

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.

- 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.

In this leaflet:

1. What Tetralysal is and what it is used for
2. Before you take Tetralysal
3. How to take Tetralysal
4. Possible side effects
5. How to store Tetralysal
6. Further 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. BEFORE YOU TAKE TETRALYSAL

Do not take Tetralysal if:

- you are allergic (hypersensitive) to lymecycline or any of the other ingredients of Tetralysal or to other tetracycline antibiotics such as doxycycline. Please check by reading the list of ingredients in section 6. If you answer yes, you must inform your doctor before starting treatment.

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).

Take special care with 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.

Taking 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

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.

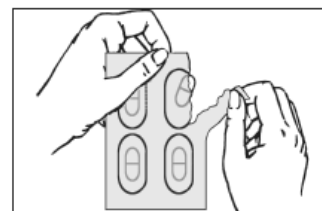
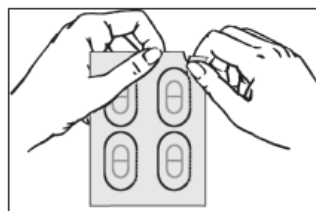
Pregnancy and breast-feeding

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.

3. HOW TO TAKE TETRALYSAL

Always take 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 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 Tetralysal than you should

If you, or anyone 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.

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 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):

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

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

5. HOW TO STORE TETRALYSAL

Keep out of the reach and sight of children.

Do not use Tetralysal after the expiry date which is stated on the carton and on the blister strips after “EXP”. 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.

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 Tetralysal contains

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

What Tetralysal looks like and contents of the pack

- Tetralysal is available as hard gelatin capsules with a red cap and yellow body.
- Tetralysal is available in blister strips of 4 capsules each, in a carton containing 28 capsules.

Procured from within the EU by the Parallel Product

Authorisation Holder:

Clear Pharma Limited, 157-173 Roden Street, Belfast, BT12 5QA, UK.

Manufacturer:

Laboratoires Sophartex, BP 129, 28501 Vernouillet, France.

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

Repackager:

Pharmaram Limited, Unit F4 Tom Bill Way, Ashby de la Zouch,

Leicestershire, LE65 2UY, United Kingdom.

Leaflet Date: JUNE 2011

20130710

The trademark for Tetralysal® is held by Galderma SA.

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.

- 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.

In this leaflet:

1. What Tetralysal is and what it is used for
2. Before you take Tetralysal
3. How to take Tetralysal
4. Possible side effects
5. How to store Tetralysal
6. Further 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. BEFORE YOU TAKE TETRALYSAL

Do not take Tetralysal if:

- you are allergic (hypersensitive) to lymecycline or any of the other ingredients of Tetralysal or to other tetracycline antibiotics such as doxycycline. Please check by reading the list of ingredients in section 6. If you answer yes, you must inform your doctor before starting treatment.

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).

Take special care with 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.

Taking 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

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.

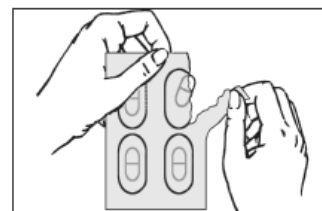
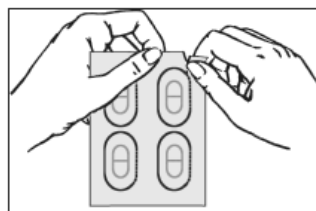
Pregnancy and breast-feeding

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.

3. HOW TO TAKE TETRALYSAL

Always take 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 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 Tetralysal than you should

If you, or anyone 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.

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 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):

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

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

5. HOW TO STORE TETRALYSAL

Keep out of the reach and sight of children.

Do not use Tetralysal after the expiry date which is stated on the carton and on the blister strips after “EXP”. 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.

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 Tetralysal contains

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

What Tetralysal looks like and contents of the pack

- Tetralysal is available as hard gelatin capsules with a red cap and yellow body.
- Tetralysal is available in blister strips of 4 capsules each, in a carton containing 28 capsules.

Procured from within the EU by the Parallel Product

Authorisation Holder:

Clear Pharma Limited, 157-173 Roden Street, Belfast, BT12 5QA, UK.

Manufacturer:

Laboratoires Sophartex, BP 129, 28501 Vernouillet, France.
Laboratoires Galderma, 74540 Alby-Sur-Cheran, France.

Repackager:

Cast Healthcare Ltd, Unit B6 The Business Centre, 5-7 Tobermore Road, BT45 7AG, UK.

Leaflet Date: JUNE 2011

20130710

The trademark for Tetralysal® is held by Galderma SA.