CELECOXIB BIOTECH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

CELECOXIB 100 mg BIOTECH, hard capsules
CELECOXIB 200 mg BIOTECH, hard capsules
Celecoxib

Contains sugar (lactose).
CELECOXIB 100 BIOTECH: Each capsule contains 25,0 mg lactose monohydrate.
CELECOXIB 200 BIOTECH: Each capsule contains 50,0 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking CELECOXIB BIOTECH
- 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.
- CELECOXIB BIOTECH has been prescribed for you personally and you should not share the medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CELECOXIB BIOTECH is and what it is used for
2. What you need to know before you take CELECOXIB BIOTECH
3. How to take CELECOXIB BIOTECH
4. Possible side effects
5. How to store CELECOXIB BIOTECH
6. Contents of the pack and other information

1. What CELECOXIB BIOTECH is and what it is used for

CELECOXIB BIOTECH belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs), and specifically a sub-group known as cyclooxygenase-2 (COX-2) inhibitors.
Your body makes substances called prostaglandins. Some prostaglandins cause pain and inflammation. In conditions such as rheumatoid arthritis and osteoarthritis your body makes more of these. CELECOXIB BIOTECH acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.
CELECOXIB BIOTECH is used in adults for the relief of signs and symptoms of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis (progressive stiffening of the spine).
CELECOXIB BIOTECH is also used in the treatment of pain following an operation, including dental surgery, musculoskeletal pain, primary dysmenorrhoea (painful menstrual periods).

2. What you need to know before you take CELECOXIB BIOTECH

Do not take CELECOXIB BIOTECH:
- if you are hypersensitive (allergic) to celecoxib or any of the ingredients of CELECOXIB BIOTECH (see section 6 "What this product contains");
- if you have had an allergic reaction to a group of medicines called "sulphonamides" (medicines that prevent the growth of bacteria);
- if you have severe liver disease;
- if you have severe kidney disease;
- if you have had allergic reactions such as asthma, nose polyps, severe nasal congestion, or an itchy skin rash, swelling of the face, lips, tongue or throat, breathing difficulties or wheezing from aspirin or other NSAIDs (anti-inflammatory and pain-relieving medicines, such as diclofenac, ibuprofen);
- established ischaemic heart disease, or cerebrovascular disease, e.g., you have been diagnosed with a heart attack, stroke, or blockages of blood vessels to the heart or brain;
- if you are about to have coronary artery bypass graft surgery;
- if you currently have an ulcer in your stomach or intestines, or if you are bleeding in your stomach or intestines (you may notice that you have black sticky stools or bloody diarrhoea);
- if you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease;
- if you are pregnant or it is possible that you could become pregnant;
- if you are breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking CELECOXIB BIOTECH:

Take special care with CELECOXIB BIOTECH:
- if you smoke, have diabetes, high blood pressure or high blood cholesterol;
- if you have had a serious allergic reaction or a serious skin reaction to any medicines;
- if you have previously had an ulcer or bleeding in your stomach or intestines. (Do not take CELECOXIB BIOTECH if you currently have an ulcer or bleeding in your stomach or intestine);
- if you are taking corticosteroid medicines (for example prednisone);
- if you are taking aspirin (even at low dose for heart protective purposes);
- if you use medicines to reduce blood clotting (e.g. warfarin/warfarin-like anticoagulants or novel oral anti-clotting medicines, e.g. apixaban).
- if you are taking CELECOXIB BIOTECH at the same time as other non-aspirin NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided;
- if you have fluid retention (such as swollen ankles and feet);
- if you have heart failure or other heart problems;
- if you have high blood pressure;
- if your liver or kidneys are not working well, as your doctor may want to keep a regular check on you;
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (medicines used to treat excess fluid in the body);
- if you feel ill due to an infection or think you have an infection, as CELECOXIB BIOTECH may mask a fever or other signs of infection and inflammation.

If you are above 65 years of age your doctor will want to monitor you regularly.
The consumption of alcohol and NSAIDs may increase the risk of gastrointestinal problems.

CELECOXIB BIOTECH may lead to an increase in blood pressure. Your doctor may want to monitor your blood pressure on a regular basis.
Some cases of severe liver reactions, including severe liver inflammation, liver damage, liver failure (some with fatal outcome or requiring liver transplant), have been reported with celecoxib. Of the cases that reported time to onset, most severe liver reactions occurred within one month of start of treatment.

CELECOXIB BIOTECH might increase the likelihood of developing renal tubal acidosis (RTA) (a kidney disease where your kidneys do not remove acids from your blood into the urine as they should) and hypokalaemia (low potassium levels in your blood causing weakness, confusion, tirednes, muscle cramps or changes in the way your heart beats).

