

# TETRALYSAL<sup>®</sup>

## Lymecycline 300mg Capsule

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### What is in this leaflet

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This leaflet answers some common questions about TETRALYSAL. Please read this leaflet carefully before you start taking the capsules. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TETRALYSAL against the benefits it might have for you.

**If you have concerns about using this medicine ask your doctor or pharmacist.**

Keep this leaflet with your pack of TETRALYSAL. You may wish to read it again later.

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### What TETRALYSAL is used for and how it works

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TETRALYSAL contains an antibiotic used to treat certain infections such as acne.

The active ingredient in TETRALYSAL is lymecycline, which belongs to the group of medicines called tetracyclines. These medicines work by killing or stopping growth of bacteria which cause infections.

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### Before you use TETRALYSAL

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#### ***When you must not use it***

Do not use **TETRALYSAL** if:

- if you have an allergy to lymecycline or medicines containing other tetracyclines or any of the ingredients listed at the end of this leaflet;
- if you have kidney problems. Tell your doctor if you have a condition affecting your kidneys;
- to treat your child if he or she is younger than 8 years old;
- if you are pregnant or breast feeding;

if you are currently using other medicines commonly referred to as oral retinoids (such as isotretinoin) to treat your acne or other skin conditions.

Some of the symptoms of an allergic reaction may include:

- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives of the skin
- redness of skin

**Do not use Tetralysal after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.** If it has expired or is damaged, return it to your pharmacist for disposal.

### ***Before you start to use it***

Tell your doctor if you have or have had any of the following medical conditions:

- kidney and liver problems
- blood pressure disorders

**Tell your doctor if you have allergies to any other medicines, preservatives, foods or dyes.**

Tetralysal contains ingredients which may cause allergic reactions (possibly delayed),

Tell your doctor if:

- you are pregnant or plan to become pregnant;
- you are breastfeeding;
- if you have or ever had any other health problems and if you are already taking medicines.

If you have not told your doctor about any of the above, tell them before you start using TETRALYSAL.

### ***Taking other medicines***

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

- medicines for epilepsy including barbiturates e.g. phenobarbitone, phenytoin and carbamazepine.
- penicillin's (another type of antibiotics)

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking TETRALYSAL.

Some medicines may interfere with TETRALYSAL. These include: the absorption of tetracyclines may be affected by the simultaneous administration of iron preparations and antacids, magnesium/aluminium and calcium, , hydroxides, oxides and salts, and activated charcoal, cholestyramine, bismuth chelates and sucralfate may decrease cycline absorption.

Avoid concurrent use of oral retinoids and vitamin A above 10,000IU/day as this may increase the risk of benign intracranial hypertension (increased pressure in the skull).

Do not give Tetralsal to patients with overt renal insufficiency (kidney failure), as Tetralsal is mainly excreted by the kidneys.

Combined use of Tetracyclines and methoxyflurane have been reported to result in fatal Kidney intoxication.

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## **How to use TETRALYSAL**

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### ***Things you must do***

- Follow carefully the instructions given to you by your doctor and pharmacist. They may differ from the instructions contained in this leaflet.
- The usual dose of Tetralsal is one capsule morning or night. However, depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose.
- Tetralsal can be taken in the morning or at night, with or without food.
- Take Tetralsal with plenty of liquid in order to reduce the risk of irritation and ulceration in the oesophagus.
- For the treatment of acne, your doctor may ask you to take Tetralsal for at least 8 weeks. Continue to use even though there may not be an immediate effect. Medicines can take several weeks to show an effect.
- Tetralsal must only be used by the person it was prescribed for.

### ***How much to take***

One capsule morning or night with or without milk or food.

The recommended dose for acne is 300 mg/day.

The usual duration of treatment is 12 weeks.

The usual recommended dose for indications other than acne for adults is 600 mg/day.

