

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 (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 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 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

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

Blisters: 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

Aluminium/PVC/PVDC blisters strips of 4 capsules presented in an overlabelled carton containing 28 or 56 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

Primecrown 2010 Ltd.
Unit 4/5 Northolt Trading Estate
Northolt
Middlesex
UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/029/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th July 2013

10 DATE OF REVISION OF THE TEXT

May 2017