

Package leaflet: Information for the user

Lymecycline Glenmark 300 mg hard capsules lymecycline (equivalent to 300 mg tetracycline)

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 {(Invented) name} is and what it is used for
2. What you need to know before you take {(Invented) name}
3. How to take {(Invented) name}
4. Possible side effects
5. How to store {(Invented) name}
6. Contents of the pack and other information

1. What {(INVENTED) NAME} is and what it is used for

{(Invented) name} belongs to a group of medicines called tetracycline antibiotics.

It is used to treat the following infections in adults and children over 12 years of age:

- Moderate to severe acne.
- Sudden worsening of bronchitis
- Pneumonia
- Urogenital infection (infection in urinary organs or genital area) caused by a type of bacteria called Chlamydia.

2. What you need to know before you take {(INVENTED) NAME}

Do not take {(Invented) name} if:

- you are **allergic** to lymecycline or to other tetracyclines or any of the other ingredients of this medicine (listed in section 6).
- you have a **kidney disease**
- you are a child **under 12 years** of age
- you are **pregnant** or are **breast-feeding**
- you use a medicine called a retinoid (such as isotretinoin, etretinate or acitretin) to treat severe acne or psoriasis or you are taking **vitamin A** (more than 10,000 IU/day).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking {(Invented) name} if:

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

- you suffer from a disease that weakens the muscles (called **myasthenia gravis**).

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.

Children and adolescents

This medicine is not recommended for use in children aged under 12 years of age as it can cause permanent discolouration of tooth enamel, and affect development of the bones.

Other medicines and {(INVENTED) NAME}

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without prescription.

Do **not** take the following medicines at the same time as {(Invented) name}. You should **take them at least 3 hours** apart.

- Indigestion remedies
- Ulcer healing medicines
- Quinapril (for high blood pressure)
- Supplements containing calcium, aluminium, magnesium, zinc, or iron.

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

- **Oral retinoids** (medicinal products used for certain skin conditions) or doses of more than 10 000 IU/day of oral or injectable Vitamin A (medicinal products used for vitamin A deficiency)
- **Anticoagulants** of coumarin type, used to stop blood clotting
- **Diuretics**, used to treat kidney disease, heart disease or high blood pressure
- The pill (**oral contraceptives**) ; {(Invented) name} may make the oral contraceptive pill less effective (see section Pregnancy, breast-feeding and fertility)
- Medicines for **epilepsy** (such as phenobarbitone, phenytoin, and carbamazepine)
- Didanosine, used to treat **HIV**
- An **anaesthetic** called methoxyflurane.

Tell your doctor if you are taking any treatment with lithium, as this medicine may increase the lithium levels.

{(INVENTED) NAME} with food and drink

{(Invented) name} can be taken with a meal. The effect of {(Invented) name} may slightly decrease if taken simultaneously with calcium-containing products such as milk. There should be at least 3 hours between the intake of {(Invented) name} and dairy products.

Always take this medicine with a glass of water.

Pregnancy, breast-feeding and fertility

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.

{(Invented) name} must not be taken if you are pregnant or breast feeding.

{(Invented) name} may affect the growth of developing teeth or bones, or lead to permanent tooth discolouration.

{{(Invented) name}} may make the oral contraceptive pill less effective. You should use additional contraceptive measures, such as a condom, while taking this medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been done. Since this medicine may cause dizziness or eyesight disturbances, you should make sure you are not affected before driving or operating machinery.

3. How to take {{(INVENTED) NAME}}

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

Dosage in adults and children over 12 years

Acne: The recommended dose is one capsule once a day (300 mg/day), preferably in the morning.

How long you will have to take {{(Invented) name}} for, will depend on how quickly your condition improves. For acne, this will normally be at least 8 weeks. The treatment should not exceed a duration of 6 months.

Other infections: The recommended dose is one 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.

How to take the capsules:

Lymecycline Glenmark capsules should always be taken with a glass of water. Take the capsules with a lot of water and whilst sitting upright to avoid injury to the oesophagus.

You should leave at least 3 hours between taking {{(Invented) name}} and dairy products.

