Applicant/PHCR: Galderma Laboratories South Africa (Pty) Ltd
Product proprietary name: Tetralysal® 300 mg
Registration no: E/20.1.1/67
Dosage form and strength: Each capsule contains Lymecycline equivalent to 300 mg Tetracycline Base

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TETRALYSAL® 150 mg CAPSULES

TETRALYSAL® 300 mg CAPSULES

Lymecycline

Read all of this leaflet carefully before you start taking TETRALYSAL®

- 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.
- **TETRALYSAL®** 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 TETRALYSAL® is and what it is used for

TETRALYSAL® belongs to a group of medicines called tetracycline antibiotics.

The main use of **TETRALYSAL®** is to treat acne. Acne appears as blackheads and whiteheads which people often refer to as pimples or spots. **TETRALYSAL®** attacks the bacteria that are one of the main causes of acne. The name of these bacteria is propionibacterium acnes.

This medicine can also be used to treat many other 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 TETRALYSAL

Do not take TETRALYSAL:

- if you are allergic to lymecycline or to other tetracycline antibiotics such as doxycycline or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash or itching.
- if you are pregnant or planning to become pregnant or breast-feeding.
- if you had/have kidney disease
- **TETRALYSAL®** must not be given to children under 12 years of age.
- If you are receiving treatment with oral retinoids (see 'Other medicines and **TETRALYSAL®**').

Warnings and precautions

Talk to your doctor or pharmacist before taking **TETRALYSAL®**.

Tell your doctor before taking **TETRALYSAL®** if you:

- have ever had liver or renal impairment (failure of liver or kidney function)
- suffer from systemic lupus erythematosus (an allergic condition that causes joint pain, skin rashes or fever) or Myasthenia Gravis (a disease that weakens the muscles).

Overdosing might result in liver problems.

You should avoid direct exposure to sunlight and artificial light from sunbeds due to the risk of photosensitivity. If you experience skin discomfort, then stop taking **TETRALYSAL®** and seek advice from your doctor.

Do not take **TETRALYSAL®** after the expiry date has passed.

The use of expired tetracyclines could lead to serious kidney damage and other metabolic disorders.

Children

TETRALYSAL® should not be used in children younger than 12 years because of the risk of permanent alterations of tooth and enamel discolouration.

Other medicines and TETRALYSAL®

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 to thin your blood e.g. warfarin
- diuretics (used to treat kidney disease, heart disease or high blood pressure)
- other medicines to treat acne

Do not take the following medicines at the same time as **TETRALYSAL®** as these could affect how well your acne medicine works. Wait at least 2 (two) hours after taking **TETRALYSAL®** before you take these types of products.

- indigestion remedies
- ulcer healing drugs
- quinapril (for high blood pressure)
- supplements containing calcium, aluminium, magnesium, zinc or iron
- cholestyramine,
- bismuth chelates
- sucralfate

Avoid use with penicillins and beta-lactam antibiotics (other types of antibiotics) for the possible interference between the two products.

Do not take antacids containing aluminium, calcium or magnesium and products containing iron salts with **TETRALYSAL®** because these products reduce the absorption of tetracycline taken by mouth.

TETRALYSAL® should not be used in combination with oral retinoids (medicines used for certain skin conditions) or doses of more than 10 000 IU/day of vitamin A.

Should not be used with methoxyflurane (risk of fatal renal toxicity).

A combination of **TETRALYSAL®** and lithium may cause an increase in the levels of lithium in the blood.

Taking TETRALYSAL® with food and drink

Absorption of **TETRALYSAL®** is not affected by moderate amounts of milk. **TETRALYSAL®** capsules should always be taken with a glass of water.

Fertility, pregnancy and breastfeeding

Tetracyclines readily cross the placental barrier and are distributed into milk. **TETRALYSAL®** must not be taken if you are pregnant or breast feeding.

Use of medicines such as **TETRALYSAL®** may affect the proper growth of developing teeth and lead to permanent discolouration

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or other healthcare provider for advice before taking **TETRALYSAL®**.

