

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Tetralysal® 300 mg Hard Capsules**  
Lymecycline

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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**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. Before you take Tetralysal**

**Do not take Tetralysal if:**

- you are pregnant, planning to become pregnant or are breast-feeding
- you have ever had an allergic reaction to lymecycline, the active ingredient in this medicine or to other tetracycline antibiotics such as doxycycline or to any of the other ingredients of Tetralysal (see section 6 for other ingredients). An allergic reaction may include either a rash or itching
- you have ever had kidney disease

Tetralysal must not be given to children under 12 years of age.

**Take special care with Tetralysal**

Tell your doctor before taking Tetralysal if you

- have ever had a liver problem
- 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).

**Taking other 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 your Tetralysal as these could affect how well your acne medicine works. Wait at least 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.

If you take a contraceptive pill, it may not work properly while you are taking Tetralysal, especially if you have sickness or diarrhoea for any reason. An additional "barrier" method of contraception (e.g a condom) should be used to make sure you don't get pregnant. Please read the leaflet that you got with your "pill" or talk to your doctor or pharmacist if you are not sure what to do or how long to take these precautions for.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**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.

**Pregnancy and breast-feeding**

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.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Tetralysal is not known to affect the ability to drive or use machines.

**3. How to take Tetralysal**

Always use Tetralysal exactly as your doctor has told you. The correct dose will be shown on the label which your pharmacist has placed on the container. You should check with your doctor or pharmacist if you are not sure.

Please tear the aluminium strip carefully to remove capsule.



## Adults and children over 12 years

### Acne

The normal dose is one Tetralsal capsule once a day, preferably in the morning. Tetralsal capsules should always be taken with a glass of water. How long you will have to take Tetralsal for will depend on how quickly your condition improves. For acne, this will normally be at least 8 weeks.

### Infections

The normal dose is one Tetralsal capsule 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.

Tetralsal capsules should always be taken with a glass of water.

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

### If you take more Tetralsal than you should

If you, or anyone else, take too many Tetralsal capsules phone your doctor for advice or go to your nearest hospital so that medical staff are made aware of the problem. Don't forget to take the container with you. This could indicate how many capsules have been taken.

### If you forget to take Tetralsal

Do not worry if you forget to take your Tetralsal 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. You should never take more capsules than your doctor recommends.**

### If you stop taking Tetralsal

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

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

## 4. Possible side effects

Like all medicines, Tetralsal can cause side effects, although not everybody gets them.

Tetralsal may cause the following side effects.

Common side effects (occur in less than 1 in 10 patients)

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

Unknown frequency of occurrence (frequency cannot be estimated from the available data)

- 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)
- 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

The following side effects may occur during treatment with the class of medicines to which Tetralsal 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

\*Tell your doctor immediately if you develop side effects such as 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. How to store Tetralsal

- Keep out of the reach and sight of children.
- Do not use Tetralsal after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original container.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Further information

### What Tetralsal contains

Tetralsal contains 408 mg of the active ingredient lymecycline (equivalent to 300 mg tetracycline base). The other ingredients are magnesium stearate and colloidal hydrated silica. The capsule shells contain gelatin, titanium dioxide (E171), erythrosine (E127), quinoline yellow (E104) and indigotine (E132).

### What Tetralsal looks like and contents of the pack

Tetralsal capsules are red and yellow. Tetralsal is available in a carton containing 28 or 56 capsules packed in polyethylene/foil blisters. Each blister strip contains 4 capsules and there are 7 or 14 blister strips in each carton.

A carton containing 28 capsules in PVC/foil blisters (14 capsules in two calendar strips) is also approved. Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Galderma (UK) Limited,

Meridien House, 69-71 Clarendon Road, Watford, Herts. WD17 1DS. UK (PL 10590/0019)

Manufacturer: Laboratoires Sophartex, B.P. 129, 28501 Vernouillet, France

or Laboratoires Galderma, 74540 Alby-Sur-Cheran, France.

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**GALDERMA**



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