Other medicines and CELECOXIB BIOTECH

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

Before you take CELECOXIB BIOTECH, make sure your doctor knows if you are taking the following medicines:
- Warfarin (used to prevent blood from clotting).
- ACE inhibitors, angiotensin II receptor antagonists, beta blockers (used for high blood pressure and heart failure).
- Diuretics (used to treat fluid retention).
- Ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants).
- Aspirin (used for pain and fever). CELECOXIB BIOTECH can be taken with low dose aspirin (75 mg or less daily). Ask your doctor for advice before taking both medicines together. CELECOXIB BIOTECH has no antiplatelet effect and is therefore not a substitute for aspirin for prevention of thrombosis.
- Neuroleptics (used to treat some mental disorders).
- Medicines for anxiety (diazepam) or to treat depression (citalopram, imipramine).
- Medicines to treat an irregular heartbeat (amiodarone, quinidine).
- Dextromethorphan (used to treat coughs).
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia).
- Lithium (used to treat some types of depression).
- Oral contraceptives.
- Glibenclamide, tolbutamide (medicines used in the management of type 2 diabetes).
- Phenytoin, a medicine used in epilepsy (seizure disorder).
- Fluconazole (used to treat fungal infections).
- Rifampicin (used to treat bacterial infections).
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression).
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders).
- Ketoconazole (an antifungal medicine).
- Antacids (used for heartburn).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking CELECOXIB BIOTECH.

Pregnancy

CELECOXIB BIOTECH must not be used by women who are pregnant or can become pregnant (i.e. women of childbearing potential who are not using adequate contraception) during ongoing treatment. If you become pregnant during treatment with CELECOXIB BIOTECH, you should discontinue the treatment and contact your doctor for alternative treatment.

Breastfeeding

CELECOXIB BIOTECH must not be used during breastfeeding.

Fertility

NSAIDs, including CELECOXIB BIOTECH, may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

You should be aware of how you react to CELECOXIB BIOTECH before you drive or operate machinery. If you feel dizzy or drowsy after taking CELECOXIB BIOTECH, do not drive or operate machinery until these effects wear off.

CELECOXIB BIOTECH contains lactose monohydrate

CELECOXIB BIOTECH contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CELECOXIB BIOTECH.

3. How to take CELECOXIB BIOTECH

Do not share medicines prescribed for you with any other person.
Always take CELECOXIB BIOTECH exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.
If you think or feel that the effect of CELECOXIB BIOTECH is too strong or too weak, talk to your doctor or pharmacist.

Use the lowest effective dose for the shortest possible time.
Your doctor will tell you what dose you should take.

The recommended dose for osteoarthritis is 200 mg taken as a single dose, or as two divided doses.
The recommended dose for rheumatoid arthritis is 100 mg or 200 mg twice daily.
The recommended dose for pain following dental surgery is 100 mg or 200 mg twice daily.
The recommended dose for pain following an operation is 200 mg once daily.
The recommended dose for musculoskeletal pain is 200 mg twice daily.
The recommended dose for primary dysmenorrhoea is 400 mg initially, followed by an additional 200 mg on the first day if needed. On subsequent days, the recommended dose is 200 mg twice daily.
The recommended dose for ankylosing spondylitis is 200 mg daily, taken as a single dose or as 100 mg twice daily.
If you have liver problems, or if you weigh less than 50 kg, your doctor will recommend the lowest recommended dose.

Children

No information is available on the use of CELECOXIB BIOTECH in children and it is therefore not recommended for use in children.

Method of administration

CELECOXIB BIOTECH is for oral use. Swallow the capsules whole with a glass of water at any time of the day, with or without food. However, try to take each dose of CELECOXIB BIOTECH at the same time each day. Do not chew or crush the granules.
Contact your doctor within two weeks of starting treatment if you do not experience any benefit.

If you take more CELECOXIB BIOTECH than you should

You should not take more capsules than your doctor tells you to.
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 CELECOXIB BIOTECH

If you forget to take a capsule, take it as soon as you remember.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking CELECOXIB BIOTECH

