Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Adatar
Gel

Active ingredients:
Each 1 gram of gel contains:
adapalene 1 mg (0.1%)
benzoyl peroxide 25 mg (2.5%)

For a list of inactive ingredients see section 6 and 'Important information about some of this medicine's ingredients' in section 2.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or 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 to yours.

1. What is this medicine intended for?
This medicine is intended for treating acne (pimples).

Therapeutic group:
Topical anti-acne agent: adapalene - retinoid (vitamin A derivative). benzoyl peroxide - peroxides.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (for a list of inactive ingredients, see section 6).
- You are pregnant or planning a pregnancy.

Special warnings about using this medicine:

- Do not use the gel on areas of injured skin (such as scrapes, cuts) or on areas with sunburn or if you have skin eczema.
- Avoid contact of the gel with the eyes, mouth, nostrils and other sensitive areas. If the gel accidentally gets into these areas, wash the place immediately with plenty of warm water.
- Avoid excessive exposure to the sun or UV radiation and make sure you have suitable protection if you must be exposed to the sun (long clothing, hat, sunscreen, etc.).
- Avoid getting the gel on your hair or on colored fabrics as it may discolor them (e.g. it can fade or turn white).
- Wash your hands thoroughly after use.

Other medicines and Adatar:
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- other acne medicines that contain retinoids and/or benzoyl peroxide; do not use while you are taking Adatar
- cosmetic products that may irritate, dry or exfoliate the skin; avoid using them while you are taking Adatar

Children and adolescents:
The gel is intended for use in children aged 9 years and over, adolescents, and adults.

Pregnancy and breastfeeding:
- Do not use the gel during pregnancy or when you are planning a pregnancy. If you become pregnant while taking Adatar, stop using it and contact your doctor for advice and further follow-up.
- The gel can be used during breastfeeding. To avoid exposing your baby to the medicine, avoid application of the gel to the chest area.

If you are pregnant or breastfeeding, consult your doctor or pharmacist before taking any medicines.

Important information about some of this medicine's ingredients:
The gel contains propylene glycol which may cause skin irritation.

3. How to use this medicine?

Always use the gel as directed by your doctor.
Check with your doctor or pharmacist if you are not sure about your dose or about how to use the gel.
Only your doctor will determine your dose, duration of treatment, and how you should use the gel.

The usually recommended dose and application method are:
- Apply a **thin layer** of gel evenly over acne (pimples) affected areas, once a day, at bedtime.
- Avoid contact with the eyes, lips and nostrils. See also under 'Special warnings about using this medicine'.
- Make sure your skin is clean and dry before applying the gel.
- Wash your hands thoroughly after you have used the gel.
- Your doctor will tell you how long you will need to use the gel.

Do not exceed the recommended dose.

This medicine is for external use only.

If you feel that the effect of the gel is too strong or too weak, talk to your doctor or pharmacist.
If you experience persistent irritation when applying the medicine, consult your doctor. You may be asked to apply a moisturizer, use the gel less often, stop for a short time, or stop using the gel altogether.

If you have used an overdose, or if a child or anyone else has accidentally used or swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you**.**
If you use more gel than you should, you will not get better or faster results, but your skin may become irritated and red.

If you forget to use this medicine at the required time, do not use a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

Do not use or take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Adatar may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop the treatment and immediately contact your doctor or go to a hospital emergency room if you experience the following side effects:
serious allergic reaction (including anaphylactic shock) or any signs of sensitivity which may include: tightening of the throat; swelling of the eyes, face, lips or tongue; fainting (including feeling faint); difficulty breathing. Stop the treatment if you develop effects like urticaria (a type of rash) or itching of the face or body.

If you experience persistent irritation while you are using the gel, **contact your doctor**.

Additional side effects:
Common side effects (affect 1-10 in 100 users):
skin effects such as dryness, local skin rash resulting from irritative contact dermatitis, burning sensation, redness, peeling/scaling.

Uncommon side effects (affect 1-10 in 1,000 users):
itching, sunburn.

Side effects of unknown frequency (the frequency of these effects has not been established yet):
swelling (edema) of face and eyelids, tightness in the throat, pain in skin (stinging), blisters, allergic contact reactions such as allergic contact dermatitis; difficulty breathing, urticaria, change in skin color, application site burn (these burns are mostly superficial but more severe cases involving blistering have been reported).

If you experience any side effects on your skin after applying the gel, they are generally mild to moderate with local signs of redness, dryness, scaling, stinging sensation, burning or pain. These side effects peak during the first week of use and later resolve without additional treatment.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (<u>www.health.gov.il</u>) which links to an online form for reporting side effects, or you can use this link:
https://sideeffects.health.gov.il/

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- After first opening, can be used for 12 months, at room temperature, but no later than the expiry date imprinted on the package.

6. Additional information

In addition to the active ingredients, this medicine also contains the following inactive ingredients:
propylene glycol, glycerin, polyacrylamide, C13-14 isoparaffin, laureth 7, poloxamer 124, edetate disodium, docusate sodium, purified water.

What the medicine looks like and contents of the pack?

Gel in a plastic tube: 30 or 60 grams.
Gel in pump: 30, 45 or 70 grams.
Not all pack sizes may be marketed.

Registration holder: Taro International Ltd., 14 Hakitor street, Haifa Bay, 2624761

Manufacturer: Taro Pharmaceuticals Inc., Ontario, Canada

Revised in April 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 163-95-35656-00