**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: S4**

**DOXYCYL 100, capsules**

**Doxycycline**

**Contains sugar: Lactose monohydrate 109,353 mg**

**Read all of this leaflet carefully before you start taking DOXYCYL 100**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DOXYCYL 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 DOXYCYL 100 is and what it is used for
2. What you need to know before you take DOXYCYL 100
3. How to take DOXYCYL 100
4. Possible side effects
5. How to store DOXYCYL 100
6. Contents of the pack and other information

**1. What DOXYCYL 100 is and what it is used for**

DOXYCYL 100 belongs to a group of medicines called tetracycline antibiotics.

It is used to treat a wide range of infections caused by bacteria, these include:

- Chest, lung or nasal infections e.g., bronchitis, pneumonia, sinusitis
- Infections of the kidneys and bladder e.g., cystitis, urethritis
- Sexually transmitted diseases e.g., gonorrhoea, syphilis
- Eye infections
- Other infections such as cholera, Whipple's disease and tropical sprue (digestive disease)
- Malaria, when chloroquine is not effective
- Rickettsial infections such as Q fever or fevers associated with louse or tick bites and brucellosis, leptospirosis, rabbit's disease, long-term bacterial infection that affects the face and neck

**2. What you need to know before you take DOXYCYL 100**

**Do not take DOXYCYL 100:**

- if you are hypersensitive (allergic) to doxycycline or any of the other ingredients of DOXYCYL 100 (listed in section 6).
- if you have a known allergy to tetracyclines
- if you are pregnant or are breastfeeding
- if you have systemic lupus erythematosus, a condition characterised by a rash (especially on the face), hair loss, fever, malaise and joint pain
- if you are taking medicines such as antacids (indigestion tablets or liquids) containing aluminium, calcium, magnesium or milk
- if you are taking medicines which affect your liver
- if you have porphyria (a rare genetic disease of blood pigments)

You should not use DOXYCYL 100 during periods of tooth development (pregnancy, infancy or in children below 12 years of age) as such use may lead to permanent discolouration (yellow-grey-brown) or affect the proper growth of the teeth.

**Warnings and precautions**

Special care should be taken with DOXYCYL 100:

- if you are likely to be exposed to strong sunlight or ultraviolet light (e.g. on a sunbed)
- if you have liver problems or are taking medicines 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 DOXYCYL 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 have inflammation and/or ulcers of the gullet (see “How to take DOXYCYL 100”)
- if you 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 DOXYCYL 100
- if you are suspected of having syphilis. Your doctor will continue to monitor you after your treatment has stopped
- if you need to have urine or glucose testing done
- if you are elderly and frail
- if you have myasthenia gravis (a disease which causes unusual tiredness and weakness of certain muscles, particularly in the eyelid, difficulty chewing and swallowing and slurred speech).
- 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**

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

**Other medicines and DOXYCYL 100**

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

- medicines such as antacids (indigestion tablets or liquids) containing aluminium, calcium, magnesium or other medicines containing iron, bismuth or zinc salts, should not be taken at the same time as your medicine, as absorption of your medicine may be reduced
- sucralfate (used to treat and prevent stomach ulcers)
- anticoagulants (used to thin the blood, e.g., warfarin)
- carbamazepine, phenytoin, primidone or other drugs used to control epilepsy
- barbiturates (strong sleeping tablets, e.g. phenobarbital)
- ciclosporin (used to affect the body’s immune response following organ transplants)
- methoxyflurane (an anaesthetic). If you need an operation, tell your doctor or dentist that you are taking DOXYCYL 100
- retinoids (used to treat various skin conditions)
- rifampicin (used to treat tuberculosis)
- lithium (to treat bipolar disorder) and digoxin (to treat heart failure)
- methotrexate (used to treat cancer, psoriasis or rheumatoid arthritis)

- ergotamine or methysergide (used to treat migraines or headaches)
- penicillin antibiotics (used to treat infections)
- oral contraceptives ('The Pill'). This medicine may make the oral contraceptive pill less effective. You should use additional contraceptive precautions whilst taking this medicine
- quinapril (used to lower high blood pressure)

**DOXYCYL 100 with food and alcohol**

Alcohol may reduce the effect of your medicine. It is therefore advisable to avoid drinking any alcohol.

**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 health care provider for advice before taking DOXYCYL 100.

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

The effect of DOXYCYL 100 on fertility is unknown.

**Driving and using machines**

It is not always possible to predict to what extent DOXYCYL 100 may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which DOXYCYL 100 affects you.

Do not drive or use machines if you suffer from visual disturbances such as blurring of vision while taking DOXYCYL 100.

**DOXYCYL 100 contains lactose monohydrate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DOXYCYL 100.

**3. How to take DOXYCYL 100**

Do not share medicines prescribed for you with any other person.

Always take DOXYCYL 100 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

DOXYCYL 100 should be taken by mouth as follows:

It is important to swallow each DOXYCYL 100 capsule whole with a glass of water.

It is best to take your capsules at the same time(s) each day, when standing or while sitting.

It is important not to lie down for at least thirty minutes after taking DOXYCYL 100 capsules, so that the capsule can move as swiftly as possible into the stomach and prevent irritation of the throat or oesophagus (canal taking food from the mouth to the stomach).

If your stomach is upset, DOXYCYL 100 can be taken with a meal.

