1 NAME OF THE MEDICINAL PRODUCT

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

Erythromycin/Zinc acetate 40 mg/12 mg powder and solvent for cutaneous solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Erythromycin-zinc complex containing the equivalent of 40 mg/ml erythromycin and 12 mg/ml zinc acetate dihydrate (as the complex) on constitution.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for cutaneous solution.

The packaging contains a bottle of powder, a bottle of solvent and an applicator in a plastic holder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Zineryt is indicated in children, adults and the elderly. It is used as topical treatment of acne vulgaris.

4.2 Posology and method of administration

For cutaneous use. Apply twice daily over the whole of the affected area for a period of 10 to 12 weeks.

4.3 Contraindications

Hypersensitivity to the active substance(s), to other macrolide antibiotics, or to any of the excipients listed in section 6.1.

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 after systemic administration. 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.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Zineryt can be used during pregnancy and during breast-feeding (but it should not be used on the chest).

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Tabulated list of adverse reactions

System Organ Class	Rare (³1/10,000 to<1/1000)	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)*

*Reported after systemic administration

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-acne, ATC code: D10A F52

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

Absorption

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

Non-clinical data from repeated dose toxicity and reproduction and developmental toxicity studies reveal no additional hazard other than those described elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Di-isopropyl sebacate, ethanol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

8 weeks after constitution

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Screw-capped HDPE bottles; an applicator assembly is fitted when dispensed. When constituted packs are of 30 ml and 90 ml.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Neon Healthcare Ltd.

8 The Chase, John Tate Road,

Hertford,

SG13 7NN

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 45043/0097

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 March 1990

Date of latest renewal: 19 December 2008

10 DATE OF REVISION OF THE TEXT

30/12/2022