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 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 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 shall be the date shown on the blister strips and outer carton of the product as marketed 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

Cartons containing 28 capsules packed in polyethylene/foil blisters. Each blister strip contains 4 capsules and there are 7 blister strips in each carton.

6.6 Special precautions for disposal and other handling

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

PPA1463/133/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th April 2013

10 DATE OF REVISION OF THE TEXT

April 2022