

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Tetralysal® 300mg 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.

The name of your medicine is Tetralysal 300mg Hard Capsules but will be referred to as Tetralysal throughout this leaflet.

### 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 ever had kidney disease.

Tetralysal must not be given to children under 12 years of age unless your doctor has prescribed it for them. 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 ever had a liver problem.

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 Tetralysal can cause kidney disorder.

### Other medicines and Tetralysal

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
- medicines for epilepsy including barbiturates e.g. phenobarbitone, phenytoin and carbamazepine
- medicines that reduce the amount of stomach acid e.g. cimetidine and ranitidine
- 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
- iron supplements

### 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.

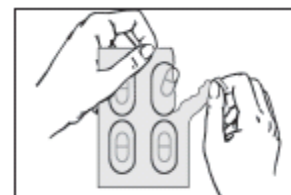
Use of medicines such as Tetralysal may affect the proper growth of developing teeth and lead to permanent discolouration.

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.

### 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.



### Adults and children over 12 years

#### Acne

The normal dose is one Tetralysal capsule 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.

After 8 weeks of treatment with Tetralysal 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 Tetralysal 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.

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

### **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
- 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

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

- 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
- You should stop taking Tetralsal if there is any evidence of pressure increase in the brain

## **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

IRELAND:

FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.imb.ie](http://www.imb.ie), email: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie).

## **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. Keep container in the outer carton in order to protect from light and moisture.
- 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 408mg lymecycline equivalent to 300mg tetracycline base.

The other ingredients are magnesium stearate and colloidal hydrated silica. The capsule shell contains gelatin, titanium dioxide (E171), erythrosine (E127), quinoline yellow (E104) and indigotine (E132).

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

Tetralsal are hard capsules with a red cap and yellow body. Tetralsal is available in blister packs containing 28 capsules. Each blister strip contains 4 capsules and there are 7 blister strips in each carton.

**Manufactured by:** Laboratoires Sophartex, B.P. 129, 28501 Vernouillet, France  
Or,  
Laboratoires Galderma, 74540 Alby-Sur-Cheran, France.

**Procured from within the EU and repackaged by the PPA holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Tetralsal® 300mg Hard Capsules**

**POM**

**PPA No: 1328/208/001**

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