest pain, heart palpitations, weakness, numbness, nausea or vomiting);
- vertigo (spinning sensation);
- fatigue (weakness/ tiredness);
- involuntary muscle movement; disease affecting peripheral nerves;
- difficulty speaking;
- parkinsonism (a group of neurological disorders that cause movement problems similar to those seen in Parkinson's disease such as tremors, slow movement and stiffness);
- muscle weakness;
- disturbances of your eyesight, blurred vision or double vision, pain of your eye or tissues surrounding your eye;
- flushing (redness of your skin);
- nosebleeds;
- feeling that you want to pass a stool even though your bowels are empty, inflammation of your anus, or bleeding, pain, burning sensation, itching or discomfort from the anal area;

Side effects which may occur but the frequency is not known:

- feeling depressed;
- drowsiness;
- difficulty sleeping;
- hallucinations (seeing or hearing things that are not real)
- deposits on the cornea of your eye (watery eyes, dry eyes, light sensitivity, pain, sensation of something in your eye);
- hearing disturbances, deafness;
- high blood pressure;
- nausea (feeling sick), vomiting (being sick);
- aggravation of psoriasis (scales and red patches that are itchy and sometimes painful)
- loss of hair;
- sweating;
- muscle weakness, acceleration of cartilage breakdown;
- proteinuria, a condition characterised by the presence of greater than normal amounts of protein in your urine;
- breast changes (including enlargement, tenderness or increased amount of breast tissue in men);
- vaginal bleeding.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effect:

If you get side effects, talk to your doctor or pharmacist. 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 INDOMETHACIN BIOTECH 25.

5. How to store INDOMETHACIN BIOTECH 25

- Store at or below 25 °C in a dry place.
- Protect from light.
- Store all medicines out of reach of children.
- Do not use the capsules after the expiry date printed on the packaging.
- 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 INDOMETHACIN BIOTECH 25 contains:

The active substance is 25 mg indomethacin per capsule.
The other ingredients are colloidal silicon dioxide (Aerosil), magnesium stearate, pre-gelatinised starch, sodium lauryl sulphate, talc, and the capsule shell (containing erythrosine, quinolene yellow, titanium dioxide).

What INDOMETHACIN BIOTECH 25 looks like and contents of the pack:

Opaque, yellow, hard gelatine capsule containing a white powder.
INDOMETHACIN BIOTECH 25 capsules are supplied in white, polypropylene securitainers of 100 and 500 capsules, amber glass bottles of 100 and 500 capsules, while, high density polyethylene containers of 500 and 1 000 capsules, and PVC/ aluminium blisters of 15 and 84 capsules.
Not all pack sizes may be marketed.

Holder of certificate of registration:

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INDOMETHACIN BIOTECH 25

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:

S3

INDOMETHACIN BIOTECH 25 kapsules
Indometasien
Suikervry.

Lees die hele inligtingsblad noukeurig deur voordat jy INDOMETHACIN BIOTECH 25 begin neem.
- Bewaar hierdie inligtingsblad. Jy sal dit dalk weer moet lees.
- As jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- INDOMETHACIN BIOTECH 25 is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat hierdie inligtingblad bevat:
1. Wat INDOMETHACIN BIOTECH 25 is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy INDOMETHACIN BIOTECH 25 neem
3. Hoe om INDOMETHACIN BIOTECH 25 te neem
4. Moontlike newe-effekte
5. Hoe om INDOMETHACIN BIOTECH 25 te bewaar
6. Inhoud van die pakkie en ander inligting.

1. Wat INDOMETHACIN BIOTECH 25 is en waarvoor dit gebruik word
INDOMETHACIN BIOTECH 25 bevat die aktiewe bestanddeel indometasien, wat behoort aan 'n groep medisyne wat niesteroïdale anti-inflammatoriese middels (NSAID's) genoem word. NSAID's word gebruik om inflammasie, pyn en koors te verminder.

