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.
Powder: White crystalline powder
Solvent: Clear colourless liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Topical treatment of acne vulgaris.

4.2 Posology and method of administration

For adolescents, adults and the elderly. Apply twice daily over the whole of the affected area and immediately surrounding skin.

4.3 Contraindications

Zineryt is contraindicated in patients who are hypersensitive to erythromycin or other macrolide antibiotics, or to zinc, di-isopropyl sebacate or ethanol.

4.4 Special warnings and precautions for use

As with other macrolides, rare serious allergic reactions, including acute generalised exanthematous pustulosis (AGEP) have been reported. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

Cross resistance may occur with other antibiotics of the macrolide group and also with lincomycin and clindamycin. Contact with the eyes or the mucous membranes of the nose and mouth should be avoided. Prolonged use of an anti-infective may result in superinfection due to micro-organisms resistant to the anti-infective.

If there is no response within 10 to 12 weeks alternative measures should be considered. Prolonged use is not recommended. A course should not usually exceed six months.

4.5 Interaction with other medicinal products and other forms of interactions

Although use with other therapies such as benzoyl peroxide has shown an additive effect, the use of Zineryt with other topical treatment should only be carried out with caution in view of possible cumulative local adverse effects.

4.6 Fertility, pregnancy and lactation

Human experience with oral erythromycin suggests that erythromycin can cause congenital malformations, such as cardiovascular malformations and pyloric stenosis, when administered during pregnancy.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).
Zineryt should not be used during pregnancy unless the clinical condition of the woman requires treatment with erythromycin.

It is recommended that the preparation should be used with caution in lactating women who are breast feeding, and on areas away from the chest.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The following adverse drug reactions were reported:

System Organ Class	Uncommon (≥1/1,000 to <1/100)	Very rare (<1/10,000) Not known (cannot be estimated from the available data)	Not known (cannot be estimated from the available data)
Immune system disorders		Hypersensitivity	
Skin and subcutaneous tissue disorders	Pruritus Erythema Skin irritation Skin burning sensation Dry skin Skin exfoliation		Acute generalised exanthematous pustulosis (AGEP)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

It is not expected that overdosage would occur in normal use. Patients showing idiosyncratic hypersensitivity should wash the treated area with copious water and simple soap. Swallowing the entire contents of a single pack of Zineryt would mainly lead to symptoms associated with alcohol intake.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Erythromycin is known to be efficacious, at 4%, in the topical treatment of acne vulgaris. Zinc, topically, is established as an aid to wound healing. The zinc acetate is solubilised by complexing with the erythromycin, and delivery of the complex is enhanced by the chosen vehicle.

5.2 Pharmacokinetic properties

The complex does not survive in the skin, and erythromycin and zinc penetrate independently. The erythromycin penetrates, and is partially systemically absorbed (0 - 10% in vitro, 40 - 50% in animal studies); that portion absorbed is excreted in 24 - 72 hours. The zinc is not absorbed systemically.

5.3 Preclinical safety data

No relevant pre-clinical safety data has been generated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Di-isopropyl sebacate

Ethanol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years
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 packs are of 30 ml and 90 ml.

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 MARKETING AUTHORISATION HOLDER

CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 24
17489
Greifswald
Germany

8 MARKETING AUTHORISATION NUMBER

PA2239/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th December 1992
Date of last renewal: 17th December 2007

10 DATE OF REVISION OF THE TEXT

May 2021