

DOXYCYCLINE BIOTECH 100

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

DOXYCYCLINE BIOTECH 100 (doxycycline 100 mg) Film-coated tablets
Doxycycline
Sugar free

Read all of this leaflet carefully before you start taking DOXYCYCLINE BIOTECH 100

- 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.
- DOXYCYCLINE BIOTECH 100 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DOXYCYCLINE BIOTECH 100 is and what it is used for
2. What you need to know before you take DOXYCYCLINE BIOTECH 100
3. How to take DOXYCYCLINE BIOTECH 100
4. Possible side effects
5. How to store DOXYCYCLINE BIOTECH 100
6. Contents of the pack and other information

1. What DOXYCYCLINE BIOTECH 100 is and what it is used for

DOXYCYCLINE BIOTECH 100 is a broad-spectrum tetracycline antibiotic and may be used to treat a wide range of infections caused by bacteria:

- Respiratory tract infections such as sinusitis, inflammation of the pharynx, lung infection caused by Mycoplasma, parrot fever and chronic bronchitis.
- Urinary tract infections.
- Sexually transmitted diseases.
- Skin infections such as acne.
- Infections of the eye.
- Other infections such as malaria, cholera, brucellosis, leptospirosis and fevers caused by lice or ticks.
- Rickettsial infections such as Q fever, tick fever.
- Rabbit fever, tropical infection of the skin (Yaws) and long-term infection that causes sores or abscesses in the body's soft tissues.

2. What you need to know before you take DOXYCYCLINE BIOTECH 100 Do not take DOXYCYCLINE BIOTECH 100:

- if you are hypersensitive (allergic) to doxycycline hyclate, other tetracyclines or any of the other ingredients of DOXYCYCLINE BIOTECH 100 (listed in section 6).
- if you have some form of kidney (renal) disease.
- if you are pregnant or breastfeeding your baby.
- if you are pregnant, you are more susceptible to severe doxycycline-induced liver damage.
- if you are younger than 12 years of age as permanent discoloration of teeth may occur.
- if you have an inflammatory disease of connective tissue (systemic lupus erythematosus).

Warnings and precautions

Take special care with DOXYCYCLINE BIOTECH 100:

- if you are likely to be exposed to direct sunlight or ultraviolet light, or if you are already sunburned,
- if you have any liver disease or are taking medicine which affect your liver,
- if you have severe kidney problems,
- if you experience severe skin reactions such as erythema multiforme (circular, irregular red patches), Stevens-Johnson syndrome (rash with flushing, fever, blisters or ulcers), toxic epidermal necrolysis (reddening, peeling and swelling that resembles burns),
- if you have diarrhoea or usually get diarrhoea when you take antibiotics or have suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhoea during or after using DOXYCYCLINE BIOTECH 100 tell your doctor immediately since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics,
- if you suffer from porphyria (a deficiency of specific enzymes within the body causing an increase of substances called porphyrins),
- are taking oral retinoids as there is a higher risk of suffering from increased pressure in your skull (severe headache with change in vision) when taken with DOXYCYCLINE BIOTECH 100,
- if you are frail or elderly,
- if you have a vaginal infection or blood infection caused by fungus,
- if you have a stomach ulcer or vomits the contents of the stomach with dark blood, oesophagitis (inflammation of the oesophagus or gullet), (see "How to take DOXYCYCLINE BIOTECH 100"),
- if you have some form of sexual transmitted disease (e.g., syphilis),
- if you suffer from myasthenia gravis, a condition characterised by muscle weakness, difficulty chewing and swallowing and slurred speech,
- if you suffer from systemic lupus erythematosus (an inflammatory disease of connective tissue), see "Do not take DOXYCYCLINE BIOTECH 100".
- if you experience shaking chills, a rise in temperature, and intensification of skin rashes known as the Jarisch–Herxheimer reaction (JHR) within 24 hours after antibiotic treatment of the spirochetal infections such as syphilis, Lyme disease, leptospirosis, and relapsing fever (RF), these symptoms are consequence of antibiotic treatment of spirochete infections and usually self-limiting.

Children

DOXYCYCLINE BIOTECH 100 should not be used in children under 12 years of age (see section 4.3).