Suddenly stopping your treatment with CELECOXIB BIOTECH may lead to your symptoms getting worse. Do not stop taking CELECOXIB BIOTECH unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If any of the following happens, stop taking CELECOXIB BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- a serious skin reaction with rash, blistering or peeling of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to CELECOXIB BIOTECH. 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:
- weakness or clumsiness of a hand, arm or leg, difficulties with speech and swallowing, vision problems and headache. These may be signs of a stroke or bleeding in the brain, which may be fatal;
- shortness of breath or difficulty breathing, sudden chest pain, cramping or tingling sensation up the left arm (heart attack);
- problems breathing, shortness of breath, chest pain. You may have a blood clot in the lung (pulmonary embolism) and will need urgent medical attention;
- throbbing or cramping pain in a leg, swelling in a leg, warm skin around painful area (deep vein thrombosis);
- severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained stools, or vomiting blood;
- liver failure (symptoms may include nausea (feeling sick), diarrhoea, jaundice (your skin or the whites of your eyes look yellow);
- bladder or kidney infections. Some signs may be fever, chills, blood in the urine or frequent urination;
- acute renal failure/nephrotic syndrome (decreased urine output, swelling of legs, fatigue, foamy urine, loss of appetite);
- painful blisters, sensitive to touch (shingles);
- red, swollen, painful skin with fever (a bacterial skin infection, known as erysipelas);
- ache or burning pain in your abdomen (Helicobacter infection).

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:
- infections of the airways such as sinusitis (swelling and redness of the nasal sinuses) or bronchitis (inflammation of the mucous membranes of the airways);
- worsening of existing allergies;
- weight gain;
- trouble sleeping;
- dizziness, abnormal muscle tension;
- headache;
- high blood pressure, worsening of existing high blood pressure. you may not know that you have high blood pressure unless you have your blood pressure tested;
- runny nose, sore throat, shortness of breath;
- nausea (feeling sick), vomiting (being sick);
- indigestion, windiness, pain on stomach;
- problem swallowing;
- sore teeth;
- skin rash, itching skin;
- accidental injury;
- flu-like illness;
- keeping fluid back in the body tissues, with swollen ankles, legs and/or hands.

Less frequent side effects:
- inflammation or infection of the inner ear (dizziness or feeling that everything is spinning around you);
- infection of the gums;
- blood disorders, such as anaemia (too few red blood cells or their haemoglobin content is too low), leukopenia (a lowered white blood cell count) or thrombocytopenia (deficiency of platelets in the blood)*;
  * You will only know that you have these disorders if your doctor orders blood tests. See your doctor if you are pale and tired, get more infections than usual or have problems to stop bleeding, or if you have unexpected bruising.
- increased sodium in blood, increased potassium in blood (determined by blood tests);
- feeling tired, confused;
- feeling anxious or depressed;
- seeing or hearing things that do not exist (hallucinations);
- blurred vision, eye inflammation and bloodshot eyes, vitreous floaters (seeing spots or strings that move when you move your eyes), bleeding in an eye, painful eyes;
- ringing in the ears, above normal hearing sense, voice disorder;
- irregular heart rhythm, increased heart rate;
- Flushing;
- inflammation of a blood vessel (you may feel unwell with fever, sweats and tiredness);
- tightness in the chest with coughing and wheezing (bronchospasm);
- shortness of breath, cough, fatigue (inflammation of the lung tissues - pneumonitis);
- abdominal pain, cramping, bloating, constipation;
- mouth ulcers, numbness, burning sensation in the mouth (stomatitis);
- hair loss;
- muscle spasms (leg cramps), muscle pain;
- lower limb fracture;
- kidney function disorders (shown by laboratory tests);
- frequent urination during the night (nocturia);
- menstrual disorders;
- swollen face;
- chest pain.

Frequency unknown:
- sleepiness;
- abnormal skin sensations (tingling or tickling or itching or burning);
- problems with coordination and speech (ataxia);
- no sense of smell or taste, or taste affected;
- worsening of existing epilepsy (seizure disorder);
- female fertility decreased;
- vaginal bleeding;
- tender breasts.

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 CELECOXIB BIOTECH.

5. How to store CELECOXIB BIOTECH

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or blister strips.
- 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 CELECOXIB BIOTECH contains

The active substance is celecoxib.
1 capsule contains 100 mg or 200 mg celecoxib.
CELECOXIB 100 BIOTECH: Each capsule contains 100 mg celecoxib.
CELECOXIB 200 BIOTECH: Each capsule contains 200 mg celecoxib.

The other ingredients are croscarmellose sodium, gelatine, lactose monohydrate, magnesium stearate (E572), povidone (E1201), sodium lauryl sulfate and titanium dioxide (E171).

Printing ink:
CELECOXIB 100 BIOTECH: FD&C blue No. 1 aluminium lake (E132), propylene glycol (E1520) and shellac.
CELECOXIB 200 BIOTECH: Propylene glycol (E1520), shellac and iron oxide yellow (E172).

