PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DOXYCYL CAPSULES, 50 mg

Doxycycline

Contains sugar: Lactose monohydrate 77,6 mg

Read all of this leaflet carefully before you start taking DOXYCYL CAPSULES

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

1. What DOXYCYL CAPSULES is and what it is used for

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

It is used to treat infections of the skin such as acne.

2. What you need to know before you take DOXYCYL CAPSULES

Do not take DOXYCYL CAPSULES:

- if you are hypersensitive (allergic) to doxycycline or any of the other ingredients of DOXYCYL CAPSULES (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 have to be treated with hepatotoxic medicines
- if you have porphyria

You should not use DOXYCYL CAPSULES 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 CAPSULES:

- 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 are likely to be exposed to strong sunlight or ultraviolet light (e.g., on a sunbed)
- 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 CAPSULES 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 CAPSULES”)
- if you experience severe headache which may be associated with visual disturbances such as blurred vision, double vision or loss of vision, this is because of increased pressure in the skull
- 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).

Children

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

Other medicines and DOXYCYL CAPSULES

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
- kaolin (used to treat diarrhoea)
- sucralfate (used to treat and prevent stomach ulcers)
- quinapril (used to lower high blood pressure)

- colestipol and medicines containing sodium carbonate
- 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)
- lithium (to treat bipolar disorder) and digoxin
- 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 and for 7 days after stopping.
- ciclosporin (used to affect the body's immune response following organ transplants)
- rifampicin (used to treat tuberculosis)
- retinoids (used to treat various skin conditions)
- methoxyflurane (an anaesthetic). If you need an operation, tell your doctor or dentist that you are taking DOXYCYL CAPSULES
- Typhoid vaccine (used to prevent typhoid fever if travelling to infected areas of the world).

DOXYCYL CAPSULES 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 CAPSULES.

Do not use DOXYCYL CAPSULES if you are pregnant or breastfeeding your baby. The effect of DOXYCYL CAPSULES on fertility is unknown.

Driving and using machines

It is not always possible to predict to what extent DOXYCYL CAPSULES 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 CAPSULES affects you.

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

DOXYCYL CAPSULES contains lactose monohydrate

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

3. How to take DOXYCYL CAPSULES

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

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

The usual dose is 1 capsule (50 mg) twice a day.

It is important to swallow each DOXYCYL CAPSULES 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 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 CAPSULES can be taken with a meal.

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

If you take more DOXYCYL CAPSULES 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 CAPSULES

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

If you stop taking DOXYCYL CAPSULES

Do not stop treatment early as your acne may return if you do not finish the course of capsules.

4. Possible side effects

DOXYCYL CAPSULES can have side effects.

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

If any of the following happens, stop taking / using DOXYCYL CAPSULES 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 CAPSULES. 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 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)
- low blood pressure
- airways become inflamed, narrow and swell and produce extra mucus, which makes it difficult to breathe (asthma)
- unusual rapid heartbeat (tachycardia)
- hives
- porphyria (sensitivity of the skin to sunlight, inflammation of nerves and stomach pains)
- swollen tongue, severe watery or bloody diarrhoea, fever and cramps (pseudomembranous colitis), stomach pains
- worsening of systemic lupus erythematosus (autoimmune disease)
- 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)

- 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.
- 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
- 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 CAPSULES treatment for infections with spirochete.

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:

- reddish-purple spots on the lower extremities, swollen and sore joints, abdominal pain or bloody urine
- headache
- feeling or being sick
- dry mouth

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
- anxiety
- bulging fontanelles (soft spot on head) of infants
- increased pressure in the skull (severe headache which may be associated with visual disturbances such as blurred vision, double vision or loss of vision)
- a ringing or buzzing noise in the ear (tinnitus)
- visual disturbance
- skin reddening (flushing)
- pancreatitis (manifested by severe upper abdominal pain)
- heartburn
- inflammation of the tongue
- inflammation and/or ulcers of the gastrointestinal tract (symptoms may include sore mouth, indigestion and difficulty swallowing)
- difficulty swallowing, stomach pain
- inflammation of the mucous membrane of the mouth
- inflammation and damage to the liver
- abnormal liver function tests
- skin hyperpigmentation (with chronic use of doxycycline)
- 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 CAPSULES.

5. How to store DOXYCYL CAPSULES

Store all medicines out of reach of children.

Store at or below 25 °C in airtight containers.

Keep in original packaging until required for use.

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 CAPSULES contains

- The active substance is doxycycline.
- The other ingredients are black oxide (C.I. 77499), gelatin, lactose monohydrate, magnesium stearate, ponceau 4R (C.I. 16255), purified talc, red oxide (C.I. 77491), starch maize dried,

titanium dioxide (C.I. 77891), yellow oxide (C.I. 77492).

What DOXYCYL CAPSULES looks like and contents of the pack

DOXYCYL CAPSULES is a yellow granular powder encapsulated within a no. 4 opaque capsule, with a red cap and brown body.

30 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.

30 capsules, together with a leaflet, are packed in a white polypropylene container and sealed with a white low density polyethylene screw cap or a white polypropylene cap.

Not all packs are necessarily marketed.

Holder of Certificate of Registration

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