

Package leaflet: Information for the patient

Lymelysal 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 Lymelysal is and what it is used for
2. What you need to know before you take Lymelysal
3. How to take Lymelysal
4. Possible side effects
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1. What Lymelysal is and what it is used for

Lymelysal belongs to a group of medicines called tetracycline antibiotics.

Lymelysal 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 Lymelysal

Do not take Lymelysal

- if you are allergic to lymecycline, other tetracyclines or any of the other ingredients of this medicine (listed in section 6)
- if you have a kidney disease
- if you are a child under 12 years of age
- if you are pregnant or breast-feeding
- if you use medicine called 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 Lymelysal

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

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 **Lymelysal**. 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, used to treat acne or vitamin A (more than 10,000 IU/day)
- Anticoagulants, used to stop blood clotting
- Diuretics, used to treat kidney disease, heart disease, or high blood pressure
- The pill (oral contraceptives); Lymelysal 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.

Lymelysal with food and drink

Lymelysal can be taken with a meal. The effect of Lymelysal may slightly decrease if taken simultaneously with calcium-containing products such as milk. There should be at least 3 hours between the intake of Lymelysal 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.

Lymelysal must not be taken if you are pregnant or breast-feeding.

Use of certain medicines, such as lymecycline, may affect the growth of developing teeth or bones, or lead to permanent tooth discolouration.

Lymelysal 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.

Lymelysal contains tartrazine

May cause allergic reactions.

3. How to take Lymelysal

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 recommended dose is one capsule once a day, preferably in the morning.

The length of treatment depends on how quickly your acne improves. Usually it is a minimum of eight weeks. The treatment should not exceed a duration of 6 months.

Other infections: The recommended dose is one capsule twice a day. Your doctor may recommend a different dose; this depends upon the type and severity of the infection. Ask your doctor if you are unsure.

Method of administration: You should take capsules with a glass of water whilst in an upright position. It is also recommended that you take the capsules with a light meal, in order to better avoid possible abdominal side effects.

Use in children and adolescents

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

If you take more Lymelysal than you should

If you have taken too much of the medicine or if, for example, a child has taken the medicine by mistake, contact your doctor or hospital for an assessment of the risk and advice.

Signs that you have taken too much Lymelysal 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 Lymelysal

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

If you stop taking Lymelysal

Acne and other infections respond slowly to antibiotics. It is very 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 could 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.

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 a 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), itchiness
- Fever
- 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 together with Lymecysal
- Anemia, 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 Lymelysal

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 and on the 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 Lymelysal contains

- The active substance is lymecycline. Each capsule contains 408 mg lymecycline equivalent to 300 mg tetracycline.
- The other ingredients are:
Capsule content: silica colloidal, hydrated (E 551), and magnesium stearate (E 470b).
Capsule shell: gelatin (E441), indigotine (E132), erythrosine (E127), titanium dioxide (E171), tartrazine (E 102).

What Lymelysal looks like and contents of the pack

Capsule, hard (capsule)

Gelatin capsules with scarlet cap, yellow body, length 21 mm containing yellow powder.

Pack sizes: 20, 100 and 100 (5x20) capsules in aluminium/aluminium blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Laboratórios Atral, S.A
Rua da Estação 42 Vala do Carregado
2600–726 Castanheira do Ribatejo
Portugal

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