

DICLOFENAC 25 BIOTECH

DICLOFENAC 100 SR BIOTECH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

 [3]

DICLOFENAC 25 BIOTECH tablets. Contains sugar. Lactose monohydrate 65 mg per tablet. DICLOFENAC 100 SR BIOTECH tablets. Sugar free Diclofenac sodium

Read all of this leaflet carefully before you start taking DICLOFENAC BIOTECH

- 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.
- DICLOFENAC BIOTECH has been prescribed for you personally and you should not share your medication with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

- What DICLOFENAC BIOTECH is and what it is used for
- What you need to know before you take DICLOFENAC BIOTECH
- How to take DICLOFENAC BIOTECH
- Possible side effects
- How to store DICLOFENAC BIOTECH
- Contents of the pack and other information

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

Diclofenac sodium, the active ingredient in DICLOFENAC 25 BIOTECH and DICLOFENAC 100 SR BIOTECH, is one of a group of medicines called non-steroidal medicine with anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

DICLOFENAC BIOTECH tablets relieve pain, reduces inflammation and swelling in conditions affecting the muscles, joints and tendons including:

- Rheumatic arthritis, osteoarthritis and ankylosing spondylitis (form of spinal arthritis).
- Post-operative and post-traumatic pain associated with inflammation and swelling.
- They are also used to treat pain and inflammation associated with dental and minor surgery.
- Relieve of dysmenorrhoea (period pains).

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

Do not take DICLOFENAC BIOTECH if:

- you are allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of DICLOFENAC BIOTECH tablets (these are listed under section 6)
- you have now, or ever had, a duodenal (peptic) ulcer or bleeding in the digestive tract, this bleeding may result in vomiting of blood, bleeding when emptying bowels, fresh blood or black blood in faeces
- you ever had asthma, seasonal allergic rhinitis or other chronic pulmonary disease
- you are breastfeeding you baby
- you are pregnant
- you have porphyria
- you have high blood pressure, high cholesterol or angina
- you have any heart problems or if you had a stroke
- you have had stomach or bowel problems after you have taken other NSAIDs

Warnings and precautions

If you are taking DICLOFENAC BIOTECH for longer than the recommended time or at higher than recommended doses, you are at risk of serious harms. These include serious harms to the stomach/ gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Tell your doctor or healthcare provider before taking DICLOFENAC BIOTECH if:

- you have liver or kidney problems
- you have heart problems
- you have high blood pressure
- you have high cholesterol
- you are smoking
- you have diabetes
- you have angina, or if you ever had a stroke or if you think you might be a risk
- you are elderly
- you suffer from any blood or bleeding disorders
- you suffer from stomach or duodenal ulcers
- you suffer from any stomach or bowl disorders including ulcerative colitis, Crohn’s disease or gastro-oesophageal reflux diseases
- you have any serious skin reaction
- you have Systemic Lupus Erythematosus SLE (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition
- you develop flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- you ever had asthma, seasonal allergic reactions, swelling of the nasal mucosa, chronic pulmonary disease or chronic infections of the respiratory tract

Children

Not recommended for children.

Other medicines and DICLOFENAC BIOTECH

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

- if you are using any other NSAIDs like ibuprofen, or other cyclo-oxygenaseo-2 inhibitors like aspirin
- antihypertensive medicines and diuretics (water tablets)
- lithium (used to treat some mental problems)
- ciclosporin and tacrolimus (used to treat some inflammatory diseases)
- any oral steroids (an anti-inflammatory drug)
- anticoagulants (blood thinning tablets)
- medicines to treat diabetes
- methotrexate (for the treatment of some inflammatory diseases and some cancers)
- quinolone antibiotics (for infections)
- phenytoin (a medicine used to treat seizures)
- colestipol and cholestyramine (lower cholesterol)
- cardiac glycosides (used to treat heart problems)
- mifepristone (used to terminate pregnancy)
- selective reuptake inhibitors (used to treat depression)

DICLOFENAC BIOTECH with food and alcohol

DICLOFENAC BIOTECH should be taken with or after food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare providers for advice before taking this medicine.