Other medicines and DOXYCYCLINE BIOTECH 100

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

- medicines such as antacids containing aluminium, calcium or magnesium or other medicines containing iron, bismuth or zinc salts. Do not take at the same time as DOXYCYCLINE BIOTECH 100 as absorption of DOXYCYCLINE BIOTECH 100 may be reduced,
- warfarin or other anticoagulants (to stop blood clotting),
- medicines to treat epilepsies such as phenobarbital, carbamazepine, primidone and phenytoin may interact with the metabolism of DOXYCYCLINE BIOTECH 100,
- penicillin should not be used with DOXYCYCLINE BIOTECH 100 as it may block the action of DOXYCYCLINE BIOTECH 100,
- DOXYCYCLINE BIOTECH 100 may diminish the effectiveness of the pill (oral contraceptives),
- methoxyflurane (an anaesthetic), if you need an operation, tell your doctor or dentist that you are taking DOXYCYCLINE BIOTECH 100,
- alcohol may decrease the amount of time it takes for DOXYCYCLINE BIOTECH 100 to lose half of its strength in blood plasma,
- ciclosporin (used following organ transplants) should be monitored appropriately,
- rifampicin (tuberculosis treatment) may interact with DOXYCYCLINE BIOTECH 100. This may result in a sub-therapeutic effect of DOXYCYCLINE BIOTECH 100 (the dosage administered at too low a level to treat the disease),
- isotretinoin or other systemic retinoids (used to treat severe acne).

DOXYCYCLINE BIOTECH 100 with food, drink and alcohol

You should not drink alcohol whilst taking DOXYCYCLINE BIOTECH 100, alcohol may reduce the effect of your medicine.

Swallow the tablets whole with a full glass of water. You should take the tablets either sitting down or standing up and well before you go to bed for the night. It is important not to lie down for at least thirty minutes after taking DOXYCYCLINE BIOTECH 100.

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 this medicine.

Do not take DOXYCYCLINE BIOTECH 100 if you are pregnant or breastfeeding your baby.

Driving and using machines

Do not drive or use machines if you suffer from visual disturbances such as blurring of vision while taking DOXYCYCLINE BIOTECH 100. It is not always possible to predict to what extent DOXYCYCLINE BIOTECH 100 may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DOXYCYCLINE BIOTECH 100 affects you.

3. How to take DOXYCYCLINE BIOTECH 100

Do not share medicines prescribed for you with any other person. Always take DOXYCYCLINE BIOTECH 100 exactly as your doctor or pharmacist has told you. Check with your doctor if you are not sure.

The usual dose is:

- 100 mg twice daily on the first day, then 100 mg daily.
 - For acne, the adult dosage is 50 mg twice daily.
- DOXYCYCLINE BIOTECH 100 should be taken by mouth. Should be taken either one hour before meals or two hours after meals. Should be taken with adequate liquid and in the upright position. Your doctor will tell you how long your treatment with DOXYCYCLINE BIOTECH 100 will last. Do not stop treatment early because you feel better. If you have the impression that the effect of DOXYCYCLINE BIOTECH 100 is too strong or too weak, tell your doctor or pharmacist.

If you take more DOXYCYCLINE BIOTECH 100 than you should

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

If you forget to take DOXYCYCLINE BIOTECH 100

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

If you stop taking DOXYCYCLINE BIOTECH 100

It is important to take the whole course of antibiotics your doctor has prescribed for you, if you do not, your condition or infection may recur or get worse.

4. Possible side effects

DOXYCYCLINE BIOTECH 100 can have side effects. Not all side effects reported for DOXYCYCLINE BIOTECH 100 are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking DOXYCYCLINE BIOTECH 100, please consult your healthcare provider for advice.

