

DICLOFENAC 25 BIOTECH

DICLOFENAC 100 SR BIOTECH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

DICLOFENAC 25 BIOTECH tablets
DICLOFENAC 100 SR BIOTECH tablets
Diclofenac sodium
Sugar free

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

1. What DICLOFENAC BIOTECH is and what it is used for
2. What you need to know before you take DICLOFENAC BIOTECH
3. How to take DICLOFENAC BIOTECH
4. Possible side effects
5. How to store DICLOFENAC BIOTECH
6. 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 agent 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

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 an elderly
- you suffer from any blood or bleeding disorders
- you suffer from stomach or duodenal ulcers
- you suffer from any stomach or bowel 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 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 health care 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-oxygenase-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 duration 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 overdosage, 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 or breathing,
- rash or itching,
- fainting.

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
- Steven's 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.

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

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 dextrose, colloidal silicon dioxide, magnesium stearate, methylcellulose and stearic acid.

The film-coating are D&C yellow #10 Lake 15 - 16 % (CI 47005), hydroxypropyl methylcellulose (2910), polyethylene glycol 3350 (Carbowax), sunset yellow lake 40 % (CI 15985), titanium dioxide (CI 77891), and Yellow ferric oxide (CI 77492).

DICLOFENAC 100 SR BIOTECH Tablets:

The active substance is 100 mg diclofenac sodium.

The other ingredients are dextrose, 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 tablets with bevelled edge plain on both sides.

DICLOFENAC 25 BIOTECH are packaged in transparent, plastic bottles of 100 and 500.

DICLOFENAC 100 SR BIOTECH are packaged in transparent Alu/PVC blister packs of 10 tablets per strip, and 3 blister strips per outer carton (pack sizes of 30).

Packs of 15, 42 or 84 are available in HDPE plastic containers or patient ready packs (PRP).

Holder of Certificate of registration

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This leaflet was last revised in

June 2021

Registration number

DICLOFENAC 25 BIOTECH: 30/3.1/0166

DICLOFENAC 100 SR BIOTECH: 30/3.1/0160

PI 300166/60-1

DICLOFENAC 25 BIOTECH

DICLOFENAC 100 SR BIOTECH

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:

S3

DICLOFENAC 25 BIOTECH tablette
DICLOFENAC 100 SR BIOTECH tablette
Natriumdiklofenak
Suikervry

Lees hierdie hele blad noukeurig deur voordat u begin om DICLOFENAC BIOTECH te drink.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrees het, moet u asseblief vir u dokter, apoteker, verpleegkundige of ander gesondheidsorgver skaffer vra.
- DICLOFENAC BIOTECH is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

WAT IN HIERDIE BLAD IS

- Wat DICLOFENAC BIOTECH is en waarvoor dit gebruik word
- Wat u moet weet voordat u DICLOFENAC BIOTECH drink
- Hou om DICLOFENAC BIOTECH te drink
- Moontlike newe-effekte
- Hoe om DICLOFENAC BIOTECH te bêre
- Inhoud van die pak en ander inligting

1. Wat Diclofenac Biotech is en waarvoor dit gebruik word

Diclofenac sodium, die aktiewe bestanddeel in DICLOFENAC 25 BIOTECH en DICLOFENAC 100 SR BIOTECH, is een van 'n groep medisyne wat nie-steroid anti-inflammatoriese middels (NSAIM's) genoem word. NSAIM's verminder pyn en inflammasie.

DICLOFENAC BIOTECH-tabletten verlig pyn, verminder inflammasie en swelling in toestande wat die spiere, gewrigte en senings beïnvloed, waaronder:

- Rumatiese artritis, osteoartrrose en ankiloserende spondylitis (vorm van spinale artritis).
- Postoperatiewe en posttraumatische pyn wat met inflammasie en swelling gepaardgaan.
- Hulle word ook gebruik om pyn en ontsteking wat verband hou met tandheelkundige en geringe chirurgie te behandel.

Verligting van dysmenorree (menstruasiepnye).

