

PACKAGE LEAFLET: INFORMATION FOR THE USER
RIMICORIM 300MG CAPSULES
Lymecycline 408 mg (equivalent to 300mg tetracycline base)

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING 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.

In this leaflet:

1. What Lymecycline is and what it is used for.
2. What you need to know before you take Lymecycline
3. How to take Lymecycline
4. Possible side effects
5. How to store Lymecycline
6. Contents of the pack and other Information

1. WHAT LYMECYCLINE IS AND WHAT IT IS USED FOR?

- Lymecycline belongs to a group of medicines called tetracycline antibiotics.
- The main use of Lymecycline is treatment of moderate to severe 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.
- 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

Do not take Lymecycline if:

- you are pregnant, planning to become pregnant or are breast-feeding
- you have ever had an allergic reaction to lymecycline, the active ingredient in this medicine or to other tetracycline antibiotics such as doxycycline or to any of the other ingredients of Lymecycline (see section 6 for other ingredients). An allergic reaction may include either a rash or itching
- you have ever had kidney disease
- Lymecycline 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).

Take special care with Lymecycline

Tell your doctor before taking Lymecycline if you

- have ever had a liver or kidney problem
- 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)

- have ever developed rashes in response to exposure to sun-light or tanning lamps

Long term use of antibiotics can lead to resistant bacterial infection (Bacteria causing infection does not respond to the course of antibiotic).

Take the medicine with adequate amounts of water to avoid irritation and ulcers of the gullet.

Other medicines and Lymecycline

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 your Lymecycline as these could affect how well your Lymecycline works. Wait at least two to three 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
- activated charcoal, bismuth chelates, and sucralfate
- didanosine for HIV infection.

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)
- systemic retinoids including oral retinoids (to treat acne e.g., Roaccutane), or medicines containing high doses of vitamin A (See 'Do not take Lymecycline' above)
- if you are taking any treatment with lithium, this medicine may increase the lithium levels in your blood
- If you take a contraceptive pill, it may not work properly while you are taking Lymecycline, especially if you have sickness or diarrhoea for any reason. An additional "barrier" method of contraception (e.g., a condom) should be used to make sure you don't get pregnant. Please read the leaflet that was included with your "pill" or talk to your doctor or pharmacist if you are not sure what to do or how long to take these precautions for.

Tell your doctor if you are going to be having a procedure which requires an anaesthetic as Lymecycline cannot be used with some anaesthetics e.g., methoxyflurane.

Tetracycline can lead to a false positive urine test for glucose. Tell your doctor if you are taking Lymecycline and need to have a urine test.

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.

Pregnancy and breast-feeding

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

Always use Lyme cycline 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.

Adults and children over 12 years Moderate to severe acne

The normal dose is one Lyme cycline capsule once a day, preferably in the morning.

How long you will have to take Lyme cycline for will depend on how quickly your condition improves.

For acne, this will normally be at least 8 to 12 weeks. Your physician may decide to continue with treatment for a maximum of 6 months.

Lyme cycline capsules should always be taken with a glass of water. They should also be taken with a light meal without dairy products.

Kidney impairment:

If you have a kidney problem your doctor may decide to reduce your dose.

Do not give Lyme cycline to children below the age of 8 years, it could harm them.

If you take more Lyme cycline than you should

If you, or anyone else, take too many Lyme cycline 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 Lyme cycline

If you forget to take a dose, simply take it when you remember and carry on as before unless it is time for the next dose. **Do not take a double dose to make up for a forgotten capsule. You should never take more capsules than your doctor recommends.**

If you stop taking Lyme cycline

Acne responds slowly to antibiotics. It is important that you take all the Lyme cycline that your doctor has prescribed for you. If you stop taking Lyme cycline 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, Lyme cycline can cause side effects although not everybody gets them.

Lyme cycline may cause the following side effects.

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)

- 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)
- Inflammation or ulceration of the gullet, causing pain or difficulty swallowing or painful heartburn.
- 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).
- Pancreatitis (inflammation of the pancreas).
- 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 Lymecycline
- 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
- Benign intracranial hypertension, symptoms of which may include headache, vomiting, visual disturbances (blurred vision, blind spots or double vision), or permanent loss of vision have been reported with tetracycline therapy.

*Tell your doctor immediately if you develop side effects such as 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, severe nausea, or any visual disturbance.

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 (see details below):

By reporting side effects you can help provide more information on the safety of this medicine

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace

IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

5. HOW TO STORE LYMECYCLINE

- Keep this medicine out of the reach and sight of children.
- Do not use Lymecline after the expiry date, which is stated on the carton and blister label. The expiry date refers to the last day of the month.
- Do not store above 25°C. Store in the original container.
- 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 Lymecline contains?

Each Lymecline capsule contains 408 mg of the active ingredient Lymecline (equivalent to 300 mg tetracycline base). The other ingredients are magnesium stearate, colloidal hydrate silica. The capsule shells contain gelatin, titanium dioxide (E171), erythrosine (E127), quinoline yellow (E104) and indigotine (E132), the ink contains potassium hydroxide, black iron oxide (E172), propylene glycol and shellac.

What Lymecline looks like and contents of the pack

Lymecline capsules are hard gelatin capsules with yellow body and red cap imprinted with NM. Lymecline capsules are packed in a carton containing 28 or 56 capsules packed in blisters. Each blister strip contains 7 capsules and there are 4 or 8 blister strips in each carton. Not all pack sizes may be marketed.

Marketing Authorisation Holder

The marketing authorisation holder of this medicine is

Brown & Burk IR Limited
22 Northumberland Road,
Ballsbridge, Dublin 4,
Ireland

Manufacturer

Kinedexe UK Limited,
Unit 15 Moorcroft, Harlington Road,
Uxbridge, UB8 3HD,
United Kingdom.

This leaflet was approved in **11/2023**.