INDOMETHACIN BIOTECH 25 word gebruik vir:
- rumatoïede artritis ('n outo-immuun en inflammatoriese siekte wat gewrigspyn, inflammasie en skade deur jou liggaam kan veroorsaak);
- osteoartritis (degeneratiewe gewrigsiekte, wat pyn en styfheid van jou gewrigte veroorsaak);
- ankiloserende spondilitis (pyn en styfheid in jou rug);
- agteruitgang van die kraakbeen wat as kussing in die gewrigte van jou heupe dien (degeneratiewe gewrigsiekte van jou heup);
- akute jigartritis ('n vorm of artritis waarin kristalle in jou gewrigte opbou);
- muskuloskeletale afwykings (soos bursitis, tendonitis, sinovitis, tenosinovitis, kapsulitis van die skouer, verstuitings en verrekkings);
- lae rugpyn;
- koors (bykomend tot jou primêre behandeling vir 'n kort tydperk om te help met die verlaging van die koors);
- pyn, inflammasie, swelling en moeilikheid om jou mond oop te maak (trismus) na tandheelkundige chirurgiese prosedures;
- pyn, inflammasie en swelling na ortopediese chirurgie of nie-chirurgiese prosedures (geassosieer met herposisionering van bene na ontwrigting of fraktuur);
- menstruasie pyn.

2. Wat jy moet weet voordat jy INDOMETHACIN BIOTECH 25 neem
Moenie INDOMETHACIN BIOTECH 25 neem nie:
- as jy hipersensitief (allergies) is vir indometasien, aspirien of vir enige van die ander bestanddele van INDOMETHACIN BIOTECH 25 is (gelys in afdeling 6);
- as u voorheen aan enige van die volgende gely het nadat u aspirien of ander NSAID's geneem het:
  - asma-aanval (hyg, benoudheid op die bors, kortasem);
  - velbulte (veluitslag/ verhoogde rooi kolle op jou vel met erge jeuk);
  - rinitis (loopneus);
  - neuspoliepe (nasale blokkasie as gevolg van swellings in die voering van jou neus)
- as jy 'n medisyne genaamd diflunisal neem vir pyn, swelling, styfheid of gewrigspyn;
- as jy masjinerie gebruik;
- as jy aan enige psigiatriese versteuring ly, epilepsie (aanvalle) of jy is gediagnoseer met Parkinsonisme (probleme om te beweeg of loop, styfheid, bewing, bewerigheid);
- as jy aan ernstige lewer- en/ of nierversaking ly;
- as jy 'n maagseer (seer in jou maag of duodenum) het of as jy aan bloeding in jou maag ly, of (geskiedenis van) maagsere, maagbloeding of bars van 'n ulkus (perforasie) gehad het nadat jy NSAID's geneem het, insluitend INDOMETHACIN BIOTECH 25;
- as jy inflammasie van jou maag en/ of ingewande het (gastritis, streeks enteritis, ulseratiewe kolitis) of 'n geskiedenis van herhalende ulkusse (sere) in jou maag of ingewande;
- as jy tans maag- en/ of dermletsels het of voorheen gehad het, insluitend maagsere, bloeding of perforasies;
- as jy voorheen 'n allergiese reaksie (sensitiwiteit) ervaar het wat swelling van jou gesig en mond (angio-edeem) veroorsaak het nadat jy NSAID's en/ of aspirien geneem het;
- as jy 'n hartoperasie ondergaan (vir vernoude of verstopte are), aangesien INDOMETHACIN BIOTECH 25 nie gebruik moet word om pyn tydens so 'n operasie te behandel nie;
- as jy 'n hartkwaal het soos hartversaking of isgemiese hartsiekte, jy 'n beroerte gehad het, of jy ly aan perifere arteriële siekte ('n toestand waarin vernoude are bloedvloei na jou arms of bene verminder);
- as jy swanger is of jou baba borsvoed (sien Swangerskap, borsvoeding en vrugbaarheid).

Die veiligheid van INDOMETHACIN BIOTECH 25 by kinders is nie vasgestel nie.

