

Package leaflet: Information for the user

Lymecycline 408 mg Capsules, hard

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 full name of this medicine is Lymecycline 408 mg Capsules, hard but within the leaflet it will be referred to as Lymecycline Capsules.

What is in this leaflet

- 1 What Lymecycline Capsules are and what they are used for
- 2 What you need to know before you take
- 3 How to take
- 4 Possible side effects
- 5 How to store
- 6 Contents of the pack and other information

1 What Lymecycline Capsules are and what they are used for

Lymecycline Capsules belongs to a group of medicines called tetracycline antibiotics.

It is used to treat acne; which appears as blackheads and whiteheads which people often refer to as pimples or spots.

This medicine can also be used to treat other infections such as:

- Ear, nose and throat infections
- bronchitis
- infections in the abdomen
- chlamydia
- some types of eye infections called trachoma
- non-gonococcal urethritis
- rickettsial fever
- soft tissue infections.

2 What you need to know before you take

Do not take Lymecycline Capsules if you:

- are **allergic** to lymecycline, any other tetracyclines or any of the other ingredients of this medicine (listed in section 6)
- have ever had **kidney** disease
- are **pregnant** or **breastfeeding**.

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

Lymecycline Capsules 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 if you:

- have had **liver** problems
- have had **kidney** problems
- suffer from **systemic lupus erythematosus** (an allergic condition that causes joint pain, skin rashes or fever)
- suffer from **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 Capsules 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 Capsules, 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 oesophagus.

Children and adolescents

Lymecycline Capsules is not recommended for use in children under 12 years of age as it can cause permanent discolouration of tooth enamel and affect bone development.

Other medicines and Lymecycline Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take the following medicines at the same time as Lymecycline Capsules, take them at least two hours before Lymecycline Capsules or two hours after:

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

Do not take antacids containing aluminum, calcium or magnesium and products containing iron salts with Lymecycline Capsules, because these products reduce the absorption of tetracycline taken by mouth.

Tell your doctor if you are taking any of the following:

- oral retinoids (to treat acne)
- doses of more than 10,000 IU/day of vitamin A
- anticoagulants (to stop the blood clotting)
- diuretics (used to treat kidney disease, heart disease or high blood pressure)
- medicines for epilepsy including barbiturates, e.g. phenobarbitone, phenytoin and carbamazepine
- methoxyflurane (an anaesthetic)
- any treatment with lithium, as this medicine may increase the lithium levels.

Avoid use with penicillins (and other types of antibiotics), for the possible interference between the two products.

Lymecycline Capsules with food and drink

Absorption of Lymecycline Capsules is not affected by moderate amounts of milk (e.g. a glass). Lymecycline Capsules should always be taken with a glass of water.

Pregnancy and breast-feeding

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.

Lymecycline Capsules must not be taken if you are pregnant or breast-feeding. Use of medicines such as Lymecycline Capsules may affect the proper growth of developing teeth and lead to permanent discolouration.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

3 How to take

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 12 years

Acne

The normal dose is one lymecycline capsule once a day, preferably in the morning. Lymecycline Capsules should always be taken with a glass of water.

How long you will have to take Lymecycline Capsules for will depend on how quickly your condition improves. For acne, this will normally be at least 8 weeks.

Infections

For other infections, the usual dosage is one lymecycline 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. Lymecycline Capsules should always be taken with a glass of water.

Use in children

Do not give Lymecycline Capsules to children below the age of 8.

The safety and efficacy of Lymecycline Capsules in children aged under 12 years of age have not been established.

If you take more Lymecycline Capsules than you should

If you (or someone else) takes too many capsules, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Lymecycline Capsules

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Lymecycline Capsules

Acne responds slowly to antibiotics. It is important that you take all the Lymecycline Capsules that your doctor has prescribed for you. If you stop taking Lymecycline Capsules 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.

If you experience any of the following serious side effects, stop taking your capsules and tell your doctor immediately or go to the nearest hospital accident and emergency department.

Unknown frequency of occurrence (frequency cannot be estimated from the available data):

- serious allergic reaction which causes swelling of the face, tongue, throat that can cause great difficulty in breathing
- serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister.

Lymecycline Capsules may also cause the following side effects.

Common side effects (occur in less than 1 in 10 patients)

- nausea (feeling sick)
- abdominal pain
- diarrhoea
- headache.

Not known frequency of occurrence (frequency cannot be estimated from the available data)

- 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 Capsules belongs (the tetracyclines):

- 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
- permanent visual loss.

* 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 Lymecycline Capsules 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

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or blister after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Store in the original package in order to protect from light.

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 pack and other information

What Lymecycline Capsules contains

- The active substance is lymecycline. Each capsule contains 408 mg of lymecycline equivalent to 300 mg tetracycline base.
- The other ingredients are colloidal hydrated silica, magnesium stearate, capsule body: titanium dioxide (E171), gelatine, capsule cap: indigo carmine FD&C Blue (E132), black iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172), gelatine.

What Lymecycline Capsules looks like and contents of the pack

Hard gelatin capsule, blue cap and white body. Pack sizes: 28 and 56 capsules in Al/Al blister strip.

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer: Balkanpharma-Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria

This leaflet was last revised in 06/2023.

PL 00289/2481