

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS**  
**(MEDICINAL PRODUCTS) – 1986**

The medicine is dispensed with a doctor's prescription only

## **Adaferin Cream**

**Cream**

**0.1% w/w**

### **The active ingredient:**

Each 1 gram of cream contains 1 mg adapalene

For a list of inactive ingredients and allergens in the medicinal product – see section 6 “Additional information”.

See also section 2 “Important information about some of the ingredients of the medicine”.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

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

### **1. What is the medicine intended for?**

The medicine is intended for treatment of acne vulgaris, where comedones, papules and pustules predominate. Acne of the face, chest or back is appropriate for treatment. The treatment is limited to 6 months in adolescents over 12 years.

#### **Therapeutic class**

A vitamin A derivative (retinoid) for external use.

### **2. Before using the medicine**

#### **Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of additional ingredients – see section 6).
- Do not use in infants and children below 12 years of age.
- You are pregnant.
- You are planning to become pregnant.

#### **Special warnings regarding the use of the medicine:**

- Adaferin Cream may cause a special sensitivity upon exposure to the sun or to UV light. Therefore, avoid exposure to the sun (or to artificial UV light) and ensure appropriate protection (long clothes, hat, sunscreens, etc.).
- If you suffer from sunburns, you should avoid using Adaferin Cream until complete recovery.
- Do not apply Adaferin Cream on open wounds, cuts, burns, abraded skin and inflamed skin (including eczema conditions).
- Do not use Adaferin Cream in severe cases of acne, or in acne that involves extensive areas of the body.

- Avoid contact with the eyes, mucous membranes (e.g. the mouth, nostrils) and avoid contact with other highly sensitive areas of your body. If Adaferin Cream accidentally comes in contact with the listed tissues, immediately wash the area with warm water.
- Stop using the medicine and inform the doctor if you suffer from sensitivity or irritation when applying Adaferin Cream. In this case, the doctor may advise you to apply Adaferin Cream less frequently or will tell you to stop using it until the effects disappear.
- If you are sensitive to any food or medicine, inform the doctor before using Adaferin Cream.

### **Tests and follow-up:**

After using Adaferin Cream for three months, it is important to refer to the doctor, to evaluate the improvement in acne.

### **Drug interactions:**

**If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.** In particular, you should inform the doctor or pharmacist if you are taking the following medicines (note that the following list mentions the active ingredients in the medicines. If you are not sure whether you are using any of these medicines, consult the doctor or pharmacist):

- Retinoids or medicines with a similar mechanism of action: do not use concomitantly with the treatment with Adaferin Cream.
- Other medicinal products for treatment of acne (that contain benzoyl peroxide, erythromycin or clindamycin): may be used concomitantly with Adaferin, but it is necessary to apply them in the morning and apply Adaferin Cream in the evening before bedtime.
- Cosmetics: may be used if they do not cause blackheads or dry the skin.
- Constricting products for shrinking skin pores.
- Peeling products such as sulfur, resorcin, salicylic acid (to remove the outer layer of the skin): the use may cause irritation.

### **Pregnancy and breastfeeding:**

- Do not use Adaferin Cream during pregnancy or if you are planning to become pregnant. If you become pregnant during treatment with Adaferin Cream, you should discontinue use and inform the doctor as soon as possible.
- Adaferin Cream may be used during breastfeeding. However, avoid applying the medicine to the chest during the breastfeeding period, to avoid contact of Adaferin Cream with the baby.

### **Use in children:**

Do not use in infants and children below 12 years of age.

### **Driving and operating machinery:**

Adaferin Cream has no effect on the ability to drive and operate machinery.

### **Important information about some of the ingredients of the medicine:**

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

### **3. How should you use the medicine?**

Always use the medicinal product according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicinal product.

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

Adaferin Cream is intended for adults and adolescents over the age of 12 years.

Adaferin Cream is intended for external use only.

Apply in the evening before bedtime unless the doctor has told you otherwise.

#### **The generally accepted dosage is:**

- Before treatment, clean the skin with warm water and gentle soap. Apply a thin layer of Adaferin Cream once a day, in the evening before bedtime.
- Wash your hands after the treatment.

#### **Do not exceed the recommended dose.**

- Overuse of Adaferin Cream will not produce better or faster results, while it may cause red marks, irritation, peeling and discomfort.
- Do not use Adaferin Cream for more than six consecutive months.
- Do not swallow! Adaferin Cream is intended for external use only.
- It is advisable to avoid concomitant use with products for topical skin treatment such as: soaps and cosmetic products with a strong drying effect or topical products that contain a high concentration of alcohol.
- Avoid contact with the eyes, mucous membranes (e.g. the mouth, nostrils). If Adaferin Cream accidentally comes in contact with any mucous membrane, wash the area immediately with warm water.

**If you have used an overdose, or if an adult or a child has accidentally swallowed this medicine,** refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

**If you have forgotten to use this medicine at the required time,** do not use a double dose. Apply the next dose at the usual time and consult a doctor.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

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

**If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.**

### **4. Side effects**

As with any medicine, using Adaferin Cream may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not suffer from any of them.

**Discontinue use and refer to a doctor immediately if the following side effects occur, urgent medical treatment may be required:**

- **Hypersensitivity, irritation, rash (rare).**

- **Swelling of the face, lips or throat causing difficulty swallowing or breathing, rash, itching, hives, and dizziness. These symptoms can occur as a result of angioedema or a severe allergic reaction (unknown frequency, which cannot be estimated from the available data).**

Additional side effects:

*Common side effects, effects that occur in 1-10 users out of 100:*

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

These effects usually go away or become milder after about a month from the beginning of treatment. In case the effects persist and/or worsen, refer to the doctor.

*Uncommon side effects, effects that occur in 1-10 users out of 1,000:*

Contact dermatitis, skin discomfort, sunburns, itching of the skin, peeling of the skin, flaking, flare-up of acne.

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

- Allergic contact reaction
- Pain or swelling of the skin
- Irritation, redness, itching or swelling of the eyelids
- Skin discoloration (darkening of fair skin, lightening of dark skin)
- Application site burns (mostly superficial burns, but also second-degree or severe burns)

**If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, or signs of an allergic reaction appear while taking the medicine, or if any of the side effects mentioned above worry you, consult with the doctor.**

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (<http://www.health.gov.il>), which will direct you to the online form for reporting side effects, or via the following link: <https://sideeffects.health.gov.il/>

## **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- After first opening, the cream may be used for 4 months, but no later than the expiry date imprinted on the package.
- Store in the original package.
- Do not discard unused Adaferin Cream in wastewater or domestic trash. Ask the pharmacist how to dispose of unused medicines. These measures will help protect the environment.

## **6. Additional information**

### **In addition to the active ingredient, the medicine also contains:**

Cyclomethicone, squalene 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 are the contents of the package?**

Shiny white cream. The cream is packed in an aluminum tube with a screw-on cap. Each pack contains 30 grams.

**Manufacturer:** Laboratories Galderma, Z.I Montdesir 74540, Alby sur Cheran, France.

**Marketing authorization holder:** A.M.I. Medical Technologies Limited., Hanagar 22, Hod Hasharon, 4501317, Israel.

**Registration number of the medicine in the national drug registry of the Ministry of Health:** 136-13-30260-00

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