2. Wat u moet weet voordat u DICLOFENAC BIOTECH drink

Moenie DICLOFENAC BIOTECH drink nie as:

- u allergies is vir natriumdiklofenak, aspirien, ibuprofeen of enige ander NSAIM, of vir enige van die ander bestanddele van DICLOFENAC BIOTECH-tablette (dit word in afdeling 6 genoem).
- u nou 'n duodenale seer (peptiese ulkus), of bloeding in die spysverteringskanal het of ooit gehad het; hierdie bloeding kan braak van bloed, bloeding tydens ontlasting, vars bloed of swart bloed in die stoelgang wees.
- u ooit asma, seisoenale allergiese rinitis of ander chroniese longsiektes gehad het
- u uuba borsvoerd
- u swanger is
- u porfirie het
- u hoe beeldruk het, hoe cholesterolvlakte of angina
- u hartprobleme het of 'n beroerte gehad het
- u maag of dermoprobleme gehad nadat u ander NSAIM's gebruik het.

Waarskuwings en voorsorgmaatreëls

Sé vir u dokter of gesondheidsorgverskaffer voordat u DICLOFENAC BIOTECH drink as:

- u lewer- of nierprobleme het
- u hartprobleme het
- u hoe beeldruk het
- u hoe cholesterolvlakte het
- u rook
- u suikersekte het
- u angina het, of as u ooit 'n beroerte gehad het of as u dink dat u 'n risiko daarvoor kan hé
- u bejaard is
- u aan enige bloed- of bloodingsversteuring ly
- u maag- of duodenale sere het
- u ly aan maag- of ingewandsiektes, waaronder ulceratieve kolitis, Crohn se siekte of gastro-esophageale refluxiekste
- u 'n ernstige lupusreumatoe (SLE) het (inflammatoriese, auto-immuunsiekte wat simptome veroorzaak soos gewrigspyn, gewrigsontsteking, veluitslag, koers) of enige soortgelyke toestand
- u ooit asma, seisoenale allergiese reaksies, swelling van die neusslymlies, chroniese longsiekte of chroniese infeksies van die lugweë gehad het

Kinders

Nie vir kinders aanbeveel nie.

Ander medisyne en DICLOFENAC BIOTECH

Sé altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder alle aanvullende of tradisionele medisyne).

- as u ander NSAIM's gebruik, soos ibuprofeen, of ander siklo-oksigenase-2-remmers soos aspirien
- antihiertensieve medisyne en diureтика (watertablette)
- litium (vir die behandeling van psigiatrisee toestande)
- siklosporien en takrolimus (om sekere inflammatoriese siektes te behandel)
- enige orale steroide (anti-inflammatoriese middels)
- antikoagulantie (middels wat bloed dun maak)
- medisyne vir depressie
- metotretoks (vir die behandeling van sommige inflammatoriese siektes en sekere kankers)
- kinoloonantibiotika (vir infeksies)
- febitone (om toevalle te behandel)
- kolestipol en cholesteramien (verlaag cholesterolvlakte)
- hartglikoside (om hartprobleme te behandel)
- mifepristoon (om swangerskap te beëindig)
- selektiewe heropnemeremmers (om depressie te behandel)

DICLOFENAC BIOTECH saam met voedsel en alkohol

DICLOFENAC BIOTECH moet tydens etes of net daarna gedrink word.

Swangerskap, borsvoeding en vrugbaarheid

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hé, moet u u dokter, apoteker of ander gesondheidsorgverskaffers asseblief om advies raadpleeg voordat u hierdie medisyne drink.

Moenie DICLOFENAC BIOTECH gebruik as u swanger is nie.

As u probeer om swanger te raak, moet die dosis DICLOFENAC BIOTECH so laag en die duur van die behandeling so kort as moontlik gehou word.

Motorbestuur en gebruik van masjinerie

U kan dusself, moeg of slapelig voel, of as u probleme met u visie ondervind, dan moet u nie bestuur of masjinerie gebruik nie.

Dit is nie altyd moontlik om te voerspel tot watter mate DICLOFENAC BIOTECH met u daaglikske aktiwiteite sal inmeng nie. U moet sorg dat u nie 'n voortuig bestuur of masjiene hanteer nie, totdat u weet hoe DICLOFENAC BIOTECH u beïnvloed.

3. Hoe om DICLOFENAC BIOTECH te drink

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

Gebruik DICLOFENAC BIOTECH altyd presies soos wat u dokter of apoteker vir u gesé het. Raadpleeg u dokter of apoteker as u nie seker is nie.

