Approved Patient Information Leaflet for Medicines for Human Use

Please note: This application for registration is submitted as a duplicate and hence [PRODUCT NAME] is used in 1.3 to indicate the names as proposed:

Master **(Proposed proprietary name)**	**Duplicate** **(Proposed proprietary name)**
Lymac 300 mg: 51/20.1.1/0887	Lymecycline 300 mg Unicorn: 51/20.1.1/0888

SCHEDULING STATUS: S4

[PRODUCT NAME] 300 mg Hard Capsules

Lymecycline

Sugar free

Read all of this leaflet carefully before you start taking [PRODUCT NAME].

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- [PRODUCT NAME] 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 [PRODUCT NAME] is and what it is used for

2. What you need to know before you take [PRODUCT NAME]

3. How to take [PRODUCT NAME]

4. Possible side effects

5. How to store [PRODUCT NAME]

6. Contents of the pack and other information

1. WHAT [PRODUCT NAME] is and what it is used for:

[PRODUCT NAME] belongs to a group of medicines called tetracycline antibiotics.

[PRODUCT NAME] is used to treat infections caused by bacteria. If you are not sure why you have been prescribed this medicine, talk to your doctor.

2. What you need to know before you take [PRODUCT NAME]

Do not take [PRODUCT NAME]

- if you are hypersensitive (allergic) to lymecycline or to other tetracycline antibiotics such as doxycycline or any of the other ingredients of [PRODUCT NAME] (listed in section 6). An allergic reaction may include either a rash or itching,
- if you ever had kidney disease,
- if you suffer from systemic lupus erythematosus (an allergic condition that causes joint pain, skin rashes or fever),
- if you are pregnant, planning to become pregnant or are breastfeeding.

[PRODUCT NAME] must not be given to children under 12 years of age.

[PRODUCT NAME] must not be taken at the same time as medicines which contain oral retinoids (these include some other medicines used to treat acne).

Warnings and precautions

Tell your doctor or health care provider before taking [PRODUCT NAME]:

Take special care with [PRODUCT NAME]:

- if you have hepatic impairment or renal insufficiency (failure of liver and kidney function). Should you undergo cycles of prolonged treatment with [PRODUCT NAME], your doctor will prescribe regular checks of blood composition and liver and kidney function,
- if you suffer from myasthenia gravis (a disease that weakens the muscles),
- if you are on other antibiotics as treatment with [PRODUCT NAME] may cause an overgrowth of bacteria and fungi and cause antibiotic resistance and superinfection.

Overdosing may result in liver problems.

Take [PRODUCT NAME] with adequate amounts of water to avoid irritation or ulceration of the oesophagus.

You should avoid direct exposure to sunlight or artificial sunlight from sunbeds. If you experience discomfort then stop taking this medicines and seek advice from your doctor.

Do not use [PRODUCT NAME] if the expiry date has passed, as expired product can cause kidney disorder.

Children

[PRODUCT NAME] should not be used in children under 12 years because of the risk of permanent alterations of tooth and enamel discoloration.

Other medicines and [PRODUCT NAME]

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

Tell your doctor if you are taking any of the following medicines:

- medicines used to thin your blood (anticoagulants) such as warfarin,
- diuretics (used to treat kidney disease, heart disease or high blood pressure),
- other medicines used to treat acne, such as oral retinoids,
- contraceptive medicine (“birth-control” pills).

Do not take the following medicines at the same time as your [PRODUCT NAME] as these could affect how well [PRODUCT NAME] works. Wait at least two hours after taking [PRODUCT NAME] before you take these types of medicines.

- indigestion remedies,
- ulcer healing medicines,
- quinapril (for high blood pressure),
- supplements containing calcium, aluminium, magnesium, zinc or iron.

Avoid use with penicillins (another type of antibiotic), as this may result in possible interference between the two types of medicines.

Do not take antacids containing aluminium, calcium or magnesium and medicines containing iron salts with [PRODUCT NAME], because these products reduce the absorption of [PRODUCT NAME] taken by mouth.
[PRODUCT NAME] should not be used in combination with oral retinoids (medicine used for certain skin conditions) or doses of more than 10 000 IU/day of Vitamin A.
[PRODUCT NAME] should not be used with methoxyflurane as this may result in death due to kidney toxicity.

[PRODUCT NAME] with food and drink

Do not take [PRODUCT NAME] with milk. [PRODUCT NAME] should always be taken with a glass of water.

Pregnancy and breastfeeding and fertility

Tetracycline crosses the placental barrier and is distributed into milk. [PRODUCT NAME] must not be taken if you are pregnant or breastfeeding.
Use of medicines such as [PRODUCT NAME] may affect the proper growth of developing teeth of breastfed children and lead to permanent discolouration.
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 this medicine.