If any of the following happens, stop taking DOXYCYCLINE BIOTECH 100 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
 - rash or itching,
 - fainting,
 - yellowing of the skin and eyes, also called jaundice.
- These are very serious side effects. If you have them, you may have had a serious reaction to DOXYCYCLINE BIOTECH 100. 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:

- upset stomach, loss of appetite, severe, persistent or bloody diarrhoea (this may occur up to two or three months after the last dose and may be associated with stomach pain or fever). This may occur after treatment with antibiotics and can be a sign of serious bowel inflammation
 - you notice that your skin is very sensitive to light (you may get a skin rash, itching, redness or severe sunburn when out in sunlight or after using a sun bed)
 - low blood pressure
 - pericarditis (inflammation of the two layers surrounding the heart)
 - fast heart rate
 - worsening of systemic lupus erythematosus (SLE)
 - serum sickness
 - shortness of breath or breathlessness (dyspnoea)
 - blood vessel inflammation
 - fever, swollen lymph nodes or skin rash. These may be symptoms of a condition known as DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) and can be severe and life-threatening
 - severe skin reactions such as erythema multiforme (circular, irregular red patches), Stevens-Johnson syndrome (rash with flushing, fever, blisters or ulcers), toxic epidermal necrolysis (reddening, peeling and swelling that resembles burns)
 - the Jarisch–Herxheimer reaction which causes fever, chills, headache, muscle pain and skin rash that is usually self-limiting. This occurs shortly after starting DOXYCYCLINE BIOTECH 100 treatment for infections with spirochete such as Lyme disease
- 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:

- headache
- feeling or being sick
- eat disorder
- reddish-purple spots on the lower extremities, swollen and sore joints, abdominal pain or bloody urine
- hives
- swelling of the legs and arms

Less frequent side effects:

- vaginal infection, vaginitis
- thrush of the vagina or mouth
- blood disorders, these are due to changes in numbers of different cell types in the blood. Symptoms may include tiredness, easy bruising or infections
- discolouration of thyroid tissue (does not affect thyroid function)
- unexplained blood disorder (porphyria) and urine discolouration is a symptom
- eating disorder (loss of appetite)
- increased pressure in the skull (severe headaches, blurred and/or double vision, blind spots), permanent loss of vision
- bulging fontanelles (soft spot on head) of infants
- anxiety
- tinnitus (ringing noise in ear)
- skin reddening (flushing)
- heartburn
- pancreatitis (manifested by severe upper abdominal pain)
- difficulty swallowing, stomach pain, diarrhoea
- inflammation and/or ulcers of the gullet (symptoms may include sore mouth, indigestion)
- oral thrush (redness and soreness)
- inflammation of the tongue
- soreness and itching of the rectal and/ or genital area
- inflammation around the vagina
- inflammation and damage to the liver
- abnormal liver function tests
- redness and peeling of the skin (dermatitis exfoliative)
- detachment of the nail from finger bed
- aches in the joints or muscles
- increased urea in the blood

Frequency unknown:

- vitamin deficiencies may occur
- discolouration of teeth.

The use of expired DOXYCYCLINE BIOTECH 100 may lead to a Fanconi-type syndrome which is characterised by polyuria and polydipsia with nausea, vomiting, proteinuria, glycosuria, acidosis, aminoaciduria, hypophosphatemia and hypocalcaemia.

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 DOXYCYCLINE BIOTECH 100.

5. How to store DOXYCYCLINE BIOTECH 100

Store all medicines out of reach of children. Store at or below 25 °C in a well-closed container.

Protect from light.

Do not use after the expiry date stated on the label and carton.

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 DOXYCYCLINE BIOTECH 100 contains

- The active substance is doxycycline.
- The other ingredients are: colloidal silicon dioxide, croscarmellose sodium and microcrystalline cellulose.
- Tablet coating: TC/530027 Orange which consist of: carnauba wax, hypromellose, polyethylene glycol/ macrogol, sunset yellow FCF aluminium lake and titanium dioxide.

What DOXYCYCLINE BIOTECH 100 looks like and contents of the pack

Round, light orange, film-coated, biconvex tablets, engrave "Dox" over "100" on one side and other side plain. DOXYCYCLINE BIOTECH 100 film-coated tablets are packed in white, opaque, HDPE plastic bottles of 100 and 250. DOXYCYCLINE BIOTECH 100 tablets are packed as blister strips of 14's in Alu/ PVC strips.

Packs of 14's (1 x strip) or 28's (2 x strips) are available and further packed in an outer carton or patient ready pack. All pack sizes and strengths may not necessarily be marketed at one time.

