

### **Package leaflet: Information for the user**

#### **Erythromycin/Zinc acetate 40 mg/12 mg 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, 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.
- In this leaflet Erythromycin/Zinc acetate 40 mg/12 mg powder and solvent for cutaneous solution will be called Erythromycin/Zinc acetate.

#### **What is in this leaflet**

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

#### **1. What Erythromycin/Zinc acetate is and what it is used for**

The active substance of Erythromycin/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/Zinc acetate**

##### **Do not use Erythromycin/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/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/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/Zinc acetate if you are pregnant. You may breast-feed during treatment with Erythromycin/Zinc acetate but do not use this medicine on the area of your chest.

**Driving and using machines**

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

**3. How to use Erythromycin/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/Zinc acetate.

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

Erythromycin/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/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/Zinc acetate).

**Frequency of administration**

Usually, Erythromycin/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/Zinc acetate than you should**

If you have applied too much Erythromycin/Zinc acetate, blot it off with some tissue.

Swallowing the entire contents of a single pack of Erythromycin/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/Zinc acetate**

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

**If you stop using Erythromycin/Zinc acetate**

If you stop using Erythromycin/Zinc acetate, the original symptoms may come back. Always contact your doctor if you want to stop using Erythromycin/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/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/Zinc acetate 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 Erythromycin/Zinc acetate 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](http://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 Erythromycin/Zinc acetate**

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

Do not use Erythromycin/Zinc acetate 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 Erythromycin/Zinc acetate 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 Erythromycin/Zinc acetate looks like and contents of the pack**

Erythromycin/Zinc acetate 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.

Erythromycin/Zinc acetate 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:**

Neon Healthcare Ltd.  
8 The Chase, John Tate Road,  
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#### **Manufacturer:**

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