Approved Patient Information Leaflet for Medicines for Human Use:

DOXYTET

SCHEDULING STATUS: S4

PRPRIETARY NAME STRENGTH AND PHARMACEUTICAL FORM

DOXYTET (CAPSULES)

Read all of this leaflet carefully before you start taking DOXYTET

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **DOXYTET** 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 DOXYTET CONTAINS

Capsule content:

The active substance:

Each capsule contains doxycycline hyclate equivalent to doxycycline 100 mg

Other ingredients: magnesium stearate, microcrystalline cellulose (pH 102), sodium lauryl sulphate.

Capsule shell: sunset yellow C.I. 15985, patent blue VC.I. 42051, quinoline yellow C.I. 47005, titanium dioxide C.I. 77891 and dry gelatin.

Sugar free.

WHAT DOXYTET IS USED FOR

DOXYTET belongs to a group of medicines called broad spectrum antibiotics, which are used to treat a range of infections caused by bacteria.

DOXYTET is indicated for the treatment of:

- Upper and lower respiratory tract: sinusitis, pharyngitis (sore throat), pneumonia, chronic bronchitis,
- Urinary tract infections such as non-specific urethritis,
- Sexually transmitted diseases such as gonorrhoea, and syphilis
- Skin infections such as acne,
- Infections of the eye such as conjunctivitis,
- Other infections such as cholera (severe sickness and diarrhoea), psittacosis (headache, nose bleeds, shivering, fever), Whipple's disease (malabsorption), brucellosis (headache, sickness, fever, swollen lymph nodes), rickettsial infections such as tick fever (severe headache, rash, high fever), leptospirosis (fever causing jaundice or meningitis) during the early infective phase.
- Malaria prophylaxis (prevention): for short-term prevention of malaria in areas where high level of chloroquine resistant has been reported and the traveller who cannot tolerate mefloquine or other agents for the prophylaxis of malaria.

BEFORE YOU TAKE DOXYTET

Do not take DOXYTET:

- If you are allergic (hypersensitive) to any tetracycline or the other similar antibiotic or any of the other ingredients of **DOXYTET.**

  Some of the symptoms of an allergic reaction may include:

  - Skin rash, itching,
  - Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing,
  - Wheezing or shortness of breath.
- If you are pregnant or breastfeeding your child.
- If the patient is a young child under the age of 12 years,
- If you have systemic lupus erythematosus.

Take special care with DOXYTET:

- In patients with liver function problems
- Symptoms of myasthenia gravis (muscle weakness, difficulty chewing, slurred speech) may be aggravated.
- Sensitivity to sunlight (photosensitivity) and development of a sunburn reaction has occurred with some individuals. If you plan to be exposed to direct sunlight, preventative use of a sunscreen is recommended (see **"Possible side effects").**
- Raised intracranial pressure may occur particularly in infants and especially if vitamin A or other compounds related to vitamin A (retinoids) are given concomitantly.
- The use of expired **DOXYTET** may lead to the Fanconi-type syndrome [polyuria abnormal large production of urine) and polydipsia (excessive thirst) with nausea, vomiting, proteinuria, glucosuria, acidosis and aminoaciduria (protein, glucose and amino acids in the urine)].
- A Jarisch-Herxheimer-like reaction has been reported in patients with relapsing fever treated with **DOXYTET.**
- In frail and elderly patients-they are susceptible to liver toxicity and a negative nitrogen balance may be induced.
- Increased severity of uraemia and hepatotoxicity (a toxic effect on the liver) in patients with kidney disease when given high doses.
- Vitamin deficiencies may occur.
- **DOXYTET** is not indicated for treating commonly occurring infections in children under 12 years of age (see **"Do not take/give DOXYTET").** Tooth discolouration, enamel hypoplasia and retarded bone growth occur in children under the age of 12 years (These effects may also occur in the fetus if given to pregnant women).
- Do not use concomitantly with hepatotoxic medicines (see **"Taking other medicines with DOXYTET").**

Taking DOXYTET with Food and Drink:

DOXYTET should be taken either one hour before meals or two hours after meals. It should be taken with adequate liquid.

