

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tetralysal 300 mg Hard Capsules
Lymecycline (equivalent to 300mg tetracycline base)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tetralysal is and what it is used for
2. What you need to know before you take Tetralysal
3. How to take Tetralysal
4. Possible side effects
5. How to store Tetralysal
6. Contents of the pack and other information

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).

Please seek immediate medical attention if you experience symptoms of an allergic reaction. Signs or symptoms of a severe allergic reaction may include a rash, with or without itching, swelling of the face, eyelids or lips and difficulty in breathing.

- you are pregnant, planning to become pregnant or are breast-feeding.
- you have severe kidney disease.

Tetralysal must not be given to children under 8 years of age.

Tetralysal 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

Talk to your doctor or pharmacist before taking Tetralysal.

Tell your doctor before taking Tetralysal if you

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

You should avoid direct exposure to sunlight or artificial sunlight from sunbeds. If you experience skin discomfort, then stop taking this medicine and seek advice from your doctor. Do not use this medicine if the expiry date has passed, expired Tetralsal can cause kidney disorder.

Stop taking Tetralsal if you experience extreme headaches. Long term use of antibiotics can lead to resistant bacterial infection.

Take the medicine with adequate amounts of water to avoid irritation and ulcers of the oesophagus.

Overdosing on this medicine can cause liver problems.

Other medicines and Tetralsal

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- medicines to thin your blood e.g. warfarin
- Other medicines to treat acne
- Other antibiotics including penicillin
- oral retinoids (medicinal products used for certain skin conditions) or doses of more than 10 000 IU/day of oral or injectable Vitamin A (medicinal products used for vitamin A deficiency)
- You should tell your doctor if you are taking any treatment with lithium, this medicine may increase the lithium levels.

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

- indigestion remedies
- iron, magnesium/aluminium and calcium supplements
- activated charcoal, cholestyramine, bismuth chelates and sucralfate
- medicines for epilepsy including barbiturates e.g. phenobarbitone, phenytoin and carbamazepine
- medicines that reduce the amount of stomach acid e.g. cimetidine and ranitidine

Use of methoxyflurane in combination with Tetralsal is not recommended as may result in fatal kidney toxicity.

Tell your doctor if you are going to be having a procedure which requires anaesthetic as Tetracycline cannot be used with some anaesthetics. Tetracycline can lead to a false positive urine test for glucose. Tell your doctor if you are taking Tetracyclines and need to have a urine test.

Tetralsal with food and drink

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

Pregnancy and breast-feeding

Tetralsal must not be taken if you are pregnant or breast-feeding.

Use of medicines such as Tetralsal may affect the proper growth of developing teeth and lead to permanent discolouration.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

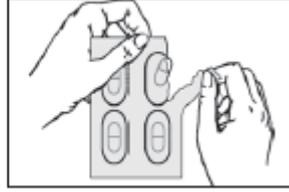
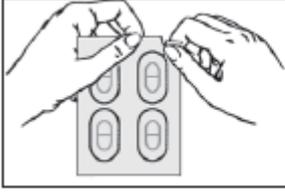
Driving and using machines

It is not known whether Tetralsal affects the ability to drive or use machines.

3. HOW TO TAKE TETRALSAL

Always take this medicine exactly as your doctor has told you. The correct dose will be shown on the label which your pharmacist has placed on the container. 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. After 8 weeks of treatment with Tetralsal it is important to see your doctor again. He or she can then check the improvement of your acne.

Infections

The normal dose is one Tetralsal capsule twice a day (600 mg/day). Your doctor may recommend a lower or higher dose depending on the severity and type of infection. Tetralsal capsules should always be taken with a glass of water. Take the capsules with a lot of water and whilst sitting upright to avoid injury to the oesophagus.

Do not give Tetralsal to children below the age of 8, 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 to make up for a forgotten capsule. 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 medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor immediately if you develop:

- signs of a severe allergic reaction such as wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is an uncommon side effect which may occur after treatment with antibiotics and can be a sign of serious bowel inflammation.
- yellowing of the skin or eyes (jaundice)
- blistering or peeling of large areas of the skin, ulcerations or lesions on the mouth, lips, genital or anal regions. Other side effects that you should tell your doctor about include:

Common: may affect up to 1 in 10 people

- Nausea (feeling sick)
- Abdominal pain

- Diarrhoea
- Headache

Not known: frequency cannot be estimated from the available data

- Changes in the number or type of certain blood cells
- Visual disturbances*
- Inflammation of the tongue
- Inflammation of the intestine
- Vomiting (being sick)
- Pain in the upper part of the abdomen
- Inflammation of the oesophagus (the tube that carries food from the throat to the stomach).
- Ulceration of the oesophagus, which may cause pain behind or just below your breastbone.
- Fever
- Yellowing of the skin or eyes (jaundice)
- Inflammation of the liver (hepatitis)
- Allergic reactions causing swelling of the face including eyes and lips which can spread to the tongue and throat
- Itchiness, skin rash or hives
- Sudden serious generalized allergic reaction
- Changes in some liver blood tests
- Increased pressure in the brain
- Dizziness
- Increased sensitivity of the skin to sunlight
- Blistering or peeling of large areas of the skin, ulcerations or lesions on the mouth, lips, genital or anal regions
- Depression
- Nightmare

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

- Systemic lupus erythematosus (an allergic condition that causes joint pain, skin rashes or fever)
- Pancreatitis (inflammation of the pancreas)
- Teeth discolouration and low development of dental enamel when used in children under 8 years of age
- Change in blood tests (decrease of red blood cells, increase of certain white blood cells)
- Increase of urea blood level which may be intensified by taking diuretics drugs with Tetralsal

* The presence of symptoms, such as visual disturbances, or headaches, could be attributed to increased pressure in the brain (intracranial hypertension). You should stop taking Tetralsal if there is any evidence of pressure increase in the brain

Benign intracranial hypertension, symptoms of which may include headache, vomiting, visual disturbances (blurred vision, blind spots or double vision), or permanent loss of vision have been reported with tetracycline therapy.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Website: www.hpra.ie

5. HOW TO STORE TETRALYSAL

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and on the blister strips. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original container in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tetralysal contains

The active substance is lymecycline. Each capsule contains 408mg of lymecycline. The other ingredients are magnesium stearate, colloidal hydrated silica. The capsule shells contain gelatin, titanium dioxide (E171), erythrosine (E127), quinoline yellow (E104) and indigotine (E132).

What Tetralysal looks like and contents of the pack

Tetralysal capsules are red and yellow. Tetralysal 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 as well as polypropylene or aluminium containers of 20 or 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma International, Tour Europlaza, 20 Avenue André Prothin, La Défense 4, 92927 Paris La Défense CEDEX, France.

(PA22743/016/001)

Manufacturer: Laboratoires Sophartex, 21 Rue Du Pressoir, BP 129, 28501 Vernouillet Cedex, France.

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