

Zineryt[®] cutaneous solution

(erythromycin 40mg and zinc acetate 12mg 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.

The name of your medicine is Zineryt cutaneous solution but will be referred to as Zineryt throughout this leaflet.

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
6. Contents of the pack and other information

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 out of the sight and reach of children.

Do not store above 25°C.

Store in the original package.

Do not use this medicine after the 'Use before' date which has been put on the label by your pharmacist. This is 5 weeks after preparation of the solution by your pharmacist.

If the solution become discoloured or show any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zineryt contains

The active ingredients in Zineryt are erythromycin and zinc acetate.

Erythromycin-Zinc complex containing the equivalent of 40mg/ml erythromycin and 12mg/ml zinc acetate (as the complex) on constitution. Contains 550mg/ml ethyl alcohol anhydrous on constitution.

The other ingredients are di-isopropyl sebacate and ethyl alcohol anhydrous.

What Zineryt looks like and the contents of the pack

Dry white powder bottle and colourless solvent bottle to be admixed on dispensing. Zineryt is 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 30ml of solution.

Manufactured by: LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup, Denmark.

OR

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

Procured from within the EU and repackaged by the

Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

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Blind or partially sighted?

Is this leaflet hard to see or read?

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