

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tetralysal 300 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 408 mg Lymecycline equivalent to 300 mg of tetracycline base.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Hard Capsule (Capsule).

Product imported from Italy and France

Hard gelatin capsule, red cap and yellow body

4 CLINICAL PARTICULARS

As per PA22743/016/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22743/016/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Colloidal Hydrated Silica

Capsule Shells:

Gelatin
Titanium dioxide (E171)
Erythrosine (E127)
Quinoline Yellow (E104)
Indigotine (E132)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original container in order to protect from light and moisture.

6.5 Nature and contents of container

Polyethylene/foil strips of 4 capsules presented in a carton containing 28 capsules.

6.6 Special precautions for disposal

As with handling of any anti-infective, care should be taken to avoid contact with the substance.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/256/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 2010

10 DATE OF REVISION OF THE TEXT

September 2022