

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

This medicine is dispensed with a doctor's prescription only

TWYNEO

Cream

Active ingredients

tretinoin 0.1%

benzoyl peroxide 3%

Inactive ingredients and allergens in this medicine: See section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

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?

TWYNEO is indicated for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older.

Therapeutic group:

benzoyl peroxide – oxidizer

tretinoin - retinoid

2. Before using this medicine

Do not use this medicine if:

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| <ul style="list-style-type: none">• You are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (see section 6).• You are pregnant. |
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Special warnings about using this medicine

Before treatment with TWYNEO, tell your doctor if:

- You have other skin problems, including atopic dermatitis (eczema), cuts, or sunburn
- You have skin sensitivity to the sun

Additional warnings

- Avoid using TWYNEO on skin areas with cuts, abrasions, atopic dermatitis (eczema), or sunburns.
- Limit your time in sunlight. You should avoid using sunlamps, tanning beds, and ultraviolet light during treatment with TWYNEO. If you have to be in the sunlight or are sensitive to sunlight, use

sunscreen and wear protective clothing or a wide-brimmed hat to cover the treated areas.

- Avoid getting TWYNEO in your hair or on colored fabric. TWYNEO may bleach hair or colored fabric.

Children and adolescents

TWYNEO is intended for use in children 9 years of age and older. Safety and effectiveness below the age of 9 have not been tested.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding

- Before treatment, tell your doctor if you are pregnant or plan to become pregnant. Do not use TWYNEO if you are pregnant. It is not known if TWYNEO will harm your unborn baby.
- Before treatment, tell your doctor if you are breastfeeding or plan to breastfeed. It is not known if TWYNEO or its breakdown products pass into your breast milk, and it is not known if there is any effect on a breastfed baby or on milk production. Talk to your doctor about the best way to feed your baby during treatment with TWYNEO.

Driving and using machines

There is no information about the effect of this medicine on the ability to drive or operate machinery.

Important information about some of this medicine's ingredients

The cream contains:

- Cetyl alcohol which may cause local skin reactions (such as contact dermatitis).
- Butylated hydroxytoluene which may cause local skin reactions (such as contact dermatitis) or irritation of the eyes and mucous membranes.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:

Apply TWYNEO to the affected areas 1 time a day.

Do not exceed the recommended dose.

Directions for use

TWYNEO is intended for use on the skin only (topical). Do not use TWYNEO in your mouth, eyes, or vagina.

Apply TWYNEO on clean and dry skin.

TWYNEO comes in a bottle with a pump. Press down on the pump to dispense a small amount of TWYNEO on your fingertip. Apply a thin layer of TWYNEO to the affected skin areas. Avoid contact with your eyes, lips, corners of your nose, and mouth.

Wash your hands right away after applying TWYNEO.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time 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

As with any medicine, using TWYNEO may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

TWYNEO may cause serious side effects, including:

- **Allergic reactions.** Stop using TWYNEO and get medical help right away if you notice any of the following symptoms during treatment with TWYNEO:
 - severe immune reaction (anaphylactic reaction)
 - angioedema
 - hives, rash or severe itching
 - swelling of your face, eyes, lips, tongue, or throat
 - trouble breathing or throat tightness
 - feeling faint, dizzy, or lightheaded
- **Skin irritation.** TWYNEO may cause skin irritation such as redness, scaling, peeling, dryness, pain, stinging or burning. If you develop these symptoms, your doctor may tell you to use a moisturizer, decrease the number of times you apply TWYNEO, or completely stop treatment with TWYNEO.
- **Light sensitivity.** Discontinue TWYNEO at the first evidence of sunburn. See section 2, under 'Additional warnings'.

Very common side effects (may affect more than 1 in 10 users):

Pain, pigmentation, swelling

Common side effects (may affect up to 1 in 10 users):

Dryness, peeling, redness, skin inflammation (dermatitis), itching, and irritation at the application site

If you experience any side effect, if any of the side effects worsen, 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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also 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 your doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package/label. The expiry date refers to the last day of that month.

Storage conditions:

- In the pharmacy: Store in a refrigerator (2°C-8°C).
After dispensing the medicine to the patient: Store the medicine below 25°C.

- Do not freeze.
- Discard the medicine 12 weeks after the date you receive it or 60 days after the first opening, whichever is sooner.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Glycerin, cyclomethicone, cetyl alcohol, mono and di-glycerides, macrogol stearate type I, silicon dioxide, carbomer homopolymer type C, sodium hydroxide, anhydrous citric acid, imidurea, squalane, TEOS, hydrochloric acid, lactic acid, polyquaternium-7, edetate disodium, cetrimonium chloride, white wax, butylated hydroxytoluene and purified water.

What the medicine looks like and contents of the pack:

Bottle with a pump that contains 30/50 grams of homogeneous yellow cream.

Not all pack sizes may be marketed.

Registration holder's name and address: SOL-GEL TECHNOLOGIES LTD., Golda Meir 7, Weizmann Science Park, Ness Ziona, 7403650

Manufacturer's name and address:

SOL-GEL TECHNOLOGIES LTD. Golda Meir 7, Weizmann Science Park, Ness Ziona, 7403650, Israel

Approved in May 2025

Registration number of the medicine in the Ministry of Health's National Drug Registry:
178-65-37889-99