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# PACKAGE LEAFLET: INFORMATION FOR THE USER

## Lymecycline 408 mg 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**
1. What Lymecycline Capsule is and what it is used for
2. What you need to know before you take Lymecycline
Capsule
3. How to take Lymecycline Capsules
4. Possible side effects
5. How to store Lymecycline Capsules
6. Contents of the pack and other information

## 1. WHAT LYMECYCLINE CAPSULE IS AND WHAT IT IS USED FOR

Lymecycline belongs to a group of medicines called tetracycline antibiotics.

The main use of Lymecycline Capsule is to treat acne. Acne appears as blackheads and whiteheads which people often refer to as pimples or spots. Lymecycline 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 LYMECYCLINE CAPSULE

**Do not take** Lymecycline Capsules 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). 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

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

Lymecycline 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 Lymecycline Capsules. Tell your doctor before taking this medicine if you
- have hepatic impairment or renal insufficiency (failure of liver and kidney function).
- 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). Overdosing might result in liver problems.

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 Lymecycline can cause kidney disorder

As with other antibiotics, treatment with tetracycline can cause secondary bacterial or mycotic infections (fungal). There is in particular the possibility of resistant staphylococcal enterocolitis (inflammation of the small intestine and colon due to bacteria that are resistant to the therapeutic action of the drug).

Should you undergo cycles of prolonged treatment with Lymecycline, your doctor will prescribe regular checks of blood composition and liver and kidney function. Take the medicine with adequate amounts of water to avoid irritation or ulceration of the esophagus.

**Children**
Lymecycline Capsules should not be used in children under 8 years because of the risk of permanent alterations of tooth and enamel discoloration.

**Other medicines and Lymecycline**
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
- diuretics (used to treat kidney disease, heart disease or high blood pressure)
- other medicines to treat acne.

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 Lymecycline as these could affect how well your acne medicine works. Wait at least two hours after taking Lymecycline before you take these types of products.
- indigestion remedies
- ulcer healing drugs
- quinapril (for high blood pressure)
- supplements containing calcium, aluminium, magnesium, zinc or iron.

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

Do not take antacids containing aluminum, calcium or magnesium and products containing iron salts with Lymecycline, 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 10 000 IU/day of vitamin A. Should not be used with methoxyflurane (risk of fatal renal toxicity).

**Lymecycline with food and drink**
Absorption of Lymecycline is not affected by moderate amounts of milk. Lymecycline capsules should always be taken with a glass of water.

**Fertility, pregnancy and breast-feeding**
Tetracyclines readily cross the placental barrier and are distributed into milk. Lymecycline must not be taken if you are pregnant or breast feeding. Use of medicines such as Lymecycline 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**
Lymecycline is not known to affect the ability to drive or use machines.

## 3. HOW TO TAKE LYMECYCLINE CAPSULES

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will determine what dose is appropriate for you. This will depend on how well your body responds to this medicine.

**Adults and children over 12 years Acne**
The normal dose is one Lymecycline capsule once a day (300 mg/day), preferably in the morning. Lymecycline capsules should always be taken with a glass of water. How long you will have to take Lymecycline 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 Lymecycline capsule twice a day (600 mg/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.

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

**Do not give Lymecycline to children below the age of 8, it could harm them.**

**If you take more Lymecycline than you should**
If you, or anyone else, take too many Lymecycline 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 Lymecycline**
Do not worry if you forget to take your Lymecycline at the right time. Take it when you remember and carry on

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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 Lymecycline**
Acne responds slowly to antibiotics. It is important that you take all the Lymecycline that your doctor has prescribed for you. If you stop taking this medicine 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 everyone gets them. The following side effects may happen with this medicine:

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,
- ulcerations or lesions on the mouth, lips, genital or anal regions,
- severe or persistent headaches or visual disturbances.

Lymecycline 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
- ulcerations or lesions on the mouth, lips, genital or anal regions
- disturbances of eyesight*
- dizziness
- vomiting (being sick)
- yellowing of the skin or eyes (jaundice)
- inflammation of the liver (hepatitis)
- increased sensitivity of the skin to sunlight
- increased pressure in the brain
- 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
- itchiness, skin rash or hives
- inflammation of the intestine
- depression
- nightmare

The following side effects may occur during treatment with the class of medicines to which Lymecycline belongs (the tetracyclines):
- systemic lupus erythematosus (an allergic condition that causes joint pain, skin rashes or fever)
- inflammation or ulceration of the gullet, causing pain or difficulty swallowing or painful heartburn.
- difficulty in swallowing
- inflammation of the pancreas
- liver damage
- teeth discolouration
- inflammation or soreness of the tongue, mouth, cheeks, gums or lips
- soreness or itching of the genital area
- yeast infection around the anus or genitals
- infection of the colon
  - o *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 this medicine 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 visual loss have been reported with tetracycline therapy.

**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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE LYMECYCLINE CAPSULES

- Keep this medicine out of the sight and reach of children.
- Store below 25$^{o}$C in the original package in order to protect from moisture.
- Do not use after the expiry date (month, year) stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- 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 PACKAGE AND OTHER INFORMATION

**What Lymecycline Capsule contains:**
- The active substance is lymecycline. Each capsule contains 408 mg of lymecycline equivalent to 300 mg tetracycline base.

  Other ingredients are:

  Capsule content: magnesium stearate and silica, colloidal hydrated.

  Capsule shell: gelatin, titanium dioxide (E171), erythrosine (E127), indigotine (E132).

  Printing ink : shellac, propylene glycol (E1520), black iron oxide (E172) and potassium hydroxide.

**What Lymecycline Capsules looks like and contents of the pack**
Lymecycline Capsule is approximately 22 mm in size with pink body imprinted with '632' in black ink and purple cap imprinted with 'G' in black ink, filled with yellow to dark yellow granules. with yellow body imprinted with '632' in black ink and Maroon cap imprinted with 'G' in black ink, filled with yellow to dark yellow granules.

Lymecycline Capsules is available as aluminium blister pack in a carton as well as available as aluminium-PVC/PVDC blisters packed in aluminium pouch; further packed in a carton

Pack size: 28, 56 or 100 capsules.

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