Waarskuwings en voorsorgmaatreëls:

> INDOMETHACIN BIOTECH 25 kan lei tot ernstige hart- en/ of bloedvatprobleme, maag- en/ of dermprobleme, of velreaksies wat tot die dood kan lei. Indien jy INDOMETHACIN BIOTECH 25 vir langer as die aanbevole tyd of teen hoër as aanbevole dosisse gebruik, loop jy die risiko van ernstige skade aan die maag/derm en niere, sowel as baie lae vlakke van kalium in jou bloed. Dit kan dadelik wees (sien afdeling 4)

Wees veral versigtig met INDOMETHACIN BIOTECH 25:
- gebruik die laagste effektiewe dosis vir die kortste tydperk wat nodig is om simptome te beheer, aangesien dit kan help om newe-effekte te verminder;
- as jy ander NSAID's gebruik, insluitend siklooksigenase-2 selektiewe inhibeerders (wat gebruik word om pyn en inflammasie te behandel);
- as jy enige hart-, lewer- of nierprobleme het. Jou lewer- en/ of nierfunksie moet noukeurig deur jou dokter gemonitor word;
- as jy 'n bloedingsversteuring het;
- as jy hoë bloeddruk het, aangesien INDOMETHACIN BIOTECH 25 vloeistofretensie en swelling kan veroorsaak, en die toestand kan vererger;
- as jy enige risikofaktore vir hartsiektes het, soos hoë bloeddruk, hoë cholesterolvlakke, diabetes (hoë bloedsuikervlakke) of as jy 'n roker is;
- as jy 'n diuretikum (watertablet) neem (gebruik verminder waterretensie in jou liggaam);
- as jy 'n infeksie het, aangesien INDOMETHACIN BIOTECH 25 die tekens en simptome van 'n infeksie (bv. koors) kan masker;
- as jy enige probleme met jou oë ervaar terwyl jy INDOMETHACIN BIOTECH 25 neem. As jy rumatoïede artritis het, sal jou dokter dalk jou oë met tussenposes wil ondersoek tydens jou behandeling met INDOMETHACIN BIOTECH 25. Jy moet jou dokter sien as jy enige verandering in jou visie ondervind;
- as jy 'n bejaarde pasiënt is, kan jy meer geneig wees om die newe-effekte van INDOMETHACIN BIOTECH 25 te ervaar;
- as jy aan asma ly;
- as jy koors, erge veluitslag of velreaksie, geswelde kliere, blase op die vel, mond of oë, skubbeling van die vel, of enige ongewone reaksie soos gesigswelling ontwikkel wanneer behandeling met INDOMETHACIN BIOTECH 25 begin word, moet jy ophou om INDOMETHACIN BIOTECH 25 te neem en vertel jou dokter dadelik. Hierdie ernstige gebeurtenisse kan sonder waarskuwing plaasvind en kan dodelik wees. Dit sluit in DRESS (geneesmiddelreaksie met eosinofilie en sistemiese simptome), eksfoliatiewe dermatitis, Stevens-Johnson-sindroom en toksiese epidermale nekrolise (TEN);
- as jy enige simptome van óf maagseer óf bloeding ervaar terwyl jy INDOMETHACIN BIOTECH 25 neem, hou op om INDOMETHACIN BIOTECH 25 te neem en raadpleeg dadelik jou dokter;
- as jy ander medisyne neem wat jou risiko vir maagsere of bloeding kan verhoog, soos kortikosteroïede (wat gebruik word om ontsteekte dele van jou liggaam te behandel), antikoagulante of antiplaatjie-medisyne (wat gebruik word om jou bloed te verdun), soos warfarien en aspirien, en selektiewe serotonien heropname inhibeerders (SSRI's) (gebruik om depressie te behandel);
- as jy aan sistemiese lupus erythematosus (SLE), 'n outo-immuunafwyking of gemengde bindweefselafwykings ly;
- as jy 'n bloedstollingsversteuring (bloedingsversteuring) het;
- as jy pas 'n operasie gehad het aangesien INDOMETHACIN BIOTECH 25 jou bloedingstyd kan verhoog;
- moenie INDOMETHACIN BIOTECH 25 as 'n plaasvervanger vir aspirien as 'n voorkomende behandeling vir hartsiektes gebruik nie;
- as jy hoofpyn, duiseligheid of lighoofdigheid ervaar terwyl jy INDOMETHACIN BIOTECH 25 neem, moet jy dalk die dosis verminder en as jou hoofpyn voortduur ten spyte van die dosisvermindering, moet jy ophou om INDOMETHACIN BIOTECH 25 te neem;
- as jy INDOMETHACIN BIOTECH 25 vir 'n lang tyd gebruik en gereelde hoofpyne het, moet jy ophou om INDOMETHACIN BIOTECH 25 te neem en jou dokter te vertel;
- as jy hoë vlakke van kalium in jou bloed ervaar (hiperkalemie), bloedarmoede of enige lewer probleme terwyl jy INDOMETHACIN BIOTECH 25 neem;

