

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tetralysal 300mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard Capsule (Capsule)

Product imported from the UK

Hard gelatin capsule, red cap and yellow body.

4 CLINICAL PARTICULARS

As per PA0590/012/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0590/012/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Colloidal Hydrated Silica

Capsule Shell:

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 an overlabelled carton containing 28 capsules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/080/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th July 2013

10 DATE OF REVISION OF THE TEXT

October 2016