Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zineryt 40mg/12mg per ml Powder and Solvent for Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Erythromycin 40 mg per ml and zinc acetate 12 mg per ml on constitution.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for cutaneous solution.

Product imported from Bulgaria:
Powder: White crystalline powder
Solvent: Clear colourless liquid.

4 CLINICAL PARTICULARS

As per PA1241/010/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1241/010/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Di-isopropyl sebacate
Ethanol

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.

Upon reconstitution: Use within 5 weeks.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The packaging contains an overlabelled bottle of white crystalline powder, an overlabelled bottle of clear colourless solvent and an applicator in a plastic holder. The contents of the bottles will be mixed together by your pharmacist to form a solution. Your pharmacist will also fit the special applicator top to the bottle containing the mixed solution. The applicator top is protected by a cap.

Zineryt is available in packs which, when made up, will contain 30 ml of the solution.

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

The powder is reconstituted with the solvent (ethanol 68% w/w) prior to dispensing as follows:

(i) Remove the caps from the powder bottle and the solution bottle; retain the cap of the powder bottle.
(ii) Pour the contents of the solution bottle into the powder bottle and recap the latter.
(iii) Immediately, shake well for one minute. Remove and retain cap.
(iv) Open the plastic holder containing the applicator assembly and use the holder to position the applicator assembly over the neck of the bottle and to push the applicator assembly firmly into the neck of the bottle.
(v) Remove the plastic holder and ensure that the applicator fits firmly into the neck of the bottle. Discard the plastic holder.
(vi) Replace the cap on the now constituted application.
(vii) Add the “Use Before” date to the bottle label; this date is 5 weeks from the date of preparation.
(viii) Ensure that the patient information leaflet is given to the patient.

After reconstitution, a clear colourless liquid is formed.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/200/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th February 2013

10 DATE OF REVISION OF THE TEXT

March 2015