What CELECOXIB BIOTECH looks like and contents of the pack

CELECOXIB 100 BIOTECH: Hard gelatine capsules, size "3", imprinted with "135" on the opaque white body in blue ink and "A" on the opaque white cap in blue ink, filled with white to off-white coloured granular powder.
CELECOXIB 200 BIOTECH: Hard gelatine capsules, size "1", imprinted with "136" on the opaque white body in golden yellow ink and "A" on the opaque white cap in golden yellow ink, filled with white to off-white coloured granular powder.

CELECOXIB BIOTECH is packed in transparent PVC/PE/PVDC and aluminium foil blister strips and placed in an outer carton.
CELECOXIB BIOTECH is packed in silver aluminium/aluminium blister strips and placed in an outer carton.
Pack sizes:
CELECOXIB 100 BIOTECH: 60 capsules
CELECOXIB 200 BIOTECH: 10, 15 or 30 capsules.
Not all pack sizes or container types may be marketed.

Holder of certificate of registration

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CELECOXIB BIOTECH

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS
S3

CELECOXIB 100 mg BIOTECH, harde kapsules
CELECOXIB 200 mg BIOTECH, harde kapsules
Selekoksib

Bevat suiker (laktose).
CELECOXIB 100 BIOTECH: Elke kapsule bevat 25 mg laktosemonohidraat.
CELECOXIB 200 BIOTECH: Elke kapsule bevat 50 mg laktosemonohidraat.

Lees die hele pamflet noukeurig deur voordat jy begin om CELECOXIB BIOTECH te neem
- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- CELECOXIB BIOTECH 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 CELECOXIB BIOTECH is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy CELECOXIB BIOTECH neem
3. Hoe om CELECOXIB BIOTECH te neem
4. Moontlike newe-effekte
5. Hoe om CELECOXIB BIOTECH te bewaar
6. Inhoud van die pak en ander inligting

1. Wat CELECOXIB BIOTECH is en waarvoor dit gebruik word

CELECOXIB BIOTECH behoort aan 'n groep medisyne genaamd niesteroïdale anti-inflammatoriese middels (NSAID's), en spesifiek 'n subgroep bekend as siklooksigenase-2 (COX-2) inhibeerders. Jou liggaam maak stowwe wat prostaglandiene genoem word. Sommige prostaglandiene veroorsaak pyn en inflammasie. In toestande soos rumatoïede artritis en osteoartritis maak jou liggaam meer hiervan. CELECOXIB BIOTECH tree op deur die produksie van prostaglandiene te verminder en sodoende die pyn en inflammasie te verminder.
CELECOXIB BIOTECH word by volwassenes gebruik vir die verligting van tekens en simptome van rumatoïede artritis, osteoartritis en ankiloserende spondilitis (progressiewe verstywing van die ruggraat).
CELECOXIB BIOTECH word ook gebruik in die behandeling van pyn na 'n operasie, insluitend tandheelkundige chirurgie, muskuloskeletale pyn, primêre dysmenorree (pynlike menstruasieperiodes).

