

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zineryt 40 mg/ml + 12 mg/ml powder and solvent for cutaneous solution

(erythromycin + zinc acetate dihydrate)

Read all of this leaflet carefully before you start using this medicine.

- 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 adverse reactions
5. How to store Zineryt
6. Further information

1. WHAT ZINERYT IS AND WHAT IT IS USED FOR

Zineryt contains the antibiotic erythromycin + zinc. Erythromycin may suppress the growth of bacteria which provoke the occurrence of pimples. Zinc reinforces the effect of erythromycin in the treatment of acne.

Zineryt may be used for treatment of moderate to severe forms of acne (pimples) for which topical treatment without antibiotics does not lead or leads to insignificant results or is not tolerated.

2. BEFORE YOU USE ZINERYT

Do not use Zineryt:

If you are allergic (hypersensitive) to erythromycin or antibiotics of the same group, zinc or any of Zineryt excipients.

You should warn your doctor if you are hypersensitive to any of these ingredients.

Take special care with the use of Zineryt

Zineryt must not get into contact with eyes, nose and mouth mucosa because it will provoke burning sensation and irritation. If this happens, you should immediately

rinse out with cold water and warn your doctor. If vial's content is split, it may blot textile and other similar materials.

Use of other drugs

Interactions have not been known up to now. The combination of different drugs may provoke adverse reactions, Please, make sure your doctor is well informed about all the other drugs you take.

Pregnancy and Lactation

Zineryt may cause foetus malformations. Do not use Zineryt if you are pregnant or try to get pregnant. Before the use of any drug, consult your doctor or pharmacist.

Effects on ability to drive and use machines

Zineryt is not expected to have influence on the ability to drive and use machines.

Important information regarding some Zineryt ingredients

Not available.

3. HOW TO TAKE ZINERYT

You should apply a layer of Zineryt with the help of the applicator on the affected by pimples skin twice daily. Preferably to apply in the morning (before making up) and in the evening (after the removal of the make up) after washing the skin. After drying, the already applied layer becomes invisible. In most cases Zineryt leads to an improvement after 10-12 weeks. In case you notice worsening, you should contact your doctor.

If you have missed to apply Zineryt

Once you have forgotten to apply Zineryt, continue using it as usual. No need to apply an extra quantity.

4. POSSIBLE ADVERSE REACTIONS

Like all medicines Zineryt may cause adverse reactions. During Zineryt application the following adverse reactions may occur:

Skin and subcutaneous tissue disorders are uncommon (they occur in more than 1 in 1,000, but less than 1 in 100 patients)

- itching, dry skin and scaling
- skin redness, burning or irritation sensation on skin. This is not common and disappears by itself.

Immune system disorders are very rare (they occur in less than 1 in 10 000 patients)
- hypersensitivity

If any of the adverse drug reactions gets serious, or if you notice any other adverse reactions, not listed in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ZINERYT

Zineryt should not be used after the expiry date, mentioned on the package.

Store Zineryt below 25°C in the package, supplied by the pharmacist. The ready for use solution may be stored during 8 weeks.

If it is necessary to continue treatment with Zineryt, your doctor will prescribe you a new package.

Keep out of the reach and sight of children.

Drugs should not be thrown in wastewater or in household waste container. Ask your pharmacist how to destroy the drugs you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

What does Zineryt contain

Zineryt contains as active substances 40 mg/ml *erythromycin* and 12 mg/ml *zinc acetate dihydrate*.

The other ingredients are: diisopropyl sebacate and alcohol.

The obtained complex of erythromycin and zinc acetate dihydrate is dissolved in alcohol to which the substance diisopropyl sebacate (softening the skin) is added.

How does Zineryt look like and what does the package contain

Zineryt is clear, colorless liquid with alcohol odor. It is in a vial with applicator with the help of which it is applied on the skin. The applicator is protected with protective screw cap. The vial is in a with yellow/grey/white carton box with printed name Zineryt.

Usually Zineryt is offered in a ready for use form – prepared by the pharmacist.

Marketing Authorization Holder:

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

Manufacturer:

Astellas Pharma Europe B.V.
Sylviusweg 62
2333 BE Leiden
The Netherlands

Instructions for preparation of the ready for use solution Zineryt by the pharmacist

1. The yellow/grey/white box contains two vials and a stopper with an applicator. Remove the caps of both vials by keeping the cap of the vial with the powder.
2. Infuse the liquid from the one vial in the vial with the powder. The empty vial may be thrown out.
3. Screw the cap of the vial in which the powder and the solvent are .
4. Shake immediately for one minute.
5. Remove the cap of the full vial and screw the stopper with the applicator.
6. Press the cap with the applicator on the full vial and tighten it.
7. Now you can remove the stopper and check if the applicator is well attached to the vial.
Press firmly on it if necessary.
8. The solution can be stored 8 weeks after preparation.
Write the expiry date on the vial.

Date of the last revision of the text.

07/2016