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 nonsurgical 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, breastfeeding 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 include 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 effects:

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 1000 capsules, and PVC/ aluminium blisters of 15 and 84 capsules.
Not all pack sizes may be marketed.

Holder of certificate of registration:

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road

Randjespark, Halfway House

Midrand 1685

Tel no.: +27 11 848 3050

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