2. Wat jy moet weet voordat jy CELECOXIB BIOTECH neem

Moenie CELECOXIB BIOTECH neem nie:
- indien jy hipersensitief (allergies) is vir selekoksib of enige van die ander bestanddele van CELECOXIB BIOTECH (sien afdeling 6 "Wat hierdie produk bevat");
- indien jy 'n allergiese reaksie gehad het vir 'n groep van medisyne genaamd "sulfonamiede" (medisyne wat die groei van bakterieë voorkom);
- indien jy ernstige lewersiekte het;
- indien jy ernstige niersiekte het;
- indien jy allergiese reaksies soos asma, neuspoliepe, erge neusverstopping, of 'n jeukende veluitslag, swelling van die gesig, lippe, tong of keel, asemhalingsprobleme of hyg van aspirien of ander NSAID's (anti-inflammatoriese en pynstillende medisyne, soos diklofenak, ibuprofen) gehad het;
- gevestigde isgemiese hartsiekte, of serebrovaskulêre siekte, bv. jy is gediagnoseer met 'n hartaanval, beroerte, of blokkasies van bloedvate na die hart of brein;
- indien jy op die punt staan om 'n koronêre aaromleidingsoperasie te ondergaan;
- as jy tans 'n ulkus/ seer in jou maag of ingewande het, of as jy in jou maag of ingewande bloei (jy mag dalk agterkom dat jy swart taai stoelgang of bloederige diarree het);
- as jy 'n inflammatoriese siekte van die ingewande het soos ulseratiewe kolitis of Crohn se siekte;
- indien jy swanger is of indien dit moontlik is dat jy swanger mag raak;
- indien jy borsvoed.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of apteker voordat jy CELECOXIB BIOTECH neem:
Neem spesiale sorg met CELECOXIB BIOTECH:
- indien jy rook, diabetes het, hoë bloeddruk of hoë bloed cholesterol; het;
- indien jy 'n ernstige allergiese reaksie of 'n ernstige velreaksie op enige medisyne gehad het;
- indien jy voorheen 'n ulkus/ seer of bloeding in jou maag of ingewande gehad het. (Moenie CELECOXIB BIOTECH neem as jy tans 'n ulkus/ seer of bloeding in jou maag of ingewande het nie);
- indien jy kortikosteroïedmedisyne (byvoorbeeld prednisoon) gebruik;
- indien jy aspirien gebruik (selfs teen 'n lae dosis vir hartbeskermingsdoeleindes);
- indien jy medisyne gebruik om bloedstolling te verminder (bv. warfarien/ warfarien-agtige antikoagulante of nuwe orale anti-stolling medisyne, bv. apiksaban).
- indien jy CELECOXIB BIOTECH gelyktydig met ander nie-aspirien NSAIDs soos ibuprofen of diklofenak neem. Die gebruik van hierdie medisyne saam moet vermy word;
- indien jy vloeistofretensie het (soos geswelde enkels en voete);
- indien jy hartversaking het of ander hartprobleme;
- indien jy hoë bloeddruk het;
- indien jou lewer en niere nie goed werk nie, aangesien jou dokter dalk gereeld na jou wil kyk;
- as jy gedehidreer is, byvoorbeeld weens siekte, diarree of die gebruik van diuretika (medisyne wat gebruik word om oortollige vloeistof in die liggaam te behandel);
- as jy siek voel weens 'n infeksie of dink jy het 'n infeksie, aangesien CELECOXIB BIOTECH 'n koors of ander tekens van infeksie en ontsteking kan masker.

Indien jy ouer as 65 jaar is, sal jou dokter jou gereeld wil monitor. Die gebruik van alkohol en NSAID's kan die risiko van gastro-intestinale probleme verhoog.

CELECOXIB BIOTECH kan lei tot 'n toename in bloeddruk. Jou dokter sal dalk jou bloeddruk op 'n gereelde basis wil monitor. Sommige gevalle van ernstige lewerreaksies, insluitend ernstige lewerontsteking, lewerskade, lewerversaking (sommige met noodlottige uitkoms of wat leweroorplanting benodig), is met seleksib aangemeld. Van die gevalle wat tyd tot aanvang gerapporteer het, het die meeste ernstige lewerreaksies binne een maand na aanvang van behandeling plaasgevind.

CELECOXIB BIOTECH kan die waarskynlikheid verhoog om nierbuisasidose (RTA) te ontwikkel ('n niersiekte waar jou niere nie sure uit jou bloed in die uriene verwyder soos hulle moet nie) en hipokalemie (lae kaliumvlakke in jou bloed wat swakheid, verwarring, moegheid, spierkrampe of veranderinge in jou hart veroorsaak).

Ander medisyne en CELECOXIB BIOTECH
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Voordat jy CELECOXIB BIOTECH neem, maak seker dat jou dokter weet indien jy die volgende medisyne neem:
- Warfarien (gebruik om te verhoed dat bloed stol).
- ACE inhibeerders, angiotensien II reseptorantagoniste, betablokkers (gebruik vir hoë bloeddruk en hartversaking).
- Diuretika (gebruik om vloeistofretensie te behandel).
- Siklosporien en takrolimus (gebruik vir immuunstelselonder-drukking, bv. na oorplantings).
- Aspirien (gebruik vir pyn en koors). CELECOXIB BIOTECH kan geneem word met 'n lae dosis aspirien (75 mg of minder daagliks). Vra jou dokter vir advies voordat jy albei medisyne saam neem. CELECOXIB BIOTECH het geen bloedplaatjie-effek nie en is dus nie 'n plaasvervanger vir aspirien vir die voorkoming van trombose nie.
- Neuroleptika (word gebruik om sekere geestesversteurings te behandel).
- Medisyne vir angs (diasepam) of om depressie te behandel (sitalopram, imipramien)
- Medisyne om 'n onreëlmatige hartklop (amiodaroon, kinidien) te behandel.
- Dekstrometorfan (gebruik om hoes te behandel).
- Metotreksaat (word gebruik vir die behandeling van rumatoïede artritis, psoriase en leukemie).
- Litium (word gebruik om sommige tipes depressie te behandel).
- Orale voorbehoedmiddels.
- Glibenklamied, tolbutamied (medisyne wat gebruik word in die hantering van tipe 2-diabetes).
- Fenitoïen, 'n medisyne wat gebruik word in epilepsie (aanvalstoornis).
- Flukonasool (gebruik om swaminfeksies te behandel).
- Rifampisien (gebruik om bakteriële infeksies te behandel).
- Karbamasepien (gebruik om epilepsie/ stuiptrekkings en sommige vorms van pyn of depressie te behandel).
- Barbiturate (gebruik om epilepsie/ stuptrekkings en sommige slaapversteurings te behandel).
- Ketokonasool ('n stenswammiddel).
- Teensuurmiddels (gebruik vir sooibrand).