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## **While you are using TETRALYSAL**

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### ***Things you must do***

**If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Tetralsal.**

**If you feel that Tetralsal is not helping your condition, tell your doctor or pharmacist.**

**Tell your doctor if, for any reason, you have not used Tetralysal exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

**If you become pregnant while using Tetralysal, tell your doctor.**

### ***Things you must not do***

Do not use broad spectrum antibiotics for longer period of time, it may result in the occurring of resistant organisms and superinfection.

### ***Things to be careful of***

Tetracyclines may cause photosensitivity reactions; however, very rare cases have been reported with lymecycline. It is recommended to avoid exposure to direct sunlight and ultraviolet light during the treatment which should be discontinued if erythematous cutaneous manifestations occur.

Exercise caution when taking tetracyclines in patients with kidney or liver impairment. Overdosage could result in liver intoxication.

Use Tetralysal with caution in patient with muscle weakness, it can cause blockade of neuromuscular transmission. It may cause worsening of systemic lupus erythematosus (an autoimmune disease occurs when the immune system attacks the body because it confuses it for something foreign).

The use of expired tetracyclines can lead to renal tubular acidosis (Pseudo-Fanconi syndrome) readily reversible when treatment is discontinued altogether.

Tetralysal use should be monitored for rise in pressure around your brain and treatment should be stopped if any evidence of this is observed. Usual signs include headache, vomiting, confusion about time, and double vision.

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## **In case of overdose**

### ***If you take too much (overdose)***

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much TETRALYSAL.

Do this even if there are no signs of discomfort or poisoning.

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## **Side Effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using TETRALYSAL.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you. **Do not be alarmed by this list of possible side effects.** You may not experience any of them. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

Tetralysal can cause the following unwanted effects: vomiting or feeling like vomiting, upset stomach, sore tongue and difficulty swallowing, skin rash, redness of skin, hives, bruising/or slow blood clotting, visual disturbance, fever, jaundice (yellow tinge to skin and eyes), hypersensitivity, dizziness, sensitivity to sunlight, increases in blood transaminases, alkaline phosphatase and bilirubin (liver enzymes), swelling of the lips and tongue, sore, itchy anus or vagina.

The most frequently reported adverse events with Tetralysal are gastrointestinal disorders of nausea, abdominal pain, diarrhoea and headache.

The most serious adverse events reported with Tetralysal are Stevens Johnson syndrome (painful red or purplish rash on skin that spreads, blisters and peels off),, anaphylactic reaction, angioneurotic oedema, neutropenia (decreased white blood count), inflammation of liver, and intracranial hypertension (increased pressure in the skull).

Tell your doctor immediately if you experience any of them or any other effects.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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## **After using TETRALYSAL**

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### ***Storage conditions***

Keep TETRALYSAL and all medicines out of reach of children.

Store TETRALYSAL below 30°C in a cool dry place and protected from light.

Medicines should not be kept indefinitely. Return to a pharmacy any unused medicine and any medicine past its expiry date as shown on its packaging.

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## **Product description**

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### ***What it looks like***

TETRALYSAL Lyme cycline capsule is a yellow and red hard gelatin capsule containing lymecycline equivalent to 300mg tetracycline base.

### ***Ingredients***

TETRALYSAL contains

Active ingredient: Lyme cycline (equivalent to tetracycline 300mg per capsule)

Inactive ingredients: magnesium stearate, colloidal hydrated silica, in hard gelatine capsules (titanium dioxide, erythrosine, quinoline yellow, indigotine).

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### **Sponsor**

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TETRALYSAL is supplied in New Zealand for:

Galderma Australia Pty Ltd  
13 B Narabang Way,  
Belrose, NSW 2085  
Australia

Distributed in New Zealand by:  
Healthcare Logistics  
58 Richard Pearse Drive  
Airport Oaks  
Auckland  
Ph: 0800 174 104

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### **Date of Preparation**

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This leaflet was revised on 20 December 2017.