Jy moet gereeld deur jou dokter gemonitor word vir enige ongewenste effekte van jou maag of ingewande, veral as jy INDOMETHACIN BIOTECH 25 vir 'n lang tyd gebruik.

Kinders:
Die veilige gebruik van INDOMETHACIN BIOTECH 25 by kinders is nie vasgestel nie. Kinders moet nie INDOMETHACIN BIOTECH 25 neem nie.

Ander medisyne en INDOMETHACIN BIOTECH 25
Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik (dit sluit alle komplementêre of tradisionele medisyne in).

Vertel jou dokter as jy enige van die volgende gebruik:
- ander niesteroïdale anti-inflammatoriese middels (NSAIDs), insluitend aspirien, diflunisal en siklooksigenase-2 selektiewe inhibeerders (gebruik om pyn en inflammasie te behandel). Diflunisal moet nie saam met INDOMETHACIN BIOTECH 25 geneem word nie (sien Moenie INDOMETHACIN BIOTECH 25 neem nie);
- teensuurmiddels (gebruik om die suur in jou maag te neutraliseer om sooibrand, spysvertering of 'n omgekrapte maag te verlig);
- antikoagulante (gebruik om bloedklonte te voorkom), soos warfarien;
- antidepressante (gebruik om depressie te behandel), soos SSRI's;
- antidiabetiese medisyne (gebruik om hoë bloedsuikervlakke te behandel), soos sulfonielureumderivate;
- antihipertensiewe medisyne (gebruik om hoë bloeddruk te behandel), soos diuretika of watertablette (bv. furosemied en triamtereen), angiotensien-omskakelende ensiem (ACE) inhi beerders, angiotensien-II-antagoniste, alfa-blokkers of beta-blokkers. INDOMETHACIN BIOTECH 25 en triamterene moet nie saam geneem word nie;
- antiplaatjie-medisyne (gebruik om jou bloed te verdun);
- antipsigotika (gebruik om geestesgesondheidstoestande te behandel), soos haloperidol;
- antivirale middels (gebruik om virale infeksies soos MIV te behandel), insluitend sidovudien en ritonavir;
- hartglikosiede (gebruik om hartversaking en 'n vinnige hartklop te behandel), soos digoksien;
- kalsineurien-inhibeerders of immuunonderdrukkende medisyne (wat gebruik word om orgaanverwerping na 'n oorplanting te voorkom), soos siklosporien of takrolimus;
- fenielpropanolamien (gebruik in verkoue- en griepmedisyne om verligting te bied vir 'n verstopte neus);
- kortikosteroïede (gebruik om ontsteekte areas van jou liggaam te behandel);
- sitotoksiese medisyne (wat gebruik word om sekere soorte kanker of outo-immuunafwykings te behandel), insluitend metotreksaat;
- desmopressien (gebruik vir die behandeling van nagtelike bednatmaak, sentrale diabetes insipidus, en verhoogde dors en urinering wat veroorsaak word deur kopchirurgie of koptrauma);
- litium (gebruik om gemoedsversteurings te behandel);
- mifepristoon (gebruik om 'n aborsie tydens die vroeë deel van 'n swangerskap te veroorsaak);
- spierverslappers (gebruik om spierspasmas te verlig), soos baklofen;
- pentoksifillien (gebruik om bloedvloei te verbeter);
- probenesied (gebruik om jig te behandel);
- kinoloon-antibiotika (gebruik om sekere bakteriële infeksies te behandel);
- salisilate, insluitend aspirien (gebruik om pyn, koors en inflammasie te behandel);
- tiludroonsuur (gebruik om Paget se siekte te behandel (gebreekte en vervormde bene en pyn in die aangetaste area));
- as jy bloedtoetse laat doen, want dit kan lei tot vals-negatiewe resultate.