Holder of Certificate of Registration

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DOXYCYCLINE BIOTECH 100

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:

[54]

DOXYCYCLINE BIOTECH 100 (100 mg doksisiklien) Filmbedekte tablette DOKSISIKLIEN Suikervry

Lees die hele pamflet noukeurig deur voordat jy DOXYCYCLINE BIOTECH 100 begin neem

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- As jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- DOXYCYCLINE BIOTECH 100 is persoonlik vir jou voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat hierdie pamflet bevat

- Wat DOXYCYCLINE BIOTECH 100 is en waarvoor dit gebruik word
- Wat jy moet weet voordat jy DOXYCYCLINE BIOTECH 100 neem
- Hoe om DOXYCYCLINE BIOTECH 100 te neem
- Moontlike newe-effekte
- Hoe om DOXYCYCLINE BIOTECH 100 te bewaar
- Inhoud van die pakkie en ander inligting

1. Wat DOXYCYCLINE BIOTECH 100 is en waarvoor dit gebruik word
DOXYCYCLINE BIOTECH 100 is ’n breëspektrum tetrasiklien-antibiotikum en mag gebruik word om ’n wye reeks infeksies wat deur bakterieë veroorsaak word, te behandel:

- Asemhalingskanaalinfeksies soos sinusitis, inflammasie van die farinks, longinfeksie veroorsaak deur Mycoplasma, papegaaikoors en chroniese brongchitis.
- Urienweginfeksies.
- Seksueel oordraagbare siektes.
- Velinfeksies soos aknee.
- Infeksies van die oog.
- Ander infeksies soos malaria, cholera, brusellose, leptospirose en koors wat deur luise of bosluise veroorsaak word.
- Rickettsiale infeksies soos Q-koors, bosluiskoors.
- Konyngoors, tropiese infeksie van die vel (Yaws) en langtermyn infeksie wat sere of absesse in die liggaam se sagte weefsel veroorsaak.

2. Wat jy moet weet voordat jy DOXYCYCLINE BIOTECH 100 neem
Moenie DOXYCYCLINE BIOTECH 100 neem nie:

- as jy hipersensitief (allergies) is vir doksisiklienhiklaat, ander tetrasiklene of enige van die ander bestanddele van DOXYCYCLINE BIOTECH 100 (gelys in afdeling 6),
- as jy een of ander vorm van nier (renale) siekte het.
- as jy swanger is of jou baba borsvoed.
- as jy swanger is, is jy meer vatbaar vir ernstige doksisiklien-geïnduseerde lewerskade.
- as jy jonger as 12 jaar oud is, aangesien permanente verkleuring van tande kan voorkom.
- as jy ’n inflammatoriese siekte van bindweefsel het (sistemiese lupus eritematose).

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met DOXYCYCLINE BIOTECH 100:

- as jy waarskynlik aan direkte sonlig of ultravioletlig blootgestel sal word, of as jy reeds sonbrand het,
- as jy enige lewersiekte het of medisyne neem wat jou lewer aantas,
- as jy ernstige nierprobleme het,
- as jy ernstige velreaksies ervaar soos eritema multiforme (sirkelvormige, onreëlmatige rooi kolle), Stevens-Johnson-sindroom (uitslag met blosing, koors, blase of sere), toksiese epidermale nekrolise (rooiwording, afskilfering en swelling wat soos brandwonde lyk),
- as jy diarree het of gewoonlik diarree kry wanneer jy antibiotika neem of aan probleme met jou maag of ingewande gely het. Indien jy ernstige langdurige of bloederige diarree ontwikkel tydens of na die gebruik van DOXYCYCLINE BIOTECH 100, vertel jou dokter dadelik aangesien dit nodig mag wees om die behandeling te onderbreek. Dit kan ’n teken wees van derminflammasie (pseudomembraneuse kolitis) wat kan voorkom na behandeling met antibiotika,
- as jy aan porfirie ly (’n tekort aan spesifieke ensieme in die liggaam wat ’n toename in stowwe genoem porfiriene veroorsaak),
- as jy orale retinoïede neem, aangesien daar ’n groter risiko is om aan verhoogde druk in jou skedel te ly (erge hoofpyn met verandering in visie) wanneer dit saam met DOXYCYCLINE BIOTECH 100 geneem word,
- as jy verswak of bejaard is,
- as jy ’n vaginale infeksie of bloedinfeksie het wat deur ’n swam veroorsaak word,
- as jy ’n maagseer het of die inhoud van die maag braak met donker bloed, slukderm (inflammasie van die slukderm), (sien “Hoe om DOXYCYCLINE BIOTECH 100 te neem”),
- as jy een of ander vorm van seksueel oordraagbare siekte het (bv. sifilis),
- as jy aan myasthenia gravis ly, ’n toestand wat gekenmerk word deur spierswakheid, moeiλικheid om te kou en te sluk en onduidelike spraak,
- as jy aan sistemiese lupus eritematose (’n inflammatoriese siekte van bindweefsel) ly, sien “Moenie DOXYCYCLINE BIOTECH 100 neem nie”.
- as jy koue rillings ervaar, ’n styging in temperatuur, en verergering van veluitslag bekend as die Jarisch-Herxheimer reaksie (JHR) binne 24 uur na antibiotika behandeling van die spirogetale infeksies soos sifilis, Lyme-siekte, leptospirose en herhalende koors (RF), hierdie simptome is die gevolg van antibiotika behandeling van spirocheet infeksies en gewoonlik selfbeperkend.