Do not take DICLOFENAC BIOTECH if you are pregnant.

Do not breastfeed your infant.

If you are trying to conceive, the dose of DICLOFENAC BIOTECH should be kept as low and dura-tion of treatment as short as possible.

Driving and using machines

You may feel dizzy, tired or sleepy or if you have difficulty with your eyesight do not drive or operate machinery.

It is not always possible to predict to what extent DICLOFENAC BIOTECH may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which DICLOFENAC BIOTECH affects you.

3. How to take DICLOFENAC BIOTECH

Do not share medicines prescribed for you with any other person. Always take DICLOFENAC BIOTECH tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take tablets with or after food. Swallow tablets whole with a glass of water. Do not crush or chew the tablets.

DICLOFENAC 25 BIOTECH Tablets

The usual dose is 1 tablet, 25 mg diclofenac, two to three times daily in divided doses.

DICLOFENAC 100 SR BIOTECH Tablets

The usual dose is 1 tablet daily.

Children

Not recommended for children.

If you take more DICLOFENAC BIOTECH than you should

See section 4 Side effects below.

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

If you forget to take DICLOFENAC BIOTECH

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

4. Possible side effects

DICLOFENAC BIOTECH can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing ore breathing,

- rash or itching,
- fainting,
- DICLOFENAC BIOTECH, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood. This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness. These are all very serious side effects. If you have them, you may have had a serious reaction to DICLOFENAC 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:

- sudden and crushing chest pain
 - angina
 - breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
 - changes in the way your heart beats, for example, if you notice it beating faster
 - sudden weakness or numbness in the face, arm or leg especially on one side of the body, sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke
 - yellowing of your skin or the whites of your eyes
 - signs of recurrent infections such as fever or sore throat
 - Stevens Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals)
 - less urine than is normal to you
 - mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with DICLOFENAC BIOTECH and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain
 - flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).
- 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:

- nausea
- vomiting
- diarrhoea
- abdominal pain
- flatulence
- anorexia
- abdominal cramps and discomfort
- local irritation
- headache
- dizziness
- feeling of off balance
- liver function abnormal

Less frequent side effects:

- inflammation of the lining of the stomach
- bleeding in the gastrointestinal tract
- stomach ulcers with or without a rupture in the gastrointestinal tract
- vomiting of blood
- bright red or black blood in stool
- inflammation of the inner lining of the colon
- constipation
- small sores in the inside of the mouth
- inflammation of the mouth
- inflammation of the pancreas
- loss of blood because of the vomiting of blood or the loss of blood after a stool
- blood disorders such as deficiency of red blood cells, low number of platelets, a low level of white blood cells in the blood, which can interfere with the ability to fight infection
- a rare condition in which the body stops producing enough new blood cells, an abnormally low count of a type of white blood cell
- a high level of disease-fighting white blood cells known as eosinophils in the blood, a disorder in which red blood cells are destroyed faster than they can be made
- asthma, inflammation of lung tissue
- disorientation
- depression
- nightmares
- irritability
- pins and needles
- anxiety
- impaired concentration
- tremor
- sweating
- memory disturbance
- fits, an illness characterised by serous inflammation of the linings of the brain (i.e., meninges)
- taste alterations, tiredness
- sleeplessness or sleepiness
- blurred vision, double vision
- changes in the colour, damage to the optic nerve
- loss of hearing, ringing of ears
- high/ low blood pressure fluctuations, inflammation of blood vessels
- liver disorders including liver failure and liver, acute toxic injury of the liver, increase in liver enzymes
- Lyell’s syndrome and other skin rashes which may be made worse by exposure to other skin rashes which may be made worse by exposure to sunlight
- loss of hair, hives
- kidney failure, presence of blood or protein in the urine, is order of the kidneys in which all or part of the renal papillae die
- kidney disorder that causes the body to excrete too much protein in the urine
- kidney disorder in which the spaces between the kidney tubules become swollen (inflamed), inflammation of the bladder
- impotence
- swelling and swelling of your lower legs and arms