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, dink dat jy dalk mag swanger wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy CELECOXIB BIOTECH neem.

Swangerskap
CELECOXIB BIOTECH moet nie gebruik word deur vroue wat swanger is of swanger kan word nie (d.w.s. vroue van vrugbare potensiaal wat nie voldoende voorbehoeding gebruik nie) tydens voortgesette behandeling. As jy swanger raak tydens behandeling met CELECOXIB BIOTECH, moet jy die behandeling staak en jou dokter kontak vir alternatiewe behandeling.

Borsvoeding
CELECOXIB BIOTECH moet nie gebruik word gedurende borsvoeding nie.

Vrugbaarheid
NSAID's, insluitend CELECOXIB BIOTECH, kan dit moeiliker maak om swanger te raak. Jy moet jou dokter vertel as jy van plan is om swanger te word of as jy probleme ondervind om swanger te raak.

Bestuur en gebruik van masjinerie
Jy moet bewus wees van hoe jy reageer op CELECOXIB BIOTECH voordat jy bestuur of masjinerie hanteer. Indien jy duiselig of slaperig voel nadat jy CELECOXIB BIOTECH geneem het, moenie bestuur of masjinerie hanteer totdat hierdie effekte afweer nie.

CELECOXIB BIOTECH bevat laktosemonohidraat
CELECOXIB BIOTECH bevat laktose ('n tipe suiker). Indien jy deur jou dokter vertel is dat jy 'n onverdraagsaamheid het vir sekere suikers, kontak jou dokter voordat jy CELECOXIB BIOTECH neem.

3. Hoe om CELECOXIB BIOTECH te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd CELECOXIB BIOTECH presies soos jou dokter of apteker vir jou vertel het. Jy moet seker maak by jou dokter of apteker indien jy nie seker is nie.
Indien jy dink of voel dat die effek van CELECOXIB BIOTECH te sterk of te swak is, praat met jou dokter of apteker.

Gebruik die laagste effektiewe dosis vir die kortste moontlike tydperk.
Jou dokter sal jou vertel watter dosis jy moet neem.

Die aanbevole dosis vir osteoartritis is 200 mg geneem as 'n enkele dosis of as twee verdeelde dosisse.
Die aanbevole dosis vir rumatoïede artritis is 100 mg of 200 mg twee keer per dag.
Die aanbevole dosis vir pyn na tandheelkundige operasies is 100 mg of 200 mg twee keer per dag.
Die aanbevole dosis vir pyn na 'n operasie is 200 mg eenkeer per dag.
Die aanbevole dosis vir muskuloskeletale pyn is 200 mg twee keer per dag.
Die aanbevole dosis vir primêre dismenorree is 400 mg aanvanklik, gevolg deur 'n addisionele 200 mg op die eerste dag indien benodig. Op die volgende dae is die aanbevole dosis 200 mg twee keer per dag.
Die aanbevole dosis vir ankiloserende spondilitis is 200 mg daagliks, geneem as 'n enkele dosis of as 100 mg twee keer per dag.
Indien jy lewerprobleme het of indien jy minder as 50 kg weeg, sal jou dokter die laagste aanbevole dosis aanbeveel.

Kinders
Geen inligting is beslkikbaar oor die gebruik van CELECOXIB BIOTECH in kinders nie, en is daarom nie aanbeveel vir gebruik in kinders nie.

Metode van toediening
CELECOXIB BIOTECH is vir orale gebruik. Sluk die kapsules heel met 'n glas water enige tyd van die dag, met of sonder voedsel. Probeer egter om elke dosis van CELECOXIB BIOTECH op dieselfde tyd elke dag te neem. Moenie die granules kou of fynmaak nie.
Kontak jou dokter binne twee weke van die begin van die behandeling indien jy geen voordeel ervaar nie.