Kinders

DOXYCYCLINE BIOTECH 100 moet nie by kinders jonger as 12 jaar gebruik word nie (sien afdeling 4.3).

Ander medisyne en DOXYCYCLINE BIOTECH 100

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

- medisyne soos teenuurmiddels wat aluminium, kalsium of magnesium bevat of ander medisyne wat yster-, bismut- of sinksoort bevat moet dit nie op dieselfde tyd as DOXYCYCLINE BIOTECH 100 neem nie, aangesien absorpsie van DOXYCYCLINE BIOTECH 100 verminder kan word,
- warfarien of ander antikoagulanste (om bloedstolling te stop),
- medisyne vir die behandeling van epilepsie soos fenobarbital, karbamasepien, primidoon en fenitotoïen kan interaksie hê met die metabolisme van DOXYCYCLINE BIOTECH 100,
- penisillien moet nie saam met DOXYCYCLINE BIOTECH 100 gebruik word nie, aangesien dit die werking van DOXYCYCLINE BIOTECH 100 kan blokkeer,
- DOXYCYCLINE BIOTECH 100 kan die doeltreffendheid van die pil (orale voorbehoedmiddels) verminder,
- metoksifluraan (’n narkosemiddel), as jy ’n operasie benodig, vertel jou dokter of tandarts dat jy DOXYCYCLINE BIOTECH 100 neem,
- alkohol kan die hoeveelheid tyd wat dit neem vir DOXYCYCLINE BIOTECH 100 verminder om die helfte van sy sterkte in bloedplasma te verloor,
- siklosporien (wat gebruik word na orgaanoorplantings) moet toepaslik gemonitor word,
- rifampisien (tuberkulosebehandeling) kan interaksie hê met DOXYCYCLINE BIOTECH 100. Dit kan lei tot ’n sub-terapeutiese effek van DOXYCYCLINE BIOTECH 100 (die dosis wat teen ’n te lae vlak toegedien word om die siekte te behandel),
- isotretinoïen of ander sistemiese retinoïede (gebruik vir die behandeling van ernstige aknee).

DOXYCYCLINE BIOTECH 100 met kos, drank en alkohol

Jy moet nie alkohol drink terwyl jy DOXYCYCLINE BIOTECH 100 neem nie, alkohol kan die effek van jou medisyne verminder. Sluk die tablette heel met ’n vol glas water. Jy moet die tablette óf sittend óf staande neem en lank voordat jy gaan slaap vir die nag. Dit is belangrik om nie vir ten minste dertig minute te gaan lê nadat jy DOXYCYCLINE BIOTECH 100 geneem het nie.

Swangerskap en borsvoeding

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om ’n baba hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik. Moenie DOXYCYCLINE BIOTECH 100 neem as jy swanger is of jou baba borsvoed nie.

Bestuur en gebruik van masjiene

Moenie bestuur of masjiene gebruik as jy aan visuele versteurings ly soos versteuring van visie terwyl jy DOXYCYCLINE BIOTECH 100 neem nie. Dit is nie altyd moontlik om te voorspel tot watter mate DOXYCYCLINE BIOTECH 100 met jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie by die bogenoemde aktiwiteite betrokke raak voordat jy bewus is van die mate waarin DOXYCYCLINE BIOTECH 100 jou affekteer nie.

