

PACKAGE LEAFLET: Information for the user

INDERM 4%

Gel – 40 mg / 1g

(Erythromycin)

Read 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

In this leaflet:

1. What Inderm 4% is and what it is used for
2. Before you use Inderm 4%
3. How to use Inderm 4%
4. Possible side effects
5. How to store Inderm 4%
6. Other information

1. WHAT INDERM 4% IS AND WHAT IT IS USED FOR

Inderm 4% contains the active substance erythromycin. It is a medicine for the external treatment of acne.

Inderm 4% is used in all forms of acne, mild to moderate in severity, especially in inflammatory forms, such as papulopustular acne (nodules and pustules formation).

It is used in combination therapy with other acne preparations.

2. BEFORE YOU USE Inderm 4%

Do not use Inderm 4% if you are hypersensitive (allergic) to erythromycin, to ethanol or to any of the excipients listed under section 6.

Take special care with Inderm 4%

Ask your doctor or pharmacist before you use Inderm 4%.

Using Inderm 4% with other medicines

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

Simultaneous use of peeling agents may lead to increased incidence of skin irritation.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, if you think you might be pregnant or intend to become pregnant, ask your pharmacist or doctor for advice before using this medicine.

Because of lack of sufficient experience, Inderm 4% should not be used during pregnancy and breastfeeding.

Driving and using machines

There is no experience regarding the impairment of driving performance or the ability to operate machinery.

Important information about some of the excipients of Inderm 4%

Butylhydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. HOW TO USE Inderm 4%

Always use Inderm 4% exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, the usual dose is:

Inderm 4% gel is applied in the morning and in the evening as a thin layer in facial acne areas, after the latter is completely washed and dried.

Method of administration

Inderm 4% is for external use only and should not come into contact with the eyes, nose, mouth and other mucous membranes.

Duration of administration

After 4 weeks of using Inderm 4%, mostly in mild acne forms, therapy should be continued with erythromycin gel 2%. In total, the treatment can last up to 3 months.

Talk to your doctor or pharmacist if you have the impression that the effect of Inderm 4% is too strong or too weak.

If you use more Inderm 4% than you should

You may continue treatment with the recommended doses. No side effects are expected from a short-term overdose.

If you forget to use Inderm 4%

Do not use a double dose to make up a forgotten dose.

If you stop using Inderm 4%

You may risk the success of the treatment. Please talk to your doctor or pharmacist before interrupting treatment with Inderm 4%.

If you have further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Inderm 4% can cause side effects, although not everybody gets them.

For the evaluation of side effects, the following frequencies are used:

Very common	More than 1 user out of 10 may be affected.
Common	Up to 1 out of 10 users may be affected
Uncommon	Up to 1 out of 100 users may be affected
Rare	Up to 1 out of 1.000 users may be affected
Very rare	Up to 1 out of 10.000 users may be affected
Not known	Frequency cannot be estimated from the available data.

Inflammatory redness, dandruff, pain, drying of the skin, itching or excessive regreasing may occur occasionally due to the alcohol content of the gel. In such case, Inderm should be used less frequently.

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).

If any of the side effects appears or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE INDERM 4%

Keep out of the sight and reach of children!

Do not store above 25°C!

Do not use Inderm 4% after the expiry date which is stated on the package and on the tube.

6. OTHER INFORMATION

What Inderm 4% contains

The active substance is erythromycin.

1 g gel contains 40 mg erythromycin.

The excipients are: butylhydroxytoluene, hydroxypropylcellulose and ethanol.

Content of the pack

Box with a 30 g tube.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in November 2023.