***Adults***

The usual dose is 200 mg (two capsules) on the first day, then 100 mg (one capsule) daily. The length of treatment is dependent on the infection being treated.

*Prevention of malaria*

100 mg daily for 1-2 days before travelling until 4 weeks after returning.

*For a bacterial infection (Trachoma)*

100 mg (one capsule) daily for 40 days.

*For inflammation of a man's urethra*

100 mg (one capsule) every 12 hours for 7 days.

DOXYCYL 100 for the treatment of acute infections in children under 8 years of age should be used in situations where other medicines are not available or are not likely to be effective. In such circumstances, the usual doses are:

*For children 50 kg or less:*

First day: 4 mg for each kg of bodyweight daily for first 24 hours, then 2 mg for each kg of bodyweight.

The length of treatment is dependent on the infection being treated.

Your doctor will tell you how long your treatment with DOXYCYL 100 will last. If you have the impression that the effect of DOXYCYL 100 is too strong or too weak, tell your doctor or pharmacist.

**If you take more DOXYCYL 100 than you should**

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

**If you forget to take DOXYCYL 100**

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

**If you stop taking DOXYCYL 100**

Do not stop treatment early because of recurrence of the infection.

## 4. Possible side effects

DOXYCYL 100 can have side effects.

Not all side effects reported for DOXYCYL 100 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DOXYCYL 100, please consult your health care provider for advice.

If any of the following happens, stop taking DOXYCYL 100 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 DOXYCYL 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:

- severe watery or bloody diarrhoea, fever and cramps (pseudomembranous colitis), stomach pains
- the Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain and skin rash that is usually self-limiting. This occurs shortly after starting DOXYCYL 100 treatment for infections with spirochete such as Lyme disease
- worsening of systemic lupus erythematosus (autoimmune disease)
- airways become inflamed, narrow and swell and produce extra mucus, which makes it difficult to breathe (asthma)
- porphyria (sensitivity of the skin to sunlight, inflammation of nerves and stomach pains)

- sudden painless swelling under the skin, triggered by an allergy to animal dander, pollen, drugs, venom, food or medicine, swelling of your lower legs or hands
- pericarditis (inflammation of the membrane surrounding the heart)
- unusual rapid heartbeat (tachycardia)
- low blood pressure
- 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)
- sensitivity to sunlight - you may get a skin rash, itching, redness or severe sunburn when out in sunlight or after using a sun bed
- aches in the joints or muscles
- shortness of breath or breathlessness (dyspnoea)

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
- 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
- oral thrush (redness and soreness)
- oral thrush that occurs in the airways
- vaginitis
- soreness and itching of the rectal and/or genital area
- 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 the thyroid tissue when given for long periods. The medicine does not impair thyroid function
- decreased appetite
- increased pressure in the skull (severe headache which may be associated with visual disturbances such as blurred vision, double vision or loss of vision)
- bulging fontanelles (soft spot on head) of infants
- anxiety
- a ringing or buzzing noise in the ear (tinnitus)
- skin reddening (flushing)
- heartburn
- pancreatitis (manifested by severe upper abdominal pain)
- inflammation and/or ulcers of the gastrointestinal tract (symptoms may include sore mouth, indigestion)
- difficulty swallowing, stomach pain, diarrhoea
- inflammation of the mucous membrane of the mouth
- inflammation of the tongue, tongue discoloration

- dry mouth
- inflammation and damage to the liver
- abnormal liver function tests, jaundice (yellowing of the skin or white of the eyes)
- skin hyperpigmentation (with chronic use of doxycycline)
- redness and peeling of the skin (dermatitis exfoliative)
- loosening of the nail from the nail bed after exposure to the sun
- increased levels of urea in the blood

*Side effects with unknown frequency:*

- vitamin deficiency
- discolouration of teeth

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 DOXYCYL 100.

**5. How to store DOXYCYL 100**

Store all medicines out of reach of children.

Store at or below 25 °C in airtight containers.

Protect from light.

Do not use after the expiry date stated on the label / carton / bottle

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 DOXYCYL 100 contains

- The active substance is doxycycline.
- The other ingredients are brilliant blue (C.I 42090), erythrosine (C.I. 45430), gelatin, lactose monohydrate, magnesium stearate, purified talc, starch maize.

### What DOXYCYL 100 looks like and contents of the pack

DOXYCYL 100 is a yellow granular powder encapsulated within a no.3 capsule with a clear body and blue transparent cap.

6 capsules are packed in a clear polyvinylchloride film sealed with silver, aluminium foil backing. One or more blister strips are packed into an outer cardboard carton together with a leaflet.

30 or 100 capsules are packed in a white polypropylene container and sealed with a white low density polyethylene snap-on cap together with a leaflet.

100 capsules are packed in a white high density polyethylene container and sealed with a white polypropylene cap, together with a white silica gel capsule and a leaflet.

500 capsules are packed in a white polypropylene securitainer and sealed with a white low density polyethylene snap-on cap together with a silica gel sachet and leaflet.

1 000 capsules are packed into amber polyvinyl chloride Xactic containers and sealed with a white high density polyethylene screw cap together with a silica gel sachet and leaflet.

1 000 capsules are packed in a white high density polyethylene container and sealed with a white polypropylene cap, together with a white silica gel capsule and a leaflet.

Not all packs are necessarily marketed.

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