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

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 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 this leaflet about?
1. What is Tetralysal® and what is it 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 is Tetralysal® and what is it 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 acne.

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 tetracyclines 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 either a rash or itching
- you have ever had kidney disease
- you are pregnant, planning to become pregnant or are breast-feeding

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

Tell your doctor or pharmacist before taking Tetralysal.

Tell your doctor before taking Tetralysal if you:

- have hepatitis (inflammation of the liver) or renal (kidney) disease
- suffer from cystic fibrosis or emphysema
- have had liver or kidney disease
- you are pregnant, planning to become pregnant or are breast-feeding
- you have ever had kidney disease
- you are on any of the following medicines:
  - medicines to thin your blood, e.g. aspirin
  - diuretics (used to treat kidney disease, heart disease or high blood pressure)
  - other medicines to treat acne

Do not start any other 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.

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

Avoid use with penicillins (another type of antibiotic) for the possible interference between the two products.

Do not take any medicines containing aluminium, calcium, magnesium or potassium as they may react with Tetralysal, because these products reduce the absorption of tetracycline taken by mouth.

This medicinal product should not be used in combination with oral retinoids (medicinal products used for certain skin conditions) or doses of more than 10 g/day of vitamin A (should not be used with methotrexate (risk of fatal renal toxicity)).

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 breast-feeding

Tetralysal normally 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 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

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

3. How to take Tetralysal

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.

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This approval applies to medication package leaflets in English, French and Spanish and to medication package leaflets for medicines imported from France.

Please verify each medicament label before its release to ensure all LaFrance and DFRTC are correct.
Adults and children over 12 years

Acne

The normal dose is one Tetralysal capsule once a day (100 mg/day), preferably in the morning. Tetralysal capsules should always be taken with a glass of water. If you are unsure, you must consult your doctor for advice on how and when to take Tetralysal. In case of overdose, please contact your nearest hospital or doctor.

4. Possible side effects

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

If you experience any of the following stop taking these tablets immediately and see a doctor:

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

Tetralysal may cause the following side effects:

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
- allergic (hypersensitivity) reaction causing swelling of the eyes, lips or tongue
- blistering or peeling of large areas of the skin
- ulcers or lesions on the mouth, lips, genital or anal regions
- diarrhoea
- loss of appetite
- vomiting
- yellowing of the skin or eyes (jaundice)
- increase in the size of the liver
- increased sensitivity of the skin to sunlight
- muscle weakness
- 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
- itching, skin rash or hives

In the event that you get acne, 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 www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tetralysal

- Keep this medicine out of the reach of children.
- Do not use this medicine 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.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer need. These measures will help prevent the environment.

6. Contents of the pack and other information

What Tetralysal contains:

The active substance is tretinoin. Each capsule contains 100mg of tretinoin. The other ingredients are magnesium stearate and colloidal hydrated silica.

The capsule shell contains gelatin, titanium dioxide (E171), erythrosine (E127), aqualine yellow (E104) and indigotene (E132).

What other substances look like and are similar to the tablets:

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

A carton containing 16 capsules in Pvc/foil blister packs in two calendar strips is also approved. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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