SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

Zineryt® 40 /12 mg Lotion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each one ml contains erythromycin 40,0 mg (4,0 % w/v) and zinc acetate 12,0 mg (1,2 % w/v).

Zineryt® Lotion contains a powder and solvent for cutaneous solution.

Powder: White crystalline powder.

Solvent: Clear colourless liquid with an alcoholic odour.

The reconstituted product is a clear, colourless lotion.

Sugar free

Contains Ethanol anhydrous (55 % w/v)

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Zineryt® 40 /12 mg Lotion is packed in a carton box containing two white polyethylene bottles with white polypropylene screw caps and an applicator with an applicator holder.

One bottle contains a white crystalline powder and the other bottle contains a clear, colourless solution with an alcoholic odour.

The reconstituted product is a clear, colourless lotion.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Moderate to severe forms of acne vulgaris, for which topical therapy without antibiotics has produced insufficient results or is not tolerated.

In severe forms of acne, the treatment with Zineryt® may be combined with, for instance, topical application of vitamin A or benzoyl peroxide or oral administration of tetracycline.

4.2 Posology and method of administration

Posology:

Zineryt® lotion should be applied to the affected skin twice daily, usually for a period of 10 - 12 weeks.

If no or insufficient improvement or even a worsening has occurred after a period of 12 weeks, the patient should consult his/her doctor.

Method of administration

Zineryt® lotion should be applied liberally into the skin of the entire face or onto other affected parts (not only onto the lesion itself), until the entire area to be treated is covered (about 0,5 ml is needed each time).

Zineryt® lotion is applied by tilting the bottle downward and rubbing the applicator top over the skin while gently applying pressure. The rate of flow of Zineryt® may be controlled by increasing the pressure against the skin.

4.3 Contraindications

Zineryt® is contra-indicated in persons who have shown hypersensitivity to erythromycin or other macrolide antibiotics, or to zinc, di-isopropyl sebacate or ethanol.

4.4 Special warnings and precautions for use

Zineryt® is for topical treatment of the skin only and should be kept away from the eyes and mucous membranes of the nose or mouth. It will cause a burning and irritating sensation in these areas.

Concomitant topical acne therapy should be used with caution because a cumulative irritant effect may occur, especially with the use of abrasive agents.

Cross resistance may occur with other antibiotics of the group of macrolides and with lincomycin and clindamycin, which could result in overgrowth of antibiotic resistant organisms on the skin. Mutual cross allergy between macrolides may occur. As with other macrolides, rare serious allergic reactions,

including acute generalised exanthematous pustulosis (AGEP) have been reported. Should this occur, administration of the preparation should be discontinued and appropriate measures taken.

Prolonged use of an anti-infective may result in superinfection due to microorganisms 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.

Hypersensitivity.

Zineryt® contains ethanol it may cause burning sensation on damaged skin.

4.5 Interaction with other medicines and other forms of interaction

Concomitant topical acne therapy should be used with caution because a cumulative irritant effect may occur, especially with the use of abrasive agents.

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

Safety in pregnancy and lactation has not been established.

Pregnancy

Human experience with oral erythromycin suggests that erythromycin can cause congenital malformations, such as cardiovascular malformations and pyloric stenosis, when administered during pregnancy.

Zineryt® should not be used during pregnancy.

Breastfeeding

There is no contra-indication to the use of Zineryt® in lactation.

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.

Fertility

No data is available.

4.7 Effects on ability to drive and use machines

No information available.

4.8 Undesirable effects

Tabulated summary of adverse reactions

The following frequency rating is used since there is no clinical trial data:

Frequent, less frequent and frequency unknown (cannot be estimated from available data).

MedDRA System Organ Class	**Frequency and description**
Immune system disorders	*Less frequent:* Hypersensitivity
Skin and subcutaneous tissue disorders	*Less frequent:* Pruritus, skin irritation, skin exfoliation, but they have disappeared on withdrawal of the preparation, erythema, burning sensation, dry skin *Frequency not known:* Acute generalised exanthematous pustulosis (AGEP)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

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.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.12 Acne Preparations

PHARMACOLOGICAL ACTION:

Erythromycin is a bacteriostatic, narrow spectrum antibiotic. The mechanism by which erythromycin acts in reducing inflammatory lesions of acne vulgaris has not been conclusively shown. Erythromycin is known to be efficacious, at 4 %, in the topical treatment of acne vulgaris.

Zinc, topically exerts anti-inflammatory effects. Zinc, topically, is established as an aid to wound healing.

Zineryt® is a topical lotion containing erythromycin and zinc acetate in a complex, 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 zinc is not absorbed systemically.

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.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Di-isopropyl sebacate,

Ethanol anhydrous

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

The reconstituted lotion may be kept for up to 8 weeks stored at or below 25 °C.

6.5 Nature and contents of container

Zineryt® 30 ml, 70 ml and 90 ml is packed in a carton box containing two white high density polyethylene bottles with white polypropylene screw caps and an applicator with an applicator holder.

Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

Instructions for the preparation of the ready-made solution of Zineryt®

1. The box contains two bottles and an applicator with an applicator holder. Remove the caps from both bottles; retain the cap of the bottle with powder.
2. Pour the liquid from the one bottle into the bottle containing the powder. Recap the latter. The empty bottle may be thrown away.
3. Immediately shake the bottle for one minute. Remove and retain the cap.

4. Remove the applicator from the plastic holder. Fit the applicator into the cap of the bottle with the reconstituted lotion. Push the cap with applicator onto the bottle and tighten.
5. Remove the cap from the bottle and ensure that the applicator fits firmly into the neck of the bottle.

6. Replace the cap on the bottle containing the reconstituted lotion.
7. The lotion may be kept for 8 weeks after preparation. Add the “Use before” date to the bottle label.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685,

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER:

34/13.12/0474

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Registration date: 11 February 2002

10. DATE OF REVISION OF THE TEXT

20 October 2025

Namibia -NS2		
	Product name	**Registration number**
	Zineryt® Lotion	05/20.1.1/0426