If you take more {{(INVENTED) NAME}} than you should

If you take too much or if a child has taken the medicine by mistake, contact your doctor or hospital.

Signs that you have taken too much may include nausea, vomiting and diarrhoea. In patients with kidney problems an overdose has resulted in liver and kidney damage.

If you forget to take {{(INVENTED) NAME}}

Take it when you remember and carry on as before unless it is time for the next dose. **You should never take more capsules than your doctor recommends.**

If you stop taking {{(INVENTED) NAME}}

Acne and other infections respond slowly to antibiotics. It is important that you take the full course of treatment 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, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If you get symptoms of the following **serious side effects** with unknown frequency of occurrence (frequency cannot be estimated from the available data), **stop taking capsules** and **tell your doctor or go to the nearest hospital immediately**.

- Changes in number or type of certain blood cells, which may appear as fatigue, bleeding from the skin and mucous membranes, bruising, tendency to infections and fever.
- **Increased pressure in the brain** (headache, vomiting, disturbances of eyesight including blurred vision, scotoma (dark spots or flickering light in the field of vision), diplopia (double vision) or permanent loss of vision associated with tetracycline, pain behind the eyes)
- **Yellowing of the skin or eyes** (jaundice), which can be sign of hepatitis or liver failure
- Symptoms of a **severe allergic reaction** are difficulty in breathing, swelling of face, tongue or throat, rash or itching (especially affecting the whole body)
- Symptoms of severe disease called **Stevens Johnson syndrome** are blistering or peeling of large areas of the skin, ulcerations or lesions on the mouth, lips, genital or anal regions.
- Cases of systemic lupus erythematosus have been observed which are generally attributed to treatment with tetracycline

Other possible side effects are:

Common: may affect up to 1 in 10 people

- Headache
- Feeling sick (nausea) Abdominal pain
- Diarrhoea

Not known: frequency cannot be estimated from the available data

- Hives
- Dizziness
- Disturbances of eyesight
- Pain in the upper part of the abdomen
- Infection of tongue
- Vomiting (being sick)
- Inflammation of the intestine
- Skin rash
- Increased sensitivity of the skin to sunlight (real or artificial)
- Fever
- Itchiness
- Changes in some blood tests (liver function tests)
- Depression
- Nightmares

The following side effects may occur during treatment with the class of medicines to which lymecycline 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 or inflammation
- Teeth discolouration
- Increase of urea in the blood, which may be enhanced if you take diuretics (water tablets) together with {(Invented) name}
- Anaemia, increased number of white blood cells (eosinophilia) and other blood disorders
- 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 (part of the lower intestine)

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 national reporting system** listed in [Appendix V](#).*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {(INVENTED) NAME}

- Keep this medicine out of the sight and reach of children.
- Do not use after the expiry date (month, year) stated on the carton and blister after Exp.. The expiry date refers to the last day of that month.
- Store below 25°C in the original package in order to protect from moisture.
- 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 {(Invented) name} contains:

- The active substance is lymecycline. Each capsule contains 408 mg of lymecycline equivalent to 300 mg tetracycline.
- Other ingredients are:
Capsule content: magnesium stearate (E470b) and silica, colloidal hydrated (E551).
Capsule shell: gelatin (E441), titanium dioxide (E171), erythrosine (E127), indigotine (E132).
Printing ink: shellac (E904), propylene glycol (E1520), black iron oxide (E172) and Potassium hydroxide (E525).

What {(Invented) name} looks like and contents of the pack

{(Invented) name} is approximately 21.7 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.

{(Invented) name} is available as aluminium blister pack in a carton as well as available as aluminium-plastic (PVC/PVDC) blisters packed in aluminium pouch; further packed in a carton.

Pack size: 28, 56 or 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

< [To be completed nationally]>

Manufacturer

Glenmark Pharmaceuticals s.r.o.
 Fibichova 143
 56617 Vysoké Myto
 Czech Republic.

This medicine is authorised in the Member States of the European Economic Area under the following names:

This leaflet was last revised in 2024-07-03.