

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS

(PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Ret-Avit Cream 0.05%, 0.025%

Ret-Avit Gel 0.05%, 0.025%

Ret-Avit Cream contains:

Tretinoin 0.05%, 0.025%

Ret-Avit Gel contains:

Tretinoin 0.05%, 0.025%

For a list of inactive ingredients and allergens in the preparation, please see section 6 – “Additional information” and the section “Important information about some 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 (acne vulgaris).

Therapeutic class: belongs to the class of topical retinoids for treatment of acne (a vitamin A derivative).

2. Before using the medicine

❗ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains. If you experience an allergic reaction following the first use of **Ret-Avit**, do not use it again.
- You or one of your family members have had skin cancer.
- You have eczema – inflamed, red, dry, itchy and peeling skin. If you have any of these symptoms, speak with your doctor or pharmacist.
- You have acne rosacea, which may cause redness in the forehead, cheeks, nose and chin.
- You have perioral dermatitis – an irritation of the skin around the mouth.
- You are pregnant or planning to become pregnant.

- You have sunburns or red, itchy and peeling skin – do not use **Ret-Avit** on these areas until they completely heal.
- You are using a skin-peeling agent, which removes the top layers of the skin. Your skin will need time to recover before you start using the medicine.
- The medicine is not intended for children under the age of 10.

❗ Special warnings regarding the use of the medicine

- The medicine should not be used without consulting a doctor before the beginning of treatment.
- **Before treatment with Ret-Avit, inform the doctor if:**
 - You are breastfeeding. Consult with your doctor (see the section “Pregnancy, breastfeeding and fertility”).
- Avoid heavy exposure to the sun and to ultraviolet light while using **Ret-Avit**, such as: tanning beds or ultraviolet tanning lamps. If you cannot avoid exposure to sunlight (e.g., due to working outdoors), you should protect the skin treated with **Ret-Avit**:
 - Use a sunscreen with SPF of at least 15.
 - Wear a wide-brimmed hat.
 - Wear long-sleeve clothes that will cover the skin treated with **Ret-Avit** and protect it from the sun.
- Cold weather and wind may cause an irritation in skin treated with **Ret-Avit**.
- You may use a moisturizer during the day, since **Ret-Avit** may cause the skin to become a bit dry.
- You may continue using other skin products during the day, such as cosmetic products, but be sure to clean your skin thoroughly before using **Ret-Avit**.
- Due to the high concentration of alcohol in **Ret-Avit** gel, the preparation is flammable. Do not light a cigarette or expose yourself to fire before the gel has completely dried.

❗ Children and adolescents

The medicine is not intended for children under the age of 10.

No information is available regarding safety and efficacy of using this preparation in children and adolescents.

❗ Drug-drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell the doctor or the pharmacist.

- Do not use harsh or rough cosmetic products while using **Ret-Avit**, such as: skin-peeling products, other products with a strong skin-drying effect (e.g., preparations containing a high concentration of alcohol).
- If you have been using other skin products for treatment of acne (including over-the-counter products), or if you have been using skin-peeling products, you should wait for their effect to wear off before using **Ret-Avit**.

Consult your doctor before applying additional medicines to the skin while using **Ret-Avit**.

❗ Pregnancy, breastfeeding and fertility:

Ret-Avit must not be used if you are pregnant, might be pregnant or are planning to become pregnant. For more information, consult your doctor.

If you are breastfeeding, inform your doctor before starting treatment with **Ret-Avit**. You may be able to use the medicine if your doctor deems it necessary.

❗ Important information about some ingredients of the medicine

Ret-Avit Cream and **Ret-Avit** Gel contain Butylated hydroxytoluene (E321), which may cause local skin reactions (e.g., contact dermatitis) or irritation in the eyes or mucous membranes.

Ret-Avit Cream contains lanolin anhydrous, sorbic acid (E200) and cetostearyl alcohol, which may cause local skin reactions (e.g., contact dermatitis).