INDOMETHACIN BIOTECH 25 saam met voedsel en drank:
Dit word aanbeveel dat INDOMETHACIN BIOTECH 25 saam met kos, melk of 'n teensuurmiddel geneem word om potensiële newe-effekte te verminder.

Swangerskap, borsvoeding en vrugbaarheid:
As 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 INDOMETHACIN BIOTECH 25 neem.
Moenie INDOMETHACIN BIOTECH 25 neem as jy swanger is of jou baba borsvoed nie (sien Moenie INDOMETHACIN BIOTECH 25 neem nie).
Die neem van INDOMETHACIN BIOTECH 25 kan dit vir jou moeiliker maak om swanger te raak.

Bestuur en gebruik van masjiene:
INDOMETHACIN BIOTECH 25 kan duiseligheid, lomerigheid, visuele versteurings en hoofpyne veroorsaak en jou vermoë om 'n voertuig te bestuur of masjinerie te gebruik, beïnvloed. Jy moet nie INDOMETHACIN BIOTECH 25 neem as jy masjinerie gebruik nie.
Dit is nie altyd moontlik om te voorspel tot watter mate INDOMETHACIN BIOTECH 25 kan inmeng met jou daaglikse aktiwiteite nie. Moenie aan bogenoemde aktiwiteite deelneem voordat jy bewus is van die mate waarin INDOMETHACIN BIOTECH 25 jou affekteer nie.

3. Hoe om INDOMETHACIN BIOTECH 25 te neem:
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd INDOMETHACIN BIOTECH 25 presies soos jou dokter of apteker vir jou gesê het. Gaan na jou dokter of apteker as jy nie seker is nie.
Gebruik die laagste effektiewe dosis vir die kortste moontlike tyd wat nodig is om simptome te beheer, aangesien dit kan help om newe-effekte te verminder.
Die dosis hang af van die mediese toestand wat behandel word. Jou dokter sal jou laat weet hoeveel jy moet neem.
Jou dokter sal jou vertel hoe lank jou behandeling met INDOMETHACIN BIOTECH 25 sal duur. Moenie behandeling vroeg staak nie, want jou dokter sal jou herstel monitor en jou adviseer wanneer om behandeling te staak.
As jy die indruk het dat die effek van INDOMETHACIN BIOTECH 25 te sterk of te swak is, of na 'n paar dae geen verbetering in jou toestand voel nie, vertel jou dokter of apteker.

Indien jy meer INDOMETHACIN BIOTECH 25 neem as wat jy moet:
In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.
Jou dokter sal jou simptome monitor en jou volgens jou toestand behandel.

Indien jy vergeet om INDOMETHACIN BIOTECH 25 te neem:
Neem die gemiste dosis sodra jy onthou. As dit egter amper tyd is vir jou volgende dosis, gaan voort om die volgende dosis op die gewone tyd te neem. Moenie 'n dubbeldosis neem om die vergete individuele dosisse op te maak nie.

As jy ophou om INDOMETHACIN BIOTECH 25 te neem
Jy moet INDOMETHACIN BIOTECH 25 neem vir so lank as wat jou dokter vir jou sê. Jy moet nie ophou om dit te neem sonder jou dokter se advies nie.

4. Moontlike newe-effekte
INDOMETHACIN BIOTECH 25 kan newe-effekte hê.
Nie alle newe-effekte wat vir INDOMETHACIN BIOTECH 25 aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien u algemene gesondheid versleg of as u enige nadelige effekte ervaar terwyl u INDOMETHACIN BIOTECH 25 neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om INDOMETHACIN BIOTECH 25 te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal;
- uitslag of jeuk;
- blase op die vel, mond, oë en geslagsdele aangesien dit kan wees as gevolg van 'n ernstige allergiese reaksie bekend as Stevens-Johnson-sindroom (SJS);
- uitbreek van letsels op die vel bekend as erythema multiforme;
- koors, griepagtige simptome, 'n pynlike rooi uitslag (kan perserige kolle insluit) wat versprei, en blase volg waar die boonste deel van die vel doodgaan en afdop, bekend as toksiese epidermale nekrolise (TEN);
- flou word.

