

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

Adaferin Cream

Composition:

Active ingredient:

Adapalene 0.1% w/w

Each 1 gram contains 1 mg Adapalene

For the list of the additional ingredients, see section 6.

See also 'Important information about some of the medicine's ingredients' in section 2.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.

1. What is the medicine intended for?

The medicine is intended for treatment of acne. The preparation works only on inflamed areas where lumps are apparent on the skin as a result of the development of the Acne Vulgaris bacteria.

Therapeutic Group

Derivative of Vitamin A (Retinoid) for external use.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of the additional ingredients, see section 6).
- Do not use on infants and children under the age of 12 years old.
- You are pregnant.
- You are planning a pregnancy.

Special warnings regarding the use of this medicine:

- This medicine may cause extra sensitivity upon exposure to sun or UV light. Therefore, avoid exposure to the sun (or artificial UV light) and make sure to use appropriate precautions (long clothing, hats, sunscreens, etc.).
- If you suffer from sunburns due to exposure to the sun, avoid using the medicine until full recovery.
- Do not apply the preparation on open wounds, cuts, burns, grazed skin and inflamed skin (including eczema).
- Do not use the preparation in severe cases of acne.

- Avoid contact with the eyes, mucous membranes (such as the mouth, nostrils) and avoid contact with other highly sensitive areas of your body. In the event of accidental contact of the preparation with the tissues indicated, rinse immediately with warm water.
- Discontinue the use and inform your doctor if you suffer from sensitivity or local irritation while applying the cream. In this case, the doctor may recommend that you apply it less frequently or will tell you to discontinue its use until the effects disappear.
- If you are sensitive to any type of food or medicine, inform your doctor before using this medicine.

Tests and follow up: after you have been using the medicine for three months, it is important to refer to your doctor, in order to evaluate the improvement of the acne.

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Retinoid medicines: Do not use simultaneously during treatment with this medicine.
- Benzoyl peroxide, Erythromycin and Clindamycin: you may use them concurrently but apply them in the morning and apply Adapalene in the evening before you go to bed.
- Cosmetics: can be used if they do not cause the appearance of blackheads and do not dry the skin.
- Astringent products to shrink the skin pores.
- Peeling preparations like sulfur, resorcin, salicylic acid (for removal of the outer layer of skin): their use may cause irritation.

Pregnancy and breastfeeding:

- Do not use the medicine if you are pregnant or are planning a pregnancy. If you become pregnant during treatment with the medicine, discontinue its use.
- You can use the medicine when breastfeeding. However, do not apply the medicine on the chest during breastfeeding.

Use in Children:

Do not use on infants and children under the age of 12 years old.

Important information about some of the medicine's ingredients:

The cream contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, that may cause allergic reactions (that may possibly appear at a later stage).

3. How to use this medicine?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure about the dosage and the treatment regimen with the medicine.

The dosage and the treatment regimen will be determined by the doctor only.

This medicine is intended for adults and adolescents over the age of 12.

This medicine is intended for external use only.

Apply in the evening before going to bed unless otherwise instructed by your doctor.

The standard dosage is usually:

- Prior to the treatment, clean the skin with warm water and a mild soap. Apply a thin layer of the preparation once a day at bedtime.
- Wash your hands after the treatment.

Do not exceed the recommended dose.

- Excessive use of this medicine will not yield better or quicker results, and on the other hand, red marks, irritation, peeling and discomfort may occur.
- Do not use the medicine for more than six consecutive months.
- Do not swallow! This medicine is intended for external use only.
- It is recommended to avoid simultaneous use with preparations for local skin treatment, such as: soaps and cosmetics with a strong drying effect or preparations for local use containing a high alcohol concentration.
- Avoid contact with the eyes, mucous membranes (such as the mouth, inside the nose). In the event of accidental contact of the preparation with any mucous membrane, wash the area with warm water immediately.

If you have taken an overdose or if a child has accidentally swallowed the medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

If you forgot to use this medicine at the designated time, do not apply a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor or your pharmacist.

Do not use or take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, use of Adaferin may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Discontinue the use and contact your doctor immediately if the following side effects appear, you may require urgent medical treatment:

Swelling of the face, lips and throat that may cause difficulties in swallowing or breathing, rash, itchiness, urticaria and dizziness.

These symptoms can appear as a result of edema or a severe allergic reaction.

Hypersensitivity, irritation, rash (rare).

Additional side effects:

Common side effects (appear in 1-10 users out of 100):

- Skin reactions, such as: dryness, irritation, burning sensation, redness.

These effects usually pass or become milder after approximately one month from the start of the treatment. If these effects continue and/or worsen, refer to the doctor.

Uncommon side effects (appear in 1-10 users out of 1000):

Local skin reaction due to contact (contact dermatitis), skin discomfort, sunburns, itching, peeling of the skin, dandruff, flare of acne.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Allergic reaction
- Pain or swelling in the skin.
- Irritation, redness, itchiness or swelling of the eyelids.
- Change of skin color
- Local burns

If a side effect appears, if any of the side effects worsens, or when you suffer from a side effect not mentioned in the leaflet, or signs of an allergic reaction appear during taking of the medicine, or if you are concerned by the appearance of any side effect indicated above, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
Adaferin Cream: After the first opening, it may be used within 4 months, but no later than the expiry date marked on the package.
- Store in the original package.

6. Additional information

In addition to the active ingredient this medicine also contains the following inactive ingredients:

Adaferin Cream

Cyclomethicone, squalane natural, methyl glucose sesquistearate, PEG-20 methyl glucose sesquistearate, glycerol, phenoxyethanol, carbomer 934P, methyl parahydroxybenzoate, propyl parahydroxybenzoate, disodium edetate, sodium hydroxide, purified water.

What does the medicine look like and what does the package contain?

Adaferin Cream: white, shiny cream. The cream is packed in an aluminum tube with a screw cap. Each package contains 30 grams.

The Manufacturer

Laboratories Galderma, France.

Registration holder: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health:

Adaferin Cream 136-13-30260

Updated in August 2020.