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.

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.

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.
- induction remedies
- ulcer healing drugs
- guanfacine (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.

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.

ATTENTION FICHER EN NOIR MAIS IMPRESSION EN 432U

PMS 432 U + Tramé
Adults and children over 12 years

Acne

The normal dose is one Tetralysal capsule once a day, preferably in the morning. Tetralysal capsule 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.

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.

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

If you take more Tetralysal than you should

If you, or someone else, take too many Tetralysal 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 Tetralysal

Do not worry if you forget to take your Tetralysal 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 Tetralysal

Acne responds slowly to antibiotics. It is important that you take all the Tetralysal that your doctor has prescribed for you. If you stop taking Tetralysal 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, Tetralysal can cause side effects, although not everybody gets them.

5. How to store Tetralysal

5.1. Keep in a tight container, away from direct light.

5.2. Do not store above 25°C. Store in the original container.

5.3. Do not use Tetralysal after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

5.4. Keep out of the reach and sight of children.

What Tetralysal contains

The active ingredient is tetracycline (equivalent to 300 mg tetracycline base) and contains the following:

- Magnesium stearate and colloidal hydrated silica.
- Silica gel, titanium dioxide (E171), erythrosine (E127), quinoline yellow (E104) and indigotine (E132).

The capsule shells contain gelatin, titanium dioxide (E171), erythrosine (E127), quinoline yellow (E104) and indigotine (E132).

M edicines 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.

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6. Further information

What Tetralysal contains

The tablet contains 408 mg of the active ingredient tetracycline (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 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 blister. 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 blister (14 capsules in two calendar strips) is also approved. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Laboratoires Galderma (UK) Limited, Marlwood House, Bk-11 Clandres Road, Walthamstow, Essex, WOD 126, UK (PL 059/0019)

Manufacturer: Gallerons Zonfrillo, R.P. 129, 38011 Vannes, France or laboratories Galderma, 7440 Aley, Sex-Cherix, France.

This leaflet was last approved in 11/2009.