Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tetralysal 300mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 408mg lymecycline (equivalent to 300mg of tetracycline base).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard Capsule

Product sourced from UK:
Hard gelatin capsule with a 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 shall be 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.

Keep container in the outer carton in order to protect from light and moisture.

6.5 Nature and contents of container

Cartons containing Aluminium and Polyethylene blister strips containing 28 hard capsules.

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

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/208/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st January 2014

10 DATE OF REVISION OF THE TEXT

November 2015