Side effects with unknown frequency

- occurs when blood flow to part of the large intestine (colon) is temporarily reduced, usually due to constriction of the blood vessels supplying the colon or lower flow of blood through the vessels due to low pressures
- confusion, hallucinations, malaise (general feeling of discomfort), disturbances of sensation
- inflammation of the nerves in the eye
- symptoms such as chest pain (relating to reduced blood flow to the heart) caused by an allergic reaction or a strong immune reaction to a drug or other substance.

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 DICLOFENAC BIOTECH.

5. How to store DICLOFENAC BIOTECH

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light and moisture

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DICLOFENAC BIOTECH contains

DICLOFENAC 25 BIOTECH Tablets:

The active substance is 25 mg diclofenac sodium.

The other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate, methylcellulose and stearic acid.

The sub coating is Instacoat universal transparent A05R00946.

The enteric-coating are D&C yellow no.10, polyethylene glycol 6000, idalacol lake sunset yellow exspl (L70), titanium dioxide, ferric oxide, methacrylic acid, talc.

DICLOFENAC 100 SR BIOTECH Tablets:

The active substance is 100 mg diclofenac sodium.

The other ingredients are dextrates, hydroxyethyl cellulose (250 HHX), magnesium stearate, and microcrystalline cellulose (PH 102).

The film-coating is Instacoat Universal Pink (A05R00870)

What DICLOFENAC BIOTECH looks like and contents of the pack

DICLOFENAC 25 BIOTECH tablets are mustard yellow coloured, round bevelled edge, biconvex, enteric coated tablets plain on both the sides.

DICLOFENAC 100 SR BIOTECH tablets are round, pink, biconvex tablet, bevel edged, plain on both sides.

DICLOFENAC 25 BIOTECH are packaged in white, plastic bottles (HDPE) of 15, 42, 84,100 and 500, or 15 and 84 in PRP.

DICLOFENAC 100 SR BIOTECH are packaged in white Alu/PVC blister packs of 10 tablets per strip, and 3 blister strips per outer carton (pack sizes of 30). Not all pack sizes may be marketed at the same time

Holder of Certificate of registration

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DICLOFENAC 25 BIOTECH

DICLOFENAC 100 SR BIOTECH

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:

[S3]

DICLOFENAC 25 BIOTECH tablette
DICLOFENAC 100 SR BIOTECH tablette
Diklofenaknatrium
Suiker vry

Lees hierdie hele pamflet deeglig deur voordat jy begin om DICLOFENAC BIOTECH te neem

- Hou hierdie pamflet. Jy mag dit dalk weer moet deurlees
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- DICLOFENAC BIOTECH is vir jou persoonlik voorgeskryf en jy moenie jou medikasie met ander mense deel nie. Dit kan hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

- Wat DICLOFENAC BIOTECH is en waarvoor dit gebruik word
- Wat jy moet weet voordat jy DICLOFENAC BIOTECH neem
- Hoe om DICLOFENAC BIOTECH te neem
- Moontlike nuwe-effekte
- Hoe om DICLOFENAC BIOTECH te bewaar
- Inhoud van die pak en ander inligting

1. Wat DICLOFENAC BIOTECH is en waarvoor dit gebruik word

Diklofenaknatrium, die aktiewe bestanddeel in DICLOFENAC 25 BIOTECH en DICLOFENAC 100 SR BIOTECH, is een van ’n groep medisyne wat nie-steroidale middels met anti-inflammatoriese middels (NSAID’s) genoem word. NSAID’s verminder pyn en inflammasie.