3. Hoe om DOXYCYCLINE BIOTECH 100 te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd DOXYCYCLINE BIOTECH 100 presies soos jou dokter of apteker vir jou gesê het. Praat met jou dokter as jy nie seker is nie.

Die gewone dosis is:

- 100 mg twee keer per dag op die eerste dag, dan 100 mg daaglik.
- Vir aknee is die volwasse dosis 50 mg twee keer per dag. DOXYCYCLINE BIOTECH 100 moet per mond geneem word. Dit moet een uur voor etes of twee uur na etes geneem word. Dit moet met voldoende vloeistof en in die regop posisie geneem word. Jou dokter sal jou vertel hoe lank jou behandeling met DOXYCYCLINE BIOTECH 100 sal duur. Moenie behandeling vroeg staak nie, selfs al voel jy voel beter.
- As jy die indruk het dat die effek van DOXYCYCLINE BIOTECH 100 te sterk of te swak is, vertel jou dokter of apteker.

As jy meer DOXYCYCLINE BIOTECH 100 neem as wat jy moet
In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As jy vergeet om DOXYCYCLINE BIOTECH 100 te neem

Moenie ’n dubbeldosis neem om vergete individuele dosisse in te haal nie.

As jy ophou om DOXYCYCLINE BIOTECH 100 te neem

Dit is belangrik om die hele kursus antibiotika te neem wat jou dokter vir jou voorgeskryf het, as jy dit nie doen nie, kan jou toestand of infeksie herhaal of vererger.

4. Moontlike newe-effekte

DOXYCYCLINE BIOTECH 100 kan newe-effekte hê. Nie alle newe-effekte wat vir DOXYCYCLINE BIOTECH 100 aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy DOXYCYCLINE BIOTECH 100 neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om DOXYCYCLINE BIOTECH 100 te neem en vertel jou dokter dadelik of gaan na die ongevallen-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat moeiλικheid met sluk of asemhaal kan veroorsaak,
- uitslag of jeuk,
- floute,
- vergeling van die vel en oë, ook genoem geelsug.

Hierdie is baie ernstige newe-effekte. As jy dit het, het jy dalk ’n ernstige reaksie op DOXYCYCLINE BIOTECH 100 gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter dadelik of gaan na die ongevallen-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- omgekrapte maag, verlies aan eetlus, erge, aanhoudende of bloederige diarree (dit kan tot twee of drie maande na die laaste dosis voorkom en kan met maagpyn of koors geassosieer word). Dit kan voorkom na behandeling met antibiotika en kan ’n teken wees van ernstige derminflammasie
 - jy agterkom dat jou vel baie sensitief is vir lig (jy kan ’n veluitslag, jeuk, rooiheid of erge sonbrand kry wanneer jy buite in sonlig is of nadat jy ’n sonbed gebruik het)
 - lae bloeddruk
 - perikarditis (inflammasie van die twee lae wat die hart omring)
 - vinnige hartklop
 - verergering van sistemiese lupus erythematosus (SLE)
 - serumsiekte
 - kortasem of asemloosheid (dyspnee)
 - bloedvatinflammasie
 - koors, geswelde limfkliere of veluitslag. Dit kan simptome wees van ’n toestand bekend as DRESS (Dwelmreaksie met Eosinofilie en Sistemiese Simptome) en kan ernstig en lewensgevaarlik wees
 - ernstige velreaksies soos eritema multiforme (sirkelvormige, onreëlmatige rooi kolle), Stevens Johnson-sindroom (uitslag met blosing, koors, blase of sere), toksiese epidermale nekrolise (rooiwording, afskilfering en swelling wat soos brandwonde lyk)
 - die Jarisch-Herxheimer-reaksie wat koors, kouekoors, hoofpyn, spierpyn en veluitslag veroorsaak wat gewoonlik selfbeperkend is. Dit vind plaas kort na die begin van DOXYCYCLINE BIOTECH 100 behandeling vir infeksies met spirocheet soos Lyme-siekte
- Hierdie is alles ernstige newe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter as jy enige van die volgende opmerk:

Gereelde newe-effekte:

- hoofpyn
- siek voel of wees
- eetversteuring
- rooiere-pers kolle op die onderste ledemate, geswelde en seer gewrigte, buikpyn of bloederige uriene
- korwe
- swelling van die bene en arms

Minder gereelde newe-effekte:

- vaginale infeksie, vaginitis
- sproei van die vagina of mond
- bloedafwykings, dit is as gevolg van veranderinge in getalle van verskillende seltypes in die bloed. Simptome kan moegheid, maklike kneusing of infeksies insluit
- verkleuring van skildklierweefsel (beïnvloed nie tiroïedfunksie nie)
- oorgeërfde bloedversteuring (porfirie) en uriënverkleuring is ’n simptoom eetversteuring (verlies aan eetlus)
- verhoogde druk in die skedel (ernstige hoofpyn, dowwe en/ of dubbelvisie, blinde kolle), permanente verlies van visie
- bultende fontanelle (sagte kol op kop) van babas
 - angs
 - tinnitus (lui geluid in die oor)
 - vel wat ooi word (blosing)
 - sooibrand
 - pankreatitis (gemanifesteer deur erge pyn in die boonste buik)
 - sukkel om te sluk, maagpyn, diarree
 - inflammasie en/ of sere van die slukderm (simptome kan seer mond en slegte spysvertering insluit)
 - mondsproei (rooiheid en seerheid)
 - inflammasie van die tong
 - seerheid en jeuk van die rektale en/ of geslagsarea
 - inflammasie rondom die vagina
 - inflammasie en skade aan die lewer
 - abnormale leverfunksietoetse
 - rooiheid en afskilfering van die vel (dermatitis exfoliative)
 - losmaak van die nael van vingerbed
 - pyne in die gewrigte of spiere
 - verhoogde ureum in die bloed

Frekwensie onbekend:

- vitamientekorte kan voorkom
- verkleuring van tande.

Die gebruik van DOXYCYCLINE BIOTECH 100 wat vervat het, kan lei tot ’n Fanconi-tipe sindroom wat gekenmerk word deur polurie en polydipsie met narkheid, braking, proteïenuurie, glikosurie, asidose, aminosidurie, hipofosfatemie en hipokalsemie.

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

Aanmelding van newe-effekte

As jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die **“6.04 Adverse Drug Reaction Reporting Form”**, wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy meer inligting verskaf oor die veiligheid van DOXYCYCLINE BIOTECH 100.

5. Hoe om DOXYCYCLINE BIOTECH 100 te bewaar

Bewaar alle medisyne buite bereik van kinders. Bewaar teen of benede 25 °C in ’n dig geslote houer. Beskerm teen lig.

Moet nie na die vervaldatum soos op die etiket en karton gebruik nie. Gee alle ongebruikte medisyne terug na jou apteker. Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting

Wat DOXYCYCLINE BIOTECH 100 bevat

- Die aktiewe bestanddeel is doksisiklien.
- Die ander bestanddele is: kolloïdale silikondioksied, kroskarmellose-natrium en mikrokristallyne sellulose.
- Tabletbedekking: TC/530027 Oranje wat bestaan uit: karnaubawas, hipromellose, poliëtiënglikol/ makrogol, sonsondergeel FCF aluminiummeer en titaandioksied.

Hoe DOXYCYCLINE BIOTECH 100 lyk en die inhoud van die verpakking
Ronde, ligoranje, filmbedekte, bikonvekse tablette, graveer “Dox” oor “100” aan die een kant en ander kant eenvoudig.

DOXYCYCLINE BIOTECH 100 filmbedekte tablette word verpak in wit, ondeursigtige HDPE plastiekbottels van 100 en 250. DOXYCYCLINE BIOTECH 100 tablette word as stulpstrokke van 14 in Alu/ PVC-stroke verpak.

Pakkies van 14 (1 x strook) of 28 (2 x stroke) is beskikbaar en verder verpak in ’n buitekarton of pasiëntgereed pak. Alle pakgroottes en sterkpunte hoef nie noodwendig op een slag bemark te word nie.

Houer van Registrasiesertifikaat

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Hierdie pamflet is laas hersien in

6 Desember 2022

Registrasienommer

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