Do not take **DOXYTET** at the same time as milk, alkalis, aluminium hydroxide and other di- and trivalent cations such as calcium, iron and magnesium (see **"Taking other medicines with DOXYTET").**

Pregnancy and Breastfeeding:

DOXYTET is contraindicated for use during pregnancy and breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **DOXYTET** (see **"Do not take/give DOXYTET").**

Taking other medicines with DOXYTET

Always tell your healthcare professional if you are taking any medicine. (This includes complementary or traditional medicines). Please tell your doctor or pharmacist if you are taking, or have recently taken:

- alkalis, aluminium hydroxide and other di- and trivalent cations such as calcium, iron and magnesium (antacids)-absorption of **DOXYTET** is diminished if they are given concomitantly (see **"Taking DOXYTET with Food and Drink").**
- anticoagulants (medicine to thin blood) – the doses of anticoagulants may need to be reduced if given concomitantly with **DOXYTET.**
- penicillin (antibiotic) – when given concomitantly with **DOXYTET** antagonism in action may occur.
- oral contraceptives – **DOXYTET** reduces the effectiveness.
- methoxyflurane – serious nephrotoxicity (damage to the kidneys) may follow with concomitant use with **DOXYTET.**

Laboratory value alterations:

Serum enzyme level values and urinary catecholamine levels may be increased with the use of **DOXYTET.**

HOW TO TAKE DOXYTET

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

Always take **DOXYTET** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Take capsules either one hour before meals or two hours after meals, with adequate liquid (see **"Taking DOXYTET with Food and Drink").**

Usual dose for the commonly occurring infections, depending on the severity of the infection:

100 mg every twelve hours.

Usual dose for uncomplicated gonorrhoea, non-gonococcal urethral, endocervical and rectal infections:

100 mg every twelve hours for seven days.

Malaria prophylaxis:

Adults: 100 mg daily is recommended.

Children over 8 years of age: 2 mg/kg given once daily up to the adult dose is recommended.

Prophylaxis should begin 1 -2 days before travelling to the malaria area and continued daily during travel in the malaria area and for 4 weeks after the traveller leaves the malaria area.

If you take more DOXYTET than you should:

If you take more **DOXYTET** than you should, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take DOXYTET

Take the missed dose as soon as you remembered it. However, if it is almost time for your next regular dose, do not take your missed dose. If you miss two or more doses, consult your doctor or pharmacist. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

DOXYTET can have side effects.

If any of the following happens, stop taking DOXYTET 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,
- Severe skin rash or itching.

These are all serious side effects. If you have them you may have had a serious allergic reaction to **DOXYTET**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following :

- Feeling or being sick (nausea or vomiting) diarrhoea, swollen tongue (glossitis), difficulty with swallowing (dysphagia), inflammation of the digestive tract (enterocolitis),
- Symptoms of raised pressure in the skull,
- Sensitivity to sunlight or artificial light (photosensitivity) and discolouration of nails,
- Blood disorders (changes in the numbers and types of your blood cells, a reduction in the number of platelets (thrombocytopenia), a reduction of the quantity of the oxygen-carrying pigment haemoglobin in the blood (anaemia) caused by increased destruction (haemolysis) of red blood cells,
- Changes in liver or kidney function, yellow skin or eyes (jaundice),
- Redness or colour change of the skin, flaky skin, thrush or irritation around your bottom and genital area (secondary fungal overgrowth),

- Secondary bacterial overgrowth – watery diarrhoea, fever and cramps (pseudomembranous colitis).

Not all side effects reported for DOXYTET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DOXYTET, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform doctor or pharmacist.

STORAGE AND DISPOSING OF DOXYTET

Store all medicine out of reach of children.

Store in a cool place at or below 25 ºC. Protect from light.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF DOXYTET

Carton containing 10 or 100 capsules in blister strips (Al foil/PVC) of 10 capsules each.

Milky white HDPE bottle containing 100 capsules.

Milky white HDPE bottle containing 500 capsules.

Opaque white HDPE round shape container containing 1 000 capsules.

White polyethylene polymer plastic Patient Ready Packs containing 14 or 28 capsules.

IDENTIFICATION OF DOXYTET:

Opaque, hard gelatin, self -locked capsules of size ‘2’ with green cap and green body, containing a yellow granular powder.

REGISTRATION NUMBER:

32/20.1.1/0254

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

Shanur Healthcare (Pty) Ltd

Loch House, Unit 003,

3A Eton Road,

Parktown,

Johannesburg, Gauteng, 2193

DATE OF PUBLICATION

Date of registration: 18 September 2000

Date of last approval by council : 28 September 2009