Indien jy meer CELECOXIB BIOTECH neem as wat jy moet
Jy moenie meer kapsules neem as wat jou dokter jou vertel het nie.
In die geval van oordosis, raadpleeg jou dokter of apteker.
Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om CELECOXIB BIOTECH te neem
Indien jy vergeet om 'n kapsule te neem, neem dit so gou as wat jy daarvan onthou. Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Indien jy ophou om CELECOXIB BIOTECH te neem
Deur skielik jou behandeling met CELECOXIB BIOTECH te staak, mag lei tot jou simptome wat erger raak. Moenie ophou om CELECOXIB BIOTECH te neem tensy jou dokter jou vertel het om op te hou nie. Jou dokter mag jou vertel om die dosis oor 'n paar dae te verlaag voordat jy heeltemal ophou om dit te neem.
Indien jy enige verdere vrae het oor die gebruik van hierdie medisyne, vra jou dokter of apteker.

4. Moontlike newe-effekte

CELECOXIB BIOTECH kan newe-effekte hê.
Nie alle newe-effekte wat vir CELECOXIB BIOTECH aangemeld is word in hierdie pamflet beskryf nie. Sou jou algemene gesondheid versleg of indien jy enige ongewensde effekte ervaar terwyl jy CELECOXIB BIOTECH neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om CELECOXIB BIOTECH te neem en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- swelling van jou hande, voete, enkels, gesig, lippe en mond of keel wat moeilike sluk of moeilike asemhaling mag veroorsaak;
- 'n ernstige velreaksie met uitslag, blasies of afskilfering van die vel.

Hierdie is almal baie ernstige newe-effekte. Indien jy hulle het mag jy dalk 'n ernstige reaksie op CELECOXIB BIOTECH gehad het. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- swakheid of lompheid van 'n hand, arm of been, probleme met spraak en sluk, sigprobleme en hoofpyn. Dit kan tekens wees van 'n beroerte of bloeding in die brein, wat dodelik kan wees;
- kortasem of moeilike asemhaling, skielike borspyn, krampe of tintelende sensasie op die linkerarm (hartaanval);
- probleme met asemhaling, kortasem, borspyn. Jy kan 'n bloedklont in die long hê (pulmonêre embolisme) en sal dringende mediese aandag benodig;
- kloppende of krampende pyn in 'n been, swelling in 'n been, warm vel rondom pynlike area (diepveneuse trombose);
- erge maagpyn of enige teken van bloeding in die maag of ingewande, soos die verbygaan van swart of bloedbevlekte stoelgang, of braking van bloed;
- lewerversaking (simptome kan naarheid (siek voel), diarree, geelsug insluit (jou vel of die wit van jou oë lyk geel));
- blaas- of nierinfeksies. Sekere tekens mag koors, kouekoors, bloed in die uriene en gereelde urinering insluit;
- akute nierversaking/ nefrotiese sindroom (verminderde urienproduksie, swelling van bene, moegheid, skuimerige uriene, verlies aan eetlus);
- pynlike blase, sensitief vir aanraking (gordelroos);
- rooi, geswelde, pynlike vel met koors ('n bakteriële velinfeksie, bekend as erisipelas);
- pyn of brandpyn in jou buik (Helicobacter-infeksie).

Hierdie is almal ernstige newe-effekte. Jy mag dalk dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- infeksies van die lugweë soos sinusitis (swelling en rooiheid van die nasale sinusse) of brongitis (ontsteking van die slymvliese van die lugweë);
- verergering van bestaande allergieë;
- gewigstoename;
- sukkel om te slaap;
- duiseligheid, abnormale spierspanning;
- hoofpyn;
- hoë bloeddruk, verergering van bestaande hoë bloeddruk. Jy weet dalk nie dat jy hoë bloeddruk het nie, tensy jy jou bloeddruk laat toets;
- loopneus, seer keel, kort van asem;
- naarheid (siek gevoel), braking (siek wees);
- slegte spysvertering, winderigheid, maagpyn;
- probleme met sluk;
- seer tande;
- veluitslag, jeukende vel;
- toevallige besering;
- griepagtige siekte;
- om vloeistof terug te hou in die liggaamsweefsel, met geswelde enkels, bene en/ of hande.