Driving and using machines

It is not always possible to predict to what extent [PRODUCT NAME] 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 [PRODUCT NAME] affects you.

3. How to take [PRODUCT NAME]

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

Always take [PRODUCT NAME] exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The normal dose is one [PRODUCT NAME] hard capsule twice a day (600 mg/day) taken with an adequate quantity of water. Your doctor may recommend a lower or higher dose depending on the severity and type of infection. Ask your doctor if you are unsure.

Do not give [PRODUCT NAME] to children below the age of 12, it could harm them.

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

If you take more [PRODUCT NAME] than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Don't forget to take your container with you. This could indicate how many capsules have been taken.

If you forget to take [PRODUCT NAME]

If you forget to take [PRODUCT NAME] take it as soon as you remember and carry on as before unless it is time for the next dose. **Do not take a double dose to make up for forgotten individual doses.**

If you stop taking [PRODUCT NAME]

It is important that you take all the [PRODUCT NAME] that your doctor has prescribed for you. If you stop taking [PRODUCT NAME] too soon, your infection could get worse or come back.

4. POSSIBLE SIDE EFFECTS

[PRODUCT NAME] can have side effects.

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

If any of the following happens, stop taking [PRODUCT NAME] and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swollen face, lips, tongue and throat,
- difficulty in breathing,
- hives,
- blistering or peeling of large areas of the skin,
- ulcerations or lesions on the mouth, lips, genital or anal regions,
- severe or persistent headaches or visual disturbances.

These are very serious side effects. If you have them, you may have had a serious reaction to [PRODUCT NAME]. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea,
- abdominal pain,
- diarrhoea,
- headache.

Frequency unknown:

- allergic (hypersensitivity) reaction causing swelling of the eyes, lips or tongue,
- blistering or peeling of large areas of the skin,
- ulcerations or lesions on the mouth, lips, genital or anal regions,
- disturbances of eyesight,

- dizziness,
- vomiting (being sick),
- yellowing of the skin or eyes (jaundice), especially in patients with kidney problems,
- inflammation of the liver (hepatitis) and the membrane around the heart (pericarditis),
- increased sensitivity of the skin to sunlight and discolouration or damage of the nails,
- increased pressure in the brain,
- changes in the number and type of certain blood cells,
- pain in the upper part of the abdomen,
- changes in some blood tests (tests of liver function, urea levels),
- fever,
- itchiness, skin rash or hives,
- inflammation of the intestine,
- reddish-purple blood spots on the lower legs, swollen and sore joints, stomach pain or bloody urine,
- a negative nitrogen balance especially in the elderly,
- vitamin deficiencies with use over long periods,
- shaking chills, a rise in temperature, and worsening of skin rashes.

The following side effects may occur during treatment with the class of medicines to which [PRODUCT NAME] belongs (the tetracyclines):

- inflammation or ulceration of the gullet, causing pain or difficulty swallowing or painful heartburn,
- difficulty in swallowing,
- inflammation of the pancreas,
- liver damage,
- teeth discolouration,
- inflammation or soreness of the tongue, mouth, cheeks, gums or lips,
- soreness or itching of the genital area,
- yeast infection around the anus or genitals,

- infection of the colon,
- permanent visual loss.

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 or 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 [PRODUCT NAME].

5. HOW TO STORE [PRODUCT NAME]

- Store all medicines out of reach and sight of children.
- Store at or below 25 °C.
- Store in the original package.
- Keep the blisters in the outer carton.
- There are no special storage instructions for [PRODUCT NAME].
- Do not use after the expiry date stated on the 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 [PRODUCT NAME] contains

- The active substance is lymecycline. Each capsule contains 408 mg of lymecyline equivalent to 300 mg tetracycline base.
- The other ingredients are: silica colloidal, hydrated, magnesium stearate.

The hard capsule shell contains: titanium dioxide (E171), gelatin, indigo carmine FD&C Blue (E132), black iron oxide (E172), titanium dioxide (E171) and yellow iron oxide (E172).

What [PRODUCT NAME] looks like and contents of the pack

[Product name] hard capsules have a blue cap and white body.

[PRODUCT NAME] is supplied in Alu/Alu blisters of 28 or 30 capsules.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

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JOHANNESBURG

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South Africa

Tel: 0860287835

This leaflet was last revised in

REGISTRATION NUMBER

[PRODUCT NAME]

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following

URL: https://austell.co.za/product-info/

Austell Pharmaceuticals (Pty) Ltd

Tel: +27 11 611 1400 or +27 860 287 835