

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zineryt® 40mg/12mg per ml Powder and Solvent for Cutaneous Solution

(erythromycin and zinc acetate dihydrate)

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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Zineryt 40mg/12mg per ml Powder and Solvent for Cutaneous Solution but will be referred to as Zineryt throughout this leaflet.

In this leaflet:

1. What Zineryt is and what it is used for
2. Before you use Zineryt
3. How to use Zineryt
4. Possible side effects
5. How to store Zineryt
6. Further information
7. Information for healthcare professionals

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, often referred to as pimples or spots. These medicines are used to reduce the growth of bacteria which cause acne.

2. BEFORE YOU USE ZINERYT

Do not use Zineryt

- if you are allergic (hypersensitive) to erythromycin, or zinc or to any of the other ingredients of Zineryt (see list in section 6 'Further information'). Your doctor may decide to give you another medicine instead.
- if you are allergic to antibiotics of the macrolide group. Ask your doctor or pharmacist if you are unsure.

Take special care with Zineryt

- Avoid contact with the eyes and mucous membranes of the nose and mouth. However, if this occurs, then rinse the affected area immediately with cold or lukewarm water for several minutes. Contact your doctor for further advice.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken, used or might use any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

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

This product should **not** be used in pregnancy unless your doctor advises otherwise.

Zineryt should be used with caution in breast-feeding patients 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

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 bottle with a special applicator pad protected by a cap which you should remove before use and replace firmly after each use. This 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 toilet 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 'Take special care with Zineryt' under section 2. 'Before you use Zineryt').

Always use Zineryt exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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 toilet tissue. If you begin to show signs of hypersensitivity (allergic reaction) you should wash the treated area with copious amount of water and simple soap.

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

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Zineryt may very 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 uncommon side effects (likely to affect more than 1 in 1000 and less than 1 in 100 patients):

- Temporary stinging or slight redness of the skin
- Dry skin
- Skin exfoliation
- Itching
- Skin irritation

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.

Long-term use of an antibiotic such as Zineryt may result in an infection due to the development of resistance to the antibiotic product.

Reporting 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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 take Zineryt after the expiry date which is stated on the carton and bottle label after 'Exp'. The date refers to the last day of that month.

Do not store above 25°C.

Once the pharmacist has reconstituted this medicine for you, do not use for longer than 5 weeks as per the use before date indicated on the bottle label.

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. FURTHER INFORMATION

What Zineryt contains

- The active substances are erythromycin and zinc acetate dihydrate.

Erythromycin-Zinc complex contains the equivalent of 40mg/ml erythromycin and 12mg/ml zinc acetate on constitution.

- The other ingredients are di-isopropyl sebacate and ethanol.

What Zineryt looks like and contents of the pack

Zineryt is made available as a cutaneous solution. The packaging contains a bottle of white crystalline powder, a bottle of clear colourless 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 solution.

Manufactured by: Astellas Pharma Europe B.V., Sylviusweg 62, 2333 BE Leiden, The Netherlands

Procured from within the EU and repackaged by the PPA holder:

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

Zineryt® 40mg/12mg per ml Powder and Solvent for Cutaneous Solution,

PPA No: 1328/200/001

POM

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INFORMATION FOR HEALTHCARE PROFESSIONALS

The following information is intended for medical or healthcare professionals only:

Instructions for use and handling

The powder is reconstituted with the solvent prior to dispensing as follows:

1. Remove the caps from the powder bottle and the solution bottle; retain the cap of the powder bottle.
2. Pour the contents of the solution bottle into the powder bottle and recap the latter.
3. Immediately, shake well for one minute. Remove and retain cap.
4. Open the plastic holder containing the applicator assembly and use the holder to position the applicator assembly over the neck of the bottle and to push the applicator assembly firmly into the neck of the bottle.
5. Remove the plastic holder and ensure that the applicator fits firmly into the neck of the bottle. Discard the plastic holder.
6. Replace the cap on the now constituted application.
7. Add the expiry date to the bottle label; this date is 5 weeks from the date of preparation.
8. Ensure that the patient information leaflet is given to the patient.

After reconstitution, a clear colourless liquid is formed.