LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lymelysal
(lymecycline)

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Lymelysal

(lymecycline)

Hard capsule, 300 mg.
Each capsule contains 408 mg of lymecycline equivalent to 300 mg tetracycline.

This is a summary of the public assessment report (PAR) for Lymelysal. It explains how Lymelysal was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Lymelysal.

For practical information about using Lymelysal, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lymelysal and what is it used for?

Lymelysal is a 'generic medicine'. This means that Lymelysal is similar to a 'reference medicine' already authorised in the European Union (EU) called Tetralysal.

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.

How does Lymelysal work?

Lymelysal is an antibiotic belonging to a group of medicines called tetracycline antibiotics.

How is Lymelysal used?

The pharmaceutical form of Lymelysal is hard capsule for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Lymelysal have been shown in studies?

Because Lymelysal is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Tetralysal. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Lymelysal?

Because Lymelysal is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Lymelysal approved?

It was concluded that, in accordance with EU requirements, Lymelysal has been shown to have comparable quality and to be bioequivalent to the reference medicine Tetralysal. Therefore, the Medical Products Agency in Sweden decided that, as for Tetralysal, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Lymelysal?

A risk management plan has been developed to ensure that Lymelysal is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lymelysal, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Lymelysal

The marketing authorisation for Lymelysal was granted on 2016-11-08 in Sweden.

The full PAR for Lymelysal can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Lymelysal, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2016-11