Hierdie is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie op INDOMETHACIN BIOTECH 25 gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Indien enige van die volgende gebeur, hou op om INDOMETHACIN BIOTECH 25 te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- nekrotiserende fasciitis (NF) is 'n seldsame maar dodelike vinnig progressiewe sagteweefselinfeksie, wat gekenmerk word deur wydverspreide nekrose van die oppervlakkige fascia en die subkutane vet;
- tekens van herhalende infeksies, soos koors of seer keel (bloedkanker (gediagnoseer deur toetse wat deur jou dokter gedoen is));
- bloedafwykings wat onverklaarbare kneusing of bloeding kan veroorsaak, insluitend speldekop bloeding of neusbloeding;
- aanvalle/ toevalle;
- koma;
- aseptiese meningitis, veral by pasiënte met bestaande outo-immuunafwykings, soos sistemiese lupus erythematose of gemengde bindweefselsiekte (simptome insluitend stywe nek, hoofpyn, naarheid, braking, koors of disoriëntasie);
- hartaanval;
- beroerte (verlies van beweging of sensasie aan die een kant van jou liggaam, probleme met praat of beweeg);
- veranderinge in die manier waarop jou hart klop, vinniger as normaal klop of 'n klop oorslaan;
- hartversaking of borspyn;
- tromboflebitis (inflammatoriese proses wat veroorsaak dat 'n bloedklont in jou are vorm wat warmte, pyn, swelling en rooiheid in die aangetaste area veroorsaak);
- moeilike asemhaling, kortasem, asma;
- pulmonêre eosinofilie (PE) (die infiltrasie van eosinofiele in die longkompartemente wat lugweë, interstitium en alveoli vorm, verhoogde eosinofiele in die longe kom voor met borspyn, droë hoes, koors);
- maagseer, perforasie of bloeding (pyn van jou maagarea, naarheid, braking, onverklaarbare gewigsverlies, donker stoelgang, bloederige braking);
- melaena verwys na donker teeragtige stoelgang wat gewoonlik 'n aanduiding is van bloeding in die spysverteringskanaal;
- verergering van kolitis en Crohn se siekte;
- hematemese (braking van bloed);
- vergeling van jou vel en oë, donker uriene en moegheid wat simptome van lewerprobleme kan wees, insluitend geelsug of hepatitis;
- blokkasie van vloei van gal uit die lewer (cholestase) met simptome soos erge pyn in die maag en rug;
- veranderinge in bloed en lewerensieme wanneer toetse gedoen word;
- nierprobleme, bloed in jou uriene, nierversaking, gereelde urinering of hoë vlakke van ureum in jou bloed wat aandui dat die niere nie goed werk nie.
- INDOMETHACIN BIOTECH 25, veral wanneer dit gebruik word teen hoër as aanbevole dosisse of vir 'n lang tydperk, kan skade aan jou niere veroorsaak en dit beïnvloed om niesure behoorlik uit jou bloed in die uriene te verwyder nie (renale tubulerê asidose). Dit kan ook baie lae vlakke van kalium in jou bloed veroorsaak (sien Waarskuwings en voorsorgmaatreëls) Tekens en simptome sluit spierswakheid en lighoofdigheid in.

Hierdie is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige reaksie op INDOMETHACIN BIOTECH 25 gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter as jy enige van die volgende opmerk:
Newe-effekte wat gereeld voorkom:
- verwarring, angstigheid, onvermoë om te slaap, 'n toestand waarin 'n mens se gedagtes en gevoelens onwerklik lyk of nie aan jouself behoort nie;
- geestesversteurings en verergering van hierdie afwykings;
- psigotiese episodes;
- hoofpyn, duiseligheid, lighoofdigheid;
- ontsteking van die senuwee in jou oog;
- gesuis van jou ore (tinnitus);
- rooiheid van jou vel;
- inflammasie van jou bloedvate;
- fotosensitiwiteit (sensitiwiteit van jou vel vir lig).

