

Package leaflet: Information for the user

Zineryt®
(erythromycin / zinc acetate)

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
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 use Zineryt after the "Use before" date which has been put on the label by your pharmacist.
- Do not store above 25°C.
- Store in the original package.
- If the solution becomes discoloured or shows any signs of deterioration, you should seek the advice of your pharmacist who will advise you what to do.
- 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

- Each ml of solution contains 40 mg erythromycin and 12 mg zinc acetate (as the complex) on constitution.
- The other ingredients are di-isopropyl sebacate and ethanol anhydrous.

What Zineryt looks like and contents of the pack

Zineryt is made available as a solution for use on the skin (cutaneous use).

Each pack of Zineryt contains a bottle of white powder, a bottle of clear solvent, and an applicator with a blue pad 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 will contain 30 ml of the solution on constitution.

Manufacturer:

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

or

LEO Pharma A/S

Industriparken 55, DK-2750 Ballerup, Denmark

Procured from within the EU.

Product Licence Holder:

Ecosse Pharmaceuticals Limited, 3 Young Place,
East Kilbride, G75 0TD.

Repackaged by:

Munro Wholesale Medical Supplies Ltd., 3 Young Place,
East Kilbride, G75 0TD.

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If you are blind or partially sighted and require this leaflet in a different format, call 01355 574450 and ask for the Regulatory Department.

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Package leaflet: Information for the user

Erythromycin and Zinc Acetate

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- 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 Erythromycin and Zinc Acetate is and what it is used for
2. What you need to know before you use Erythromycin and Zinc Acetate
3. How to use Erythromycin and Zinc Acetate
4. Possible side effects
5. How to store Erythromycin and Zinc Acetate
6. Contents of the pack and other information

1. What Erythromycin and Zinc Acetate is and what it is used for

The active substance of Erythromycin and Zinc Acetate 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 Erythromycin and Zinc Acetate

Do not use Erythromycin and Zinc Acetate

- 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 Erythromycin and Zinc Acetate.

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 Erythromycin and Zinc Acetate

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 Erythromycin and Zinc Acetate if you are pregnant. You may breast-feed during treatment with Erythromycin and Zinc Acetate but do not use this medicine on the area of your chest.

Driving and using machines

It is not likely that Erythromycin and Zinc Acetate affects your ability to drive or use machines.

3. How to use Erythromycin and Zinc Acetate

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 Erythromycin and Zinc Acetate.

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

Erythromycin and Zinc Acetate 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 Erythromycin and Zinc Acetate 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 Erythromycin and Zinc Acetate).

Frequency of administration

Usually, Erythromycin and Zinc Acetate 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 Erythromycin and Zinc Acetate than you should

If you have applied too much Erythromycin and Zinc Acetate, blot it off with some tissue. Swallowing the entire contents of a single pack of Erythromycin and Zinc Acetate 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 Erythromycin and Zinc Acetate

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

If you stop using Erythromycin and Zinc Acetate

If you stop using Erythromycin and Zinc Acetate, the original symptoms may come back. Always contact your doctor if you want to stop using Erythromycin and Zinc Acetate.

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).

Erythromycin and Zinc Acetate 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.

Erythromycin and Zinc Acetate may cause the following rare side effects (may affect up to 1 in 1,000 people):

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5. How to store Erythromycin and Zinc Acetate

- Keep out of the sight and reach of children.
- Do not use Erythromycin and Zinc Acetate after the "Use before" date which has been put on the label by your pharmacist.

- Do not store above 25°C.
- Store in the original package.
- If the solution becomes discoloured or shows any signs of deterioration, you should seek the advice of your pharmacist who will advise you what to do.
- 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 Erythromycin and Zinc Acetate contains

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What Erythromycin and Zinc Acetate looks like and contents of the pack

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Erythromycin and Zinc Acetate is available in packs which will contain 30 ml of the solution on constitution.

Manufacturer:

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

LEO Pharma A/S
Industriparken 55, DK-2750 Ballerup, Denmark
Procured from within the EU.

Product Licence Holder:

Ecosse Pharmaceuticals Limited, 3 Young Place,
East Kilbride, G75 0TD.

Repackaged by:

Munro Wholesale Medical Supplies Ltd., 3 Young Place,
East Kilbride, G75 0TD.

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