DICLOFENAC BIOTECH tablette verlig pyn, verminder inflammasie en swelling in toestande **wat die spiere, gewigte en senings affekteer, insluitend:**

- Rumatiese artritis, osteoartrose en ankiloserende spondilitis (vorm van spinale artritis).
- Post-operatiewe en post-traumatiese pyn geassosieer met inflammasie en swelling.
- Hulle word ook gebruik om pyn en ontsteking wat met tandheelkundige en klein operasies geassosieer word, te behandel.
- Verligting van dysmenorree (menstruasiepyne).

2. Wat jy moet weet voordat jy DICLOFENAC BIOTECH neem

Moenie DICLOFENAC BIOTECH neem nie indien:

- Jy allergies is vir diklofenaknatrium, aspirien, ibuprofen of enige ander NSAID, of vir enige van die ander bestanddele van DICLOFENAC BIOTECH tablette (hierdie is gelys onder afdeling 6)
- Jy nou, of ooit gehad het, ’n duodenale (peptiese) ulkus of bloeding in die spysverteringskanaal, hierdie bloeding kan lei tot braking van bloed, bloeding tydens leegmaak van ingewande, vars bloed of swart bloed in stoelgang
- Jy ooit asma, seisoenale allergiese rinitis of ander chroniese longsiekte gehad het
- Jy jou baba borsvoed
- Jy swanger is
- Jy porferie het
- Jy hoë bloeddruk, hoë cholesterol of angina het
- Jy enige hartprobleme het of as jy ’n beroerte gehad het
- Jy maag- of dermprobleme gehad het nadat jy ander NSAID’s geneem het

Waarskuwings en voorsorgmaatreëls

Indien jy DICLOFENAC BIOTECH vir ’n langer tydperk neem as die aanbeveelde tyd of teen hoër as aanbeveelde dosisse, loop jy die risiko van ernstige skade. Dit sluit in ernstige skade aan die maag/ derm en niere, sowel as baie lae vlakke van kalium in jou bloed in. Dit kan noodlottig wees (sien afdeling 4).

Vertel jou dokter of gesondheidsorgverskaffer voordat jy DICLOFENAC BIOTECH neem indien:

- Jy lewer- of nierprobleme het
- Jy hartprobleme het
- Jy hoë bloeddruk het
- Jy hoë cholesterol het
- Jy rook
- Jy diabetes het
- Jy angina het, of as jy ooit ’n beroerte gehad het of as jy dink jy kan ’n risiko wees
- Jy bejaard is
- Jy aan enige bloed- of bloedingsversteurings ly
- Jy aan maag- of duodenale ulkuse ly
- Jy aan enige maag- of dermafwykings ly, insluitend ulseratiewe kolitis, Crohn se siekte of gastro-esofageale refluks siektes
- Jy enige ernstige velreaksie het
- Jy sistemiese lupus erythematosus (SLE) het (inflammatoriese, outo-immuun versteuring wat simptome soos gewrigspyn, gewrigsinflammasie, veluitslag, koors veroorsaak) of enige soortgelyke toestand
- Jy griepagtige simptome met ’n uitslag, koors, geswelde kliere en abnormale bloedtoets-resultate ontwikkel (insluitend verhoogde witbloedselle (eosinofilie en lewerensieme) (Dwelm reaksie met Eosinofilie en Sistemiese Simptome (DRESS))
- Jy ooit asma, seisoenale allergiese reaksies, swelling van die neusslymvlies, chroniese longsiekte of chroniese infeksies van die lugweg gehad het

Kinders

Nie aanbeveel vir kinders nie.