Driving and using machinery

TETRALYSAL® is not known to affect the ability to drive or use machines

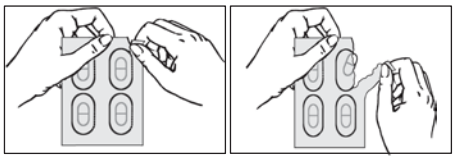
It is not always possible to predict to what extent **TETRALYSAL®** may interfere with the daily activities of a patient. Patients should ensure that they do not perform or execute tasks or activities requiring mental alertness, judgment and / or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines / equipment until they are aware of the measure to which **TETRALYSAL®** affects them.

3. How to take TETRALYSAL

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

Always take **TETRALYSAL®** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Please tear the aluminium strip carefully to remove capsule.



Acne

The normal dose is 300 mg once a day, preferably in the morning. **TETRALYSAL®** capsules should always be taken with a glass of water.

How long you will have to take **TETRALYSAL®** for will depend on how quickly your condition improves. For acne, this will normally be at least 8 weeks.

Infections

The normal dose is 300 mg twice a day. Your doctor may recommend a lower or higher dose depending on the severity and type of infection. Ask your doctor if you are unsure.

TETRALYSAL® capsules should always be taken with a glass of water.

Do not give TETRALYSAL® to children below the age of 12, it could harm them.

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

If you take more TETRALYSAL® than you should

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

If you forget to take TETRALYSAL®

Try to take **TETRALYSAL®** as prescribed. Do not worry if you forget to take your **TETRALYSAL®** at the right time. Take it when you remember and carry on as before unless it is time for the next dose

Do not double up the dose to make up for a forgotten capsule. You should never take more capsules than your doctor recommends.

If you stop taking TETRALYSAL®

Acne responds slowly to antibiotics. It is important that you take all the **TETRALYSAL®** that your doctor has prescribed for you. If you stop taking **TETRALYSAL®** too soon, your acne or infection could get worse or come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The following serious side effects have been reported in association with the use of **TETRALYSAL®**. If any of the following happen, stop taking **TETRALYSAL®** 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 skin,
- ulcerations or lesions on the mouth, lips, genital or anal regions,
- severe or persistent headaches or visual disturbances.

These are all very serious side effects. You may need urgent medical attention or hospitalisation.

The following side-effects have been reported frequently during treatment, tell your doctor if you notice any of the following:

- nausea (feeling sick)
- abdominal pain
- diarrhoea
- headache

The following side-effects have been reported, the frequency of which is unknown, tell your doctor if you notice any of the following:

- 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)
- inflammation of the liver (hepatitis)
- increased sensitivity of the skin to sunlight
- increased pressure in the brain
- changes in the number or type of certain blood cells
- pain in the upper part of the abdomen
- changes in some blood tests (tests of liver function)
- fever
- itchiness, skin rash or hives
- inflammation of the intestine
- depression
- nightmare

The following side effects may occur during treatment with the class of medicines to which **TETRALYSAL®** 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. 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 **TETRALYSAL®**.

5. How to store TETRALYSAL®

Store all medicines out of reach of children.

Store in a cool dry place at or below 25 ºC. Store in the original package.

Do not use after the expiry date printed on the pack after "EXP". The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

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

6. Contents of the packs and other information

What TETRALYSAL® 150 mg contains

The active substance is lymecycline. Each capsule contains Lymecycline equivalent to 150 mg Tetracycline Base as the active ingredient.

The other ingredients are magnesium stearate, colloidal hydrated silica, maize starch and lactose monohydrate.

Gelatin capsule is composed of gelatin, erythrosin colour, quinoline yellow, titanium dioxide

What TETRALYSAL® 300 mg contains

The active substance is lymecycline. Each capsule contains Lymecycline equivalent to 300 mg Tetracycline Base as the active ingredient.

The other ingredients are magnesium stearate and colloidal hydrated silica.

Gelatin capsule is composed of gelatin, erythrosin colour, indigo carmine colour, titanium dioxide

What TETRALYSAL® capsules look like and contents of the packs

TETRALYSAL® 150 mg capsules are yellow and orange containing a granular yellow powder.

TETRALYSAL® 300 mg capsules are yellow and red containing a granular yellow powder.

TETRALYSAL® 150 mg and 300 mg are available in cartons containing 28 capsules packed in foil blisters.

Each blister strip contains 4 capsules and there are 7 blister strips in each carton.

Holder of Certificate of Registration

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Registration Number

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