Minder gereelde newe-effekte:
- inflammasie of infeksie van jou binne-oor (duiseligheid of gevoel dat alles rondom jou draai);
- infeksie van die tandvleis;
- bloedafwykings, soos anemie (te min rooibloedselle of hul hemoglobieninhoud is te laag), leukopenie ('n verlaagde witbloedseltelling) of trombositopenie (tekort aan bloedplaatjies in die bloed)*;
  * Jy sal net weet dat jy hierdie afwykings het as jou dokter bloedtoetse aanbeveel. Sien jou dokter as jy bleek en moeg is, meer infeksies as gewoonlik kry of probleme het om bloeding te stop, of as jy onverwagte kneusing het.
- verhoogde natrium in bloed, verhoogde kalium in bloed (bepaal deur bloedtoetse);
- moeg, verward voel;
- angstige- of depressiewe gevoel;
- dinge sien of hoor wat nie bestaan nie (hallusinasies);
- versteurde visie, oogontsteking en bloedbelope oë, glasagtige swewers (sien kolle of stringe wat beweeg wanneer jy jou oë beweeg), bloeding in 'n oog, pynlike oë;
- gelui in die ore, bo normale gehoorsintuig, stemversteuring;
- onreëlmatige hartritme, verhoogde hartklop;
- blosing;
- inflammasie van 'n bloedvat (jy mag dalk onwel voel met koors, sweet en moegheid);
- benoudheid in die bors met hoes en hyg (brongospasma);
- kortasem, hoes, moegheid (ontsteking van die longweefsel - pneumonitis);
- maagpyn, krampe, opgeblaasheid, hardlywigheid;
- mondsere, gevoelloosheid, brandende sensasie in die mond (stomatitis);
- haarverlies;
- spierspasmas (been krampe), spierpyn;
- onderste ledemaat fraktuur;
- nierfunksieversteurings (gewys deur laboratoriumtoetse);
- gereelde urinering gedurende die nag (nokturie);
- menstruele versteurings;
- geswelde gesig;
- borspyn.

Frekwensie onbekend:
- slaperigheid;
- abnormale velsensasies (tinteling of kielie of jeuk of brand);
- probleme met koördinasie en spraak (ataksie);
- geen reuk- of smaaksintuig, of smaak aangetas;
- verergering van bestaande epilepsie (aanval-/ stuiptrekkingsversteuring);
- verlaagde vroulike vrugbaarheid;
- vaginale bloeding;
- teer borste.

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

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 CELECOXIB BIOTECH te verskaf.

5. Hoe om CELECOXIB BIOTECH te bewaar

- Bewaar teen of benede 25 °C.
- Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
- BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum wat op die karton of stulpstroke gedruk is nie.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat CELECOXIB BIOTECH bevat
Die aktiewe stof is selekoksib.
1 kapsule bevat 100 mg of 200 mg selekoksib.
CELECOXIB 100 BIOTECH: Elke kapsule bevat 100 mg selekoksib.
CELECOXIB 200 BIOTECH: Elke kapsule bevat 200 mg selekoksib.

Die ander bestanddele is natriumkruiskarmellose, gelatien, laktosemonohidraat, magnesiumstereaat (E572), povidoon (E1201), natriumlaurielsulfaat en titaandioksied (E171).

Drukink:
CELECOXIB 100 BIOTECH: FD&C blou Nr. 1 aluminiummeer (E132), propileenglikol (E1520) en shellak.
CELECOXIB 200 BIOTECH: Propileenglikol (E1520), shellak en ysteroksied geel (E172).

Hoe CELECOXIB BIOTECH lyk en die inhoud van die pak
CELECOXIB 100 BIOTECH: Harde gelatienkapsules, grootte "3", gedruk met "135" op die ondeursigtige wit liggaam in blou ink en "A" op die ondeursigtige wit doppie in blou ink, gevul met wit tot naaswit gekleurde korrelpoeier.
CELECOXIB 200 BIOTECH: Harde gelatienkapsules, grootte "1", gedruk met "136" op die ondeursigtige wit liggaam in goudgeel ink en "A" op die ondeursigtige wit doppie in goudgeel ink, gevul met wit tot naaswit gekleurde korrelpoeier.

CELECOXIB BIOTECH word verpak in deurskynende PVC/PE/PVDC en aluminiumfoelie stulpstroke en in 'n buitenste karton geplaas.
CELECOXIB BIOTECH word verpak in silver aluminium/aluminium stulpstroke en in 'n buitenste karton geplaas.
Pakgroottes:
CELECOXIB 100 BIOTECH: 60 kapsules
CELECOXIB 200 BIOTECH: 10, 15 of 30 kapsules.
Nie alle pakgroottes en verpakking tipes mag bemark word nie.

Houer van die sertifikaat van registrasie
Biotech Laboratories (Edms.) Bpk.
Grondvloer, Blok K Wes, Central Park
16de Weg 400, Randjespark
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Hierdie pamflet is laas hersien
Datum van registrasie: 21 September 2021.
Datum van hersiening: 13 Julie 2023.

Registrasienommers
CELECOXIB 100 BIOTECH: 50/3.1/0438
CELECOXIB 200 BIOTECH: 50/3.1/0439