Drink die tablette tydens of na 'n ete. Sluk die tablette heel met 'n glas water af.

Moenie die tablette fyndruk of kou nie.

DICLOFENAC 25 BIOTECH-tablette

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

DICLOFENAC 100 SR BIOTECH-tablette

Die gewone dosis is 1 tablet per dag.

Kinders

Nie vir kinders aanbeveel nie.

As u meer DICLOFENAC BIOTECH gedrink het as wat u moes

Lees afdeling 4 hier onder vir newe-effekte.

Raadpleeg u dokter of apoteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet om DICLOFENAC BIOTECH te drink

Moenie 'n dubbel dosis gebruik om vir vergeet individuele dosisse op te maak nie.

4. Moontlike newe-effekte

DICLOFENAC BIOTECH kan newe-effekte hé.

Nie al die newe-effekte wat vir DICLOFENAC BIOTECH aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar terwyl u DICLOFENAC BIOTECH drink, moet u gesondheidsorgverskaffer asseblief om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om DICLOFENAC BIOTECH te drink/gebruik en onmiddellik vir u dokter sé of na die ongevalle-afdeling van u naaste hospitaal gaan:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk
- floute

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksie op DICLOFENAC BIOTECH het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sé dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:

- skielike en verplerkende pyn op die bors
- angina
- uitasemheid, probleme met asemhalen wanneer u lê, swelling van die voete of bene (tekens van hartversaking)
- veranderinge in die manier waarop u hart klop, as u byvoorbeeld opmerk dat dit vinniger klop.
- skielike swakheid of gevoelloosheid in die gesig, arm of been, veral aan die kant van die liggaam,
- skielike verlies of versteuring in visie, skielike probleme om die praat of spraak te verstaan, skielike migraine-agtige hoofpyn wat vir die eerste keer voorkom, met of sonder versteuring in visie.
- Hierdie simptome kan 'n vroeë teken van 'n beroerte wees.
- geel verkleuring van die vel of die wit van die oë
- tekens van herhalende infeksies soos koort of seer keel
- Stevens-Johnsonsyndroom (ernstige siekte met blase op die vel, mond, oë en geslagsdele)
- mindier urien as wat normaal vir u is
- ligte kramp en teerheid van die buik, wat kort na die aanvang van die behandeling met DICLOFENAC BIOTECH begin en deur reukrale bloeding of bloedige diarree gevolg word, gewoonlik binne 24 uur na die aanvang van die buikpyn

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sé vir u dokter as u enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- naarheid
- braking
- diarree
- buikpyn
- wingerdheid
- anoreksie
- buikkramp of -ongemak
- lokale irritasie
- hoofpyn
- duiselheid
- gevoel van wanbalans
- abnormale leverfunksie

Newe-effekte wat minder dikwels voorkom:

- Inflammasis in die voering van die maag
- bloeding vanuit die spysverteringskanaal
- maagserre met of sonder 'n breuk in die spysverteringskanaal
- braking van bloed
- helderooi of swart bloed in die stoelgang
- inflammasis in die voering van die kolon
- hardwingerdheid
- Klein serre in die mond
- inflammasis in die pankreas
- bloedverlygings as gevolg van die braking van bloed of die verlies van bloed na 'n stoelgang
- bloedafwykings soos 'n tekort aan rooibloedselle, 'n lae aantal bloedplaatjies, 'n lae vlak van witbloedselle in die bloed, wat die vermoeiing van infeksie te beveg, kan belemmer
- 'n seldsame toestand waarin die liggaam ophou om genoeg nuwe bloedselle te produseer, 'n abnormaal lae telling van 'n tipe witbloedsel
- 'n hoë vlak van skeletbestrydigheid witbloedselle bekend as eosinofiele in die bloed, 'n afwyking waarin rooibloedselle vinniger vernietig word as wat hulle gemaak kan word
- asma, inflammasis van longweefsel
- disoriëntering
- depresie
- nagmerries
- geirriteerdheid
- naalde en spelde
- angs
- swak kontrasie
- bewerasie
- sweet
- geheueversteuring
- toevale, 'n siekte gekenmerk deur ernstige ontsteking van die voering van die brein (breinvlies)
- smaakverandering, moegheid
- slapeloosheid of slaperheid
- dowwe visie, dubbelvisie
- veranderinge in kleurvisie, skade aan die optiese senuwee
- gehoerverlies, gelui in die ore
- skommelinge van hoe/lae beeldruk, ontsteking van bloedvatte
- lewersiektes, waaronder lewersersaking en lewerskade, akute toksiese besering van die lewer, toename in lewersensime
- Lyell-syndroom en ander veluitslag wat vererger kan word deur blootstelling aan sonlig
- haarverlies, galbulte
- nierversaking, die teenwoordigheid van bloed of proteïne in die urien, versteuring van die niere waarin die hele of 'n deel van die renale papille sterv
- nierversteuring wat veroorsaak dat die liggaam te veel proteïne in die urien uitskei
- nierversteuring waarin die spasies tussen die nierbuisies swel (ontsteek), ontsteking van die blaas
- impotensie
- swelling en swelling van die onderbene en arms

