Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zineryt 40 mg + 12 mg powder and solvent for cutaneous solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Erythromycin 40 mg per ml and zinc acetate dihydrate 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 PA2239/018/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/018/001

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 carton of the product as marketed 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

Screw-capped HDPE bottles; a dabbing applicator cap is fitted when dispensed.
When constituted pack is of 30 ml.

6.6 Special precautions for disposal and other handling

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

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/522/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 2026

10 DATE OF REVISION OF THE TEXT