Ander medisyne en DICLOFENAC BIOTECH

Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

- indien jy enige ander NSAID’s soos ibuprofen, of ander siklo-oksigenase-2 inhibeerders soos aspirien gebruik
- antihipertensiewe medisyne en diuretika (watertablette)
- litium (gebruik om sekere geestelike probleme te behandel)
- siklosporien en takrolimus (gebruik om sommige inflammatoriese siektes te behandel)
- enige orale steroïede (’n anti-inflammatoriese middel)
- antikoagulante (bloedverdundingstabellette)
- medisyne om diabetes te behandel
- metotreksaat (vir die behandeling van sommige inflammatoriese siektes en sommige kankers)
- kinoloon antibiotika (vir infeksies)
- fenitoeien (’n medisyne wat gebruik word om aanvalle/stuiptrekkings te behandel)
- kolestipol en kolistiramien (verlaag cholesterol)
- hartglikosiede (gebruik om hartprobleme te behandel)
- mifepristoon (gebruik om swangerskap te beëindig)
- selektiewe heropname inhibeerders (gebruik om depressie te behandel)

DICLOFENAC BIOTECH met kos en drank

DICLOFENAC BIOTECH moet met of na voedsel geneem word.

Swangerskap, borsvoeding en vrugbaarheid

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 hierdie medisyne neem.

Moenie DICLOFENAC BIOTECH neem indien jy swanger is nie.

Moenie jou baba borsvoed nie.

Indien jy probeer swanger word moet die dosis van DICLOFENAC BIOTECH so laag as moontlik gehou word en die duur van behandeling so kort as moontlik.

Bestuur en die gebruik van masjiene

Jy kan duiselig, moeg of slaperig voel of as jy sukkel met jou sig, moenie bestuur of masjinerie gebruik nie.

Dit is nie altyd moontlik om te voorspel tot watter mate DICLOFENAC BIOTECH met jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie ’n voertuig bestuur of masjiene gebruik totdat jy bewus is van die mate waarin DICLOFENAC BIOTECH jou beïnvloed nie.

3. Hoe om DICLOFENAC BIOTECH te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd DICLOFENAC BIOTECH tablete presies soos jou dokter of apteker jou vertel het.
Raadpleeg jou dokter of apteker indien jy nie seker is nie.
Neem tablette met of na voedsel. Sluk die tablette heel met ’n glas water.
Moenie die tablette fynmaak of kou nie.

DICLOFENAC 25 BIOTECH Tablette

Die gewone dosis is 1 tablet, 25 mg diklofenak, twee tot drie keer per dag in verdeelde dosisse.

DICLOFENAC 100 SR BIOTECH Tablette

Die gewone dosis is 1 tablet daagliks.

Kinders

Nie aanbeveel vir kinders nie.

Indien jy meer DICLOFENAC BIOTECH neem as wat jy moet

Sien afdeling 4 Nuwe-effekte onderaan.
In die geval van ’n oordosis, raadpleeg jou dokter of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om DICLOFENAC BIOTECH te neem

Moenie ’n dubbeldosis neem om op te maak vir vergete individuele dosisse nie.

4. Moontlike nuwe-effekte

DICLOFENAC BIOTECH kan nuwe-effekte hê.
Nie alle nuwe-effekte wat vir DICLOFENAC BIOTECH aangemeld is word in hierdie pamflet ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongewense effekte ervaar terwyl jy DICLOFENAC BIOTECH neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om DICLOFENAC BIOTECH te neem/ gebruik en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat moeilike sluk of moeilike asemhaling veroorsaak,

- veluitslag of jeuk,
- floute.
- DICLOFENAC BIOTECH, veral wanneer dit teen hoër as aanbevole dosisse geneem word of vir ’n lang tydperk, kan skade aan jou niere veroorsaak en dit beïnvloed om sure behoorlik uit jou bloed in die uriene te verwyder (renale tubulêre asidose). Dit kan ook baie lae vlakke van kalium in jou bloed veroorsaak. Dit is ’n baie ernstige toestand en sal onmiddellike behandeling vereis. Tekens en simptome sluit spierswakheid en lighoofdigheid in.
- Hierdie is almal baie ernstige nuwe-effekte. Indien jy hulle het, mag jy dalk ’n ernstige reaksie op DICLOFENAC 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 die volgende opmerk:

