SCHEDULING STATUS: **S4**

Zineryt® 40 /12 mg Lotion

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

Sugar free

Contains Ethanol anhydrous (70 % v/v)

Read all of this leaflet carefully before you start taking Zineryt® lotion.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Zineryt® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZINERYT® is and what it is used for

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.

2. What you need to know before you use ZINERYT®

Do not use ZINERYT®:

If you have shown hypersensitivity to erythromycin or other macrolide antibiotics, or to zinc, di-isopropyl sebacate or ethanol.

Warnings and precautions

Take special care with Zineryt®

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 linomycin and clindamycin, which could result in overgrowth of antibiotic resistant organisms on the skin.

Mutual cross allergy between macrolides may occur. A small elevation of the skin containing pus and having inflamed base (acute generalised exanthematous pustulosis (AGEP)) is reported. Should this occur, administration of the preparation should be discontinued and appropriate measures taken.
Long-term use of an antibiotic such as Zineryt may result in an infection due to the development of resistance to the antibiotic product.
Hypersensitivity.

Other medicines and Zineryt®

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

Zineryt® with food and drink:

Zineryt® Lotion is for topical external use only.

Tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have your baby please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

You should not use Zineryt® if you are pregnant.

You may breast-feed during treatment with Zineryt® but do not use this medicine on the area of your chest.

Driving and using machines

No information available.

Zineryt® contains ethanol

Ethanol may cause burning sensation on damaged skin.

3. HOW TO USE ZINERYT®:

Do not share medicines prescribed for you with any other person.

Always take Zineryt® as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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 tell your doctor or pharmacist. 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.

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.

If you use more ZINERYT® than you should

If you have accidentally swallowed, treatment is symptomatic and supportive.

If you have applied too much Zineryt®, blot it off with some tissue.

Swallowing the entire contents of a single pack of Zineryt® would mainly lead to symptoms associated with alcohol intake.

If the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you stop using ZINERYT®

Always contact your doctor if you want to stop using ZINERYT®

4. Possible side effects

Zineryt® can have side effects.

Not all side effects reported for Zineryt® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Zineryt®, please consult your healthcare provider for advice.

If any of the following happens, stop taking/using Zineryt® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

These are all very serious side effects. If you or your child have them, you may have had a serious allergic reaction to Zineryt®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (Acute generalised exanthematous pustulosis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent

Redness of skin (Erythema), skin burning sensation and dry skin.

Pruritus (itching), skin irritation, skin exfoliation, but they may disappear on withdrawal of Zineryt®.

Hypersensitivity

Frequency unknown:

A red, scaly rash with bumps under the skin and blisters (Acute generalised exanthematous pustulosis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Zineryt® Lotion.

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

5. How to store Zineryt®

Store at or below 25 °C.

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

Store all medicines out of reach of children.

Do not use after expiry date on the bottle.

6. Contents of the pack and other information

What Zineryt® lotion contains:

The active substance in Zineryt® are erythromycin 40 mg (4,0 % w/v) and zinc acetate 12 mg (1,2 % w/v) in each ml of the lotion.

The other ingredients in Zineryt® lotion are Di-isopropyl sebacate, ethanol.

What Zineryt® lotion looks like and contents of the pack

Zineryt® 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.

PRESENTATION OF ZINERYT®:

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

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road, Erand Gardens

Midrand 1685,

Customer Care: 0860 ADCOCK / 232625

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	Zineryt Lotion	05/20.1.1/0426