

Package leaflet: Information for the user

Zineryt® 40 mg + 12 mg powder and solvent for cutaneous solution
erythromycin 40 mg and zinc acetate dihydrate 12 mg per ml on constitution

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zineryt® is and what it is used for
2. What you need to know before you use Zineryt®
3. How to use Zineryt®
4. Possible side effects
5. How to store Zineryt®
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1. What Zineryt® is and what it is used for

The active substance of Zineryt belongs to the group of antibiotics for treatment of acne vulgaris, often referred to as pimples or spots. These medicines are used to reduce the growth of bacteria which cause acne.

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

Do not use Zineryt

- if you are allergic to erythromycin or zinc or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to antibiotics of the macrolide group. Your doctor or pharmacist will be able to tell you if that is the case.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Zineryt.

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. However, if this occurs, then rinse the affected area immediately with cold or lukewarm water for several minutes.

Other medicines and Zineryt

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

You may 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

It is not likely that Zineryt affects your ability to drive or use machines.

3. How to use Zineryt®

This medicine is for cutaneous use. Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for proper use

Wash the affected area first before using Zineryt.

If you want to apply make-up, use the medicine first and let it dry.

Zineryt comes to you in a special bottle with a special applicator pad protected by a cap which you should remove just before use and replace firmly after each use. The pad makes it easy to apply the solution to the whole of the affected area of the skin to be treated.

To use Zineryt unscrew the protective cap, hold the bottle upside down, place the pad against the skin, and spread the solution over the whole of the affected area (including the surrounding skin). The flow of solution can be increased by pressing the pad a little more firmly against the skin.

If you use the applicator properly, just the right quantity should be applied. But if you do put too much on, blot it off with some tissue, and make sure it does not run into the eyes, nose or mouth. If it does, wash well with plenty of water (see also “Warnings and precautions” under section 2. What you need to know before you use Zineryt).

Frequency of administration

Usually, Zineryt should be applied all over the affected area and the surrounding skin twice a day.

Duration of treatment

Successful treatment of acne may take several weeks or even months. The normal treatment time is 10 to 12 weeks. Consult your doctor if you still have acne at the end of the prescribed course of treatment.

If you use more Zineryt than you should

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. You should contact your doctor or pharmacist if you or somebody else accidentally swallows this medicine.

If you forget to use Zineryt

Try not to forget to use Zineryt, as missing an application will slow down the healing process. If you have missed an application, use Zineryt when you remember, but leave about three hours before you use it again.

If you stop using Zineryt

If you stop using Zineryt, the original symptoms may come back. Always contact your doctor if you want to stop using Zineryt.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).

Zineryt may rarely cause allergic reactions. Symptoms may include rash, itching, swelling of the mouth, face and lips or tongue and difficulty breathing. Please contact your doctor immediately if you experience any of these side effects.

Zineryt may cause the following rare side effects (may affect up to 1 in 1,000 people):

- Temporary stinging or slight redness of the skin.

If you get a very painful rash or burning feeling after using Zineryt which does not go away in a few hours, or gets worse each time you use it, stop using it and tell your doctor as soon as possible.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zineryt®

Keep this medicine out of the sight and reach of children.

Do not use Zineryt after the expiry date as stated on the label and carton. The expiry date refers to the last day of the month. Do not use this medicine after the “Use before” date which

has been put on the label by your pharmacist. The “Use before” date is 8 weeks after the pharmacist has prepared this medicine into a solution.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zineryt contains

- The active substances are erythromycin (40 mg/ml) and zinc acetate (12 mg/ml) combined in a special way.
- The other ingredients are di-isopropyl sebacate and ethanol.

What Zineryt looks like and contents of the pack

Zineryt is made available as a solution for use on the skin (cutaneous use). The packaging contains a bottle of powder, a bottle of solvent and an applicator in a plastic holder. The contents of the bottles will be mixed together by your pharmacist to form a solution. Your pharmacist will also fit the special applicator top to the bottle containing the mixed solution. The applicator top is protected by a cap.

Zineryt is available in packs which, when made up, will contain 30 ml or 90 ml of the solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark

Manufacturers:

Astellas Pharma Europe B.V.
Hogemaat 2
7942 JG Meppel
The Netherlands

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For information in large print, Braille or audio/CD, telephone +44 (0)1844 347333