- skielike en verpletterende borspyn
- angina
- asemloosheid, moeilike asemhaling wanneer jy lê, swelling van die voete of bene (tekens van hartversaking)
- veranderinge in die manier hoe jou hart klop, byvoorbeeld, indien jy agterkom dat dit vinniger klop
- skielike swakheid of gevoelloosheid in die gesig, arm of been veral aan die een kant van die liggaam, skielike verlies of versteuring van visie; skielike probleme met praat of vermoë om spraak te verstaan; skielike migraine-agtige hoofpyne wat vir die eerste keer gebeur, met of sonder versteurde visie. Hierdie simptome kan ’n vroeë teken van ’n beroerte wees
- vergeling van jou vel of die wit van jou oë
- tekens van herhalende infeksies soos koors of ’n seer keel
- Stevens Johnson se sindroom (ernstige siekte met blase op die vel, mond, oë en geslagsdele)
- minder uriene as wat normal is vir jou
- ligte krampe en teerheid van die buik, wat begin kort na die aanvang van die behandeling met DICLOFENAC BIOTECH en gevolg deur rektale bloeding of bloederige diarree gewoonlik binne 24 uur na die aanvang van buikpyn
- griepagtige simptome met ’n veluitslag, koors, geswelde kliere en abnormale bloedtoetsuitslae (insluitend verhoogde witbloedselle (esinofilie en lewerensieme) (Dwelmreaksie met eosinofilie en sistemiese simptome (DRESS)).
- Hierdie is almal ernstige nuwe-effekte. Jy mag dalk dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:

Gereelde nuwe-effekte:

- naarheid
- braking
- diarree
- maagpyn
- winderigheid
- anoreksie
- maagkrampe en ongemak
- lokale irritasie
- hoofpyn
- duiseligheid
- gevoel van wanbalaans
- abnormale leverfunksie

Minder gereelde nuwe-effekte:

- inflammasie van die voering van die maag
- bloeding in die gastroïntestinale kanaal
- maagsere met of sonder ’n skeur in die gastroïntestinale kanaal
- braking van bloed
- helder rooi of swart bloed in die stoelgang
- inflammasie van die binneste voering van die kolon
- hardlywigheid
- klein sere in die binnekant van die mond
- inflammasie van die mond
- inflammasie van die pankreas
- verlies van bloed as gevolg van die braking van bloed of die verlies van bloed na ’n stoelgang
- bloedafwykings soos ’n tekort aan rooibloedselle, lae aantal bloedplaatjies, ’n lae vlak van witbloedselle in die bloed, wat kan inmeng met die vermoë om infeksie te beveg
- ’n seldsame toestand waarin die liggaam ophou om genees nuwe bloedselle te vervaardig, ’n abnormale lae telling van ’n tipe witbloedsel
- ’n hoë vlak van siektebestrydende witbloedselle bekend as eosinofiele in die bloed, ’n afwyking waarin rooibloedselle vinniger vernietig word as wat dit gemaak kan word
- asma, inflammasie van die longweefsel
- disoriëntasie
- depressie
- nagmerries
- prikkelbaarheid
- naalde en spelde
- angstigheid
- benadeelde konsentrasie
- bewing
- sweet
- geheueversteuring
- aanvalle/ stuiptrekkings, ’n siekte gekenmerk deur ernstige inflammasie van die voerings van die brein (bv. meninges)
- smaakveranderinge, moegheid
- slapeloosheid of slaperigheid
- versteurde visie, dubbelvisie
- veranderinge in die kleur, skade aan die optiese senuwee
- gehoorverlies, lui geluid in die ore
- hoë/ lae bloeddruk skommelinge, inflammasie van bloedvate
- lewerafwykings insluitend lewersversaking en lewer, akute toksiese besering van die lewer, toename in lewerensieme
- Lyell se sindroom en ander veluitslag wat vererger kan word deur blootstelling aan ander veluit-slag wat vererger kan word deur blootstelling aan sonlig
- haarverlies, korwe
- nierversaking, teenwoordigheid van bloed of proteien in die uriene, is die volgorde van die niere waarin die hele of ’n gedeelte van die nierpapille sterf
- nierversteuring wat veroorsaak dat die liggaam te veel proteiene in die uriene uitskei
- nierversteuring waarin die spasies tussen die nierbuisies geswel word (inflammasie), inflammasie van die blaas
- impotensie
- swelling van jou laer bene en arms

