

DOXYCYCLINE BIOTECH 100 Film-coated tablets
(31/20.1.2/0425)

Each tablet contains doxycycline 100 mg

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.

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- Urinary tract infections.
- Sexually transmitted diseases.
- 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),

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- 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 Do not take DOXYCYCLINE BIOTECH 100).

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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 epilepsy 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

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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.

DOXYCYCLINE BIOTECH 100 should be taken by mouth.

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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:

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- 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

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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)
- inherited 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

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- 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.

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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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. 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

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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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Access to the corresponding Professional Information

The Professional Information is available from Biotech Laboratories (Pty) Ltd. To request a digital copy please email info@biotechlabs.co.za.