SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Zineryt contains 40 mg/ml *erythromycin* and 12 mg/ml *zinc acetate dihydrate*.

3. PHARMACEUTICAL FORM

Powder and solvent for cutaneous solution. Powder in a bottle and solvent in a bottle for mixing prior use.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Moderate to severe forms of acne, for which local treatment without antibiotics does not show result or lead to insignificant results or it is not tolerated.

4.2 Posology and method of administration

Posology

Zineryt should be applied twice daily on the affected skin usually for a duration of 10-12 weeks. A significant healing effect is present in the first 12 weeks.
If there is no improvement or improvement is insufficient, or the condition even deteriorated after this period, patients should consult their physician and consider the likelihood of bacterial resistance. If bacterial resistance is found the product should be suspended for a duration of two months.

Method of administration

Zineryt should be administered freely on the skin of the whole face or on other affected areas (not only on the lesion) while covering the entire area (each time about 0.5 ml of the product are applied).

Zineryt is administered as the bottle is turned downwards and the end of the applicator is pointed towards the skin while the applicator is rubbed against the skin and pressed gently at the same time. The flow rate of Zineryt is controlled by increasing or decreasing the pressure of the applicator on the skin.

4.3 Contraindications

Zineryt is contraindicated in patients with known hypersensitivity to erythromycin or other antibiotics of the macrolide group, to zinc, diisopropyl sebacate or ethanol.

4.4 Special warnings and precautions for use

Zineryt is indicated for topical use on skin only and should not come in contact with the eyes or mucous of the nose and mouth.
Cross resistance may occur with other antibiotics of the macrolide group and also with lincomycin and clindamycin. Cross hypersensitivity may occur among the macrolides.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 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.

4.7 Effects on ability to drive and use machines

There is no data about the Zineryt effects on the ability to drive and use machines, however such effects are unlikely.

4.8 Undesirable effects

System Organ Class	**Uncommon >1/1000,<1/100**	**Very rare <1/10,000, 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	

* Erythema, skin irritation and skin burning sensation are transient and of little clinical significance.

4.9 Overdose

Accidental overdose is unlikely given the medicinal formulation of the drug.

Accidental swallowing the entire contents of a single pack of Zineryt would mainly lead to symptoms of acute toxicity due to the absolute alcohol which is one of the product excipients.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Anti-acne products, ATC D10A F52

Mechanism of action

Erythromycin is a bacteriostatic antibiotic with a narrow spectrum of activity and belongs to the macrolide group. Microorganisms susceptible to this antibiotic include bacteria that are often observed in acne *S. epidermidis* u *P. acnes*. Applied topically erythromycin may have a beneficial effect on acne. During treatment skin flora can become resistant to erythromycin. This resistance is usually reversible after treatment discontinuation. Zinc enhances the effect of erythromycin in the treatment of acne.

In severe forms of acne treatment with Zineryt may be combined for example with dermal administration of vitamin A or benzyl peroxide or oral administration of tetracycline.

After drying the applied Zineryt is invisible and is therefore acceptable from a cosmetic point of view.

5.2 Pharmacokinetic properties

Applied topically erythromycin is not absorbed or is absorbed to a minimum.

5.3 Preclinical safety data

There is no data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Diisopropyl sebacate,
Ethanol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Separately packed powder and liquid are stable until the expiry date printed on the packaging. Shelf life is 2 years.
Expiry date after the solution is reconstituted is 8 weeks.

6.4 Special precautions for storage

Zineryt (powder for cutaneous solution) and the prepared solution should not be stored at temperatures above 25^0C.

As soon as the solution is prepared the expiry date should be indicated on the bottle.

6.5 Nature and contents of container

Zineryt is available in the form of powder, containing erythromycin and zinc acetate dihydrate, and a liquid solvent containing ethanol and a softener. Powder and liquid solution are placed in individual bottles.

6.6 Special precautions for disposal/handling

In the beginning of any treatment the liquid from the solution bottle is poured into the powder bottle, it is then well shaken until Zineryt gets dissolved and the cap with the applicator is placed. The following is detailed instructions for mixing:

1. The box has yellow/grey/white colors and contains 2 bottles and an applicator. Caps of both bottles should be removed.
Retain the cap of the powder bottle.
2. Pour the contents of the solution bottle into the powder bottle. The empty bottle may be discarded.
3. Screw the cap of the bottle containing the powder and the solvent.
4. The bottle is immediately shaken for 1 minute.
5. The cap of the full bottle is unscrewed and the applicator is positioned on the stopper.
6. The stopper with the applicator is pressed onto the full bottle and slightly screwed.
7. Now the cap can be unscrewed from the bottle and the applicator can be checked if it is well fixed. If required, the applicator may be pressed firmly.
8. Solution can be stored for 8 weeks after reconstitution. Add the expiry date on the bottle.

One bottle with prepared solution contains 30 ml Zineryt which is sufficient for a one-month treatment.

7. MARKETING AUTHORIZATION HOLDER

LEO Pharma A/S

Industriparken 55
DK-2750 Ballerup
Denmark

8. MARKETING AUTHORIZATION NUMBER(S)

20010281

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorisation: 06.03.2001
Date of latest renewal: 17.05.2006

10. DATE OF REVISION OF THE TEXT

07/2016