Nuwe-effekte met onbekende frekwensie:

- vind plaas wanneer bloedvloei na ’n deel van die dikderm (kolon) tydelik verminder word, gewoonlik as gevolg van vernouing van die bloedvate wat die kolon voorsien of laer vloei van bloed deur die vate as gevolg van lae druk
- verwarring, hallusinasies, malaise (algemene gevoel van ongemak), sensasieversteurings
- inflammasie van die senuwees in die oog
- simptome soos borspyn (wat verband hou met verminderde bloedvloei na die hart) wat veroorsaak word deur ’n allergiese reaksie of ’n sterk immuunreaksie op ’n geneesmiddel of ander stof.

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

Aanmelding van nuwe-effekte

Indien jy nuwe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook nuwe-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 nuwe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van DICLOFENAC BIOTECH te verskaf.

5. Hoe om DICLOFENAC BIOTECH te bewaar

Bewaar alle medisyne buite bereik van kinders.
Bewaar teen of benede 25 °C. Beskerm teen lig en vog.
Gee alle ongebruikte medisyne terug aan jou apteker.
Moenie ongebruikte medisyne in dreïne of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat DICLOFENAC BIOTECH bevat

DICLOFENAC 25 BIOTECH Tablette:

Die aktiewe bestanddeel is 25 mg diklofenaknatrium.
Die ander bestanddele is dekstrate, kolloïdale silikondioksied, magnesiumstearaat, metielsingelulose en steariensuur.
Die filmbedekking is D&C geel #10 Lake 15 – 16 % (CI 47005), hidroksi-propylmetielsellulose (2910), poliëtileenglikol 3350 (Carbowax), sonsonganggeel meer 40 % (CI 15985), titaandioksied (CI 77891), en Geel ysteroksied (CI 77492).

DICLOFENAC 100 SR BIOTECH Tablette:

Die aktiewe bestanddeel is diklofenaknatrium.
Die ander bestanddele is dekstrate, hidroksielsingelulose (250 HHX), magnesiumstearaat en mikrokristallyne sellulose (PH 102).
Die filmbedekking is Instacoat Universal Pink (A05R00870).

Hoe DICLOFENAC BIOTECH lyk en die inhoud van die pak
DICLOFENAC 25 BIOTECH tablette is mosterdgeelkleurig met ronde afgeplatte rante, bikonvekse en enteries bedekte tablette, wat aan beide kante glad is.
DICLOFENAC 100 SR BIOTECH tablette is ronde, bikovekse tablette met afgeronte rante, ongedruk aan beide kante.

DICLOFENAC 25 BIOTECH word verpak in wit plastiekbottels (HDPE) van 15, 42, 84,100 en 500, of 15 en 84 in PRP (pasiëntgereed pakkies).
DICLOFENAC 100 SR BIOTECH word verpak in wit Alu/PVC stulpstroe van 10 tablette per stulpstrook en 3 stulpstroeke per buitenste karton (pakgroottes van 30).
Nie alle pakgroottes mag terselftyd bemark word nie.

Houer van die Sertifikaat van Registrasie

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Hierdie pamflet is laas hersien op

13 Junie 2023

Registrasienuommer

DICLOFENAC 25 BIOTECH: 30/3.1/0166

DICLOFENAC 100 SR BIOTECH: 30/3.1/0160