Newe-effekte wat minder gereeld voorkom:
- hoë bloedsuikervlakke (verhoogde dors en urinering), of oortollige suiker in jou uriene;
- hoë vlakke van kalium in jou bloed (borspyn, hartkloppings, swakheid, gevoelloosheid, naarheid of braking);
- vertigo (spinnende sensasie);
- moegheid (swakheid/ moegheid);
- onwillekeurige spierbeweging; siekte wat perifere senuwees aantas;
- sukkel om te praat;
- parkinsonisme ('n groep neurologiese afwykings wat bewegingsprobleme veroorsaak soortge lyk aan dié wat in Parkinson se siekte gesien word soos bewing, stadige beweging en styfheid);
- spierswakheid;
- versteurings van jou sig, versteurde visie of dubbelvisie, pyn van jou oog of weefsel rondom jou oog;
- blosing (rooiheid van jou vel);
- neusbloeding;
- voel dat jy 'n stoelgang wil hê al is jou ingewande leeg, inflammasie van jou anus, of bloeding, pyn, brandende sensasie, jeuk of ongemak van die anale area;

Newe-effekte wat mag voorkom, maar die frekwensie is nie bekend nie:
- voel depressief;
- lomerigheid;
- sukkel om te slaap;
- hallusinasies (sien of hoor dinge wat nie werklik is nie)
- neerslae op die kornea van jou oog (waterige oë, droë oë, ligsensitiwiteit, pyn, sensasie van iets in jou oog);
- gehoorversteurings, doofheid;
- hoë bloeddruk;
- naarheid (siek voel), braking (siek wees);
- verergering van psoriase (skubbe en rooi kolle wat jeuk en soms pynlik is)
- haarverlies;
- sweet;
- spierswakheid, versnelling van kraakbeenafbreking;
- proteïenurie, 'n toestand wat gekenmerk word deur die teenwoordigheid van groter as normale hoeveelhede proteïen in jou uriene;
- borsveranderinge (insluitend vergroting, teerheid of verhoogde hoeveelheid borsweefsel by mans);
- vaginale bloeding.

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

Aanmelding van newe-effekte
As jy newe-effekte kry, praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van INDOMETHACIN BIOTECH 25 te verskaf.

5. Hoe om INDOMETHACIN BIOTECH 25 te bewaar
- Bewaar teen of benede 25 °C in 'n droë plek.
- Beskerm teen lig.
- Bewaar alle medisyne buite bereik van kinders.
- Moenie die kapsules na die vervaldatum wat op die verpakking gedruk is, gebruik nie.
- Gee alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting
Wat INDOMETHACIN BIOTECH 25 bevat:
Die aktiewe bestanddeel is 25 mg indometasien per kapsule.
Die ander bestanddele is kolloïdale silikoondioksied (Aerosil), magnesiumstearaat, voorafgelatineerde stysel, natriumlaurielsulfaat, talk en die kapsuledop (wat eritrosien, kinoleengeel, titaandioksied bevat).

Hoe INDOMETHACIN BIOTECH 25 lyk en die inhoud van die verpakking:
Ondeursigtige, geel, harde gelatienkapsule wat 'n wit poeier bevat.
INDOMETHACIN BIOTECH 25-kapsules word verskaf in wit polipropileen-sekurithouers van 100 en 500 kapsules, amberglasbottels van 100 en 500 kapsules, terwyl hoëdigtheid poliëtileenhouers van 500 en 1000 kapsules van 500 en 1 000 kapsules en stulpstroke aluminium en PVC aluminium stroke 15 en 84 kapsules bevat.
Nie alle pakgroottes word dalk bemark nie.

Houer van registrasiesertifikaat:
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Hierdie pamflet is laas hersien:
06 Julie 2023

Registrasienommer:
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18 Augustus 1987