Ret-Avit Gel contains sodium propyl hydroxybenzoate and methyl hydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).

3. How should you use the medicine?

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

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

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

The generally accepted dosage is: lightly apply to the entire affected area once a day in the evening before bedtime. For people with light or sensitive skin, it is recommended to apply the preparation once a day or every other day, depending on how the skin reacts.

Do not exceed the recommended dose

Do not swallow. For external use only.

Before treatment, you should clean the skin with lukewarm water and/or gentle soap, dry the skin gently without rubbing it and wait for 20-30 minutes before applying the medicine. Do not wash the

treated area more than twice per day. Wash your hands after the treatment.

Apply a small amount of **Ret-Avit** and cover only the affected areas. You can use cotton wool or clean cotton swabs. Avoid accumulation of too much **Ret-Avit** in skin folds, such as the area where the nose meets the face. Do not apply to a cracked or eczematous area, to the eyes, eyelids, nostrils or mouth. If **Ret-Avit** comes into contact with these areas, wash them thoroughly with water.

Duration of treatment – the results of the treatment are visible after two to three weeks, but it may take six to eight weeks to achieve maximum results. The minimal duration of treatment is three months.

After applying of **Ret-Avit**, the skin may feel warm or sting slightly for a while. If these sensations continue or become worse, consult your doctor.

If you have accidentally applied a higher dosage of Ret-Avit: it is unlikely that a higher dosage will harm you. However, always try to exactly follow the instructions for use.

If you applied an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you have forgotten to use Ret-Avit on time: do not apply a double dose. Use **Ret-Avit** at the usual time.

Follow the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, use of **Ret-Avit** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and contact a doctor immediately if the following side effects occur:

- Severe symptoms.
 - Blisters or crusts on the skin.
 - Swelling or a burning sensation on the skin.
- Additional side effects**
Common side effects - side effects that occur in 1-10 out of 100 users:
- Redness, peeling, scaly skin and possibly swelling of the skin.
 - Dry, itchy skin.
 - Sensation of warmth or burning on the skin.

- Rashes.
- Pain or tingling sensation.
- Temporary changes (increase or decrease) in skin pigmentation.

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

- Eye irritation and swelling.
- Blisters and crusts on the skin.

Very rare side effects - side effects that occur in less than one out of 10,000 users:

- Allergy to contact with medicines containing tretinoin has been reported.

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, 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 (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on 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) appearing on the package. The expiry date refers to the last day of that month.

Store at a temperature lower than 25°C.

Can be used for up to two months from opening.

6. Additional information

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

Ret-Avit Cream:

Oleic acid decylester, Cetostearyl alcohol, Glycerol monostearate SE, Sorbitol solution 70%, Cetomacrogol 1000, Lanolin anhydrous, Dimethicone 350, Sorbic acid, Butylated hydroxytoluene (BHT), Potassium sorbate, Purified water.

Ret-Avit Gel:

Purified water, Cremophor RH 40, Isopropyl alcohol, Softigen 767, Carbomer 980, Butylated hydroxytoluene, Methyl hydroxybenzoate, Sodium propyl hydroxybenzoate, Hydrochloric acid, Sodium hydroxide.

What does the medicine look like and what are the contents of the package:

Ret-Avit Gel: clear, yellowish gel with a characteristic odor.

Ret-Avit Cream: homogenous, yellowish emulsion with a characteristic odor.

The pack contains a tube of 7 or 20 grams. Not all package sizes may be marketed.

Name and address of the manufacturer and marketing authorization holder: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health on 06/2013, and has been updated in accordance with the Ministry of Health instructions on 11/2020.

Registration number of the medicine in the national drug registry of the Ministry of Health:

Ret-Avit Cream 0.05%: 33262540000

Ret-Avit Cream 0.025%: 60202704200

Ret-Avit Gel 0.05%: 33252539900

Ret-Avit Gel 0.025%: 60212704500