Newe-effekte met onbekende frekwensie

- kom voor wanneer bloedvloeい na 'n deel van die dikderm (kolon) tydelik minder is, gewoonlik as gevolg van verouwing van die bloedvloeい wat die kolon voorsien of 'n laer bloedvloeい deur die vase as gevolg van lae druk
- verwardheid, hallusinasië, malaise (algemene gevoel van ongemak), sensasierversteurings.
- ontsteking van die senuwees in die oë
- simptome soos pyn op die bors wat met minder bloedvloeい na die hart verband hou wat veroorsaak word deur 'n allergiese reaksie van 'n sterke immuunreaksie op 'n genesmiddel of ander stof
- As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apoteker asseblief in kennis stel.

Aanneld van newe-effekte

Praat met u dokter, apoteker of verpleegkundige as u newe-effekte kry. U kan newe-effekte ook by SARO GP (SAHRA) aanmeld via die vorm vir die aanneld van nadelige genesmiddelreaksies, naamlik "6.04 Adverse Drug Reaction Reporting Form" wat aanlyn by SAHRA se publikasies gekry kan word: <https://www.sahra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van DICLOFENAC BIOTECH te gee.

5. Hoe om DICLOFENAC BIOTECH te bêre

Bêre teen of onder 25 °C. Beskerm teen lig en vog.

6. Inhoud van die pak en ander inligting

WAT DICLOFENAC BIOTECH BEVAT

DICLOFENAC 25 BIOTECH-tablette:

Die aktiewe bestanddeel is 25 mg natriumdiklofenak.

Die ander bestanddele is dekstrate, kolloïdale silikondioksiëks, magnesiumstearaat, metiellelluloë en steariënsuur.

Die filmlaag is D&C Yellow #10 lak 15-16 % (CI 47005), hidroksi-propielmetiellelluloë (2910), polietileneglikol 3350 (Carbowax), Sunset Yellow lak 40 % (CI 15985), titaandioksied (CI 77891) en geel steroksied (CI 77492).

DICLOFENAC 100 SR BIOTECH-tablette

Die aktiewe bestanddeel is 100 mg natriumdiklofenak.

Die ander bestanddele is dekstrate, hidroksi-etylellelluloë (250 HHX), magnesiumstearaat en mikrokristalline elluloë (PH 102).

Die filmlaag is Instacote Universal Pink (A05R00870).

Hoe DICLOFENAC BIOTECH lyk en die inhoud van die pak

DICLOFENAC 25 BIOTECH-tablette is mosterdgeel gekleurde, rond met afergeronde rante, bikonveks, enteriesbedekte tablette, glad aan beide kante.

DICLOFENAC 100 SR BIOTECH-tablette is ronde, pienk bikonveks tablette met afergeronde rante en glad aan beide kante.

DICLOFENAC 25 BIOTECH word verpak in deursigtige plastiekbottels van 100 en 500.

DICLOFENAC 100 SR BIOTECH word verpak in deursigtige Alu/PVC stuifpstoek pakke met 10 tablete per strook, en 3 stuifpstoek per buitenste carton (pakk groottes van 30).

Verpakkingen van 15, 42 of 84 is beskikbaar in HDPE plastiek hours of pasiënt gereed pakke.

Houer van die registrasiesertifikaat

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Hierdie blad is laas hersien op

Junie 2021

Registrasienommers

Diclofenac 25 Biotech: 30/3.1/0166

Diclofenac 100 SR Biotech: 30/3.1/0160