

PACKAGE LEAFLET: INFORMATION FOR THE USER

Minoxidil/Target[®]
5% w/v cutaneous solution
Minoxidil

Read all of this leaflet carefully because it contains important information for you.

To get the best results you need to use **Minoxidil/Target[®]** carefully and in accordance with the instructions.

- Keep this leaflet; you may need to read it again.
- Ask your pharmacist if you need more information or advice.
- Contact your doctor if no improvement occurs after 12 months.
- Tell your doctor or pharmacist, if any of the side effects gets serious or if you notice any side effects not listed in this leaflet.

This leaflet contains:

1. What **Minoxidil/Target[®]** is and what it is used for
2. Before using **Minoxidil/Target[®]**
3. How to use **Minoxidil/Target[®]**
4. Possible side effects
5. How to store **Minoxidil/Target[®]**
6. Content of the pack and other information

1. WHAT MINOXIDIL/TARGET[®] IS AND WHAT IS USED FOR

Minoxidil/Target[®] is a cutaneous solution that contains 5% minoxidil.

Minoxidil/Target[®] is indicated for the treatment of male and female of pattern baldness. It acts effectively in the growth of new hair, inhibiting hair loss in men and women with thinning hair or baldness.

It is intended for use only on the scalp.

Use **Minoxidil/Target[®]** twice a day, as part of your daily routine for your hair. Since hair grow slowly, it may take 4 months of administration or more until any result appears.

Initiation and extend of new hair growth may vary between different patients. If you stop the use of this medicine, you may revert to the previous state of hair thinning after 3-4 months from discontinuation.

2. BEFORE USING MINOXIDIL/TARGET[®]

Do not use Minoxidil/Target[®]:

- if you are allergic to minoxidil or any of the ingredients of **Minoxidil/Target[®]** (hypersensitivity)
- if you are under the age of 18 years or over 65 years. Safety and efficacy has not been established in these age groups.
- if the skin of your scalp is red, irritated or has an open wound.
- if you are using other products on your scalp
- if you are pregnant or breast-feeding

Tell your doctor before using Minoxidil/Target[®]

If you suffer a heart disease (ischemic heart disease) or you have hypertension (and you receive medication to lower your blood pressure).

Take special care when using Minoxidil/Target[®]

Make sure that you apply **Minoxidil/Target**[®] directly on the skin of the scalp and not on the hair. Do not apply on any other body parts and do not mix with any other preparations that may be used on the hair.

Do not ingest this product. Sun exposure is not recommended when you administer the product. Oral administration may lead to serious side effects.

Taking other medicines

If you are taking or you have recently taken other medicines (including medicines that are purchased without prescription) and you will use **Minoxidil/Target**[®] consult with your doctor or pharmacist.

Topical preparations that may contain tretinoin, anthralin, corticosteroids or guanethidine, may affect safety and efficacy of **Minoxidil/Target**[®].

Pregnancy and lactation

Minoxidil/Target[®] is not indicated during pregnancy and lactation.

Driving and using machinery

Minoxidil/Target[®] does not affect your ability to drive or use machinery.

Important information about some of the ingredients of Minoxidil/Target[®]

Minoxidil/Target[®] contains alcohol that may induce local skin reaction, burning sensation or irritation (e.g. contact dermatitis)

3. HOW TO USE MINOXIDIL/TARGET[®]

Hair and scalp should be thoroughly dried before using **Minoxidil/Target**[®]

Apply 6 sprayings (equals to 1ml of the product) on hair loss area, twice a day.

- Remove cover and then remove the smaller inner screwed cap.
- Insert the pump spray applicator to the bottle and screw firmly.
- Aim the applicator to the center of the hair loss area and press once, then apply **Minoxidil/Target**[®] using your fingertips to cover the whole affected area. One dose of 1ml corresponds to 6 sprayings; therefore repeat the process 6 times in total to administer one dose of the solution.

When you are not using the product you may replace the pump spray applicator with the small cap.

When using Minoxidil/Target[®]:

- Do not apply to any other part of the body.
- Avoid contact with the eyes, mouth and sensitive skin areas. At any accidental contact you should wash the area thoroughly with excess fresh water.
- Avoid inhalation of the spray mist.
- After the use you should wash your hands thoroughly.
- Do not use hairdryer to dry your hair after **Minoxidil/Target**[®] application
- Apply only to healthy skin.

Stop using the product and talk to your doctor if:

- You feel chest pain, rapid heartbeat, faintness or dizziness.
- Your weight is increased suddenly and unexpectedly
- You experience sweating of the palms and the feet
- Your scalp becomes red or irritated.
- You don't have any improvement after 12 months

What to expect during use of Minoxidil/Target[®]

| | |
|------------|---|
| 1-2 months | Minoxidil/Target [®] will start acting below the scalp surface before you may see any visible hair re-growth result. Some users may experience increased hair-loss after first use. This may be due to Minoxidil action that causes hair in their |
|------------|---|

| | |
|------------|--|
| | resting phase (telogen) to be replaced by new hair that are growing (anagen, in fact old hair fall out and new take their place). This temporary shedding generally occurs 2-6 weeks after beginning of treatment and then subsides. If shedding continues after the 6 th week, you should talk with your doctor. |
| 3-4 months | Initially, new hair grows soft, colorless and downy. After longer term use the new hair should have the same color and thickness as the rest of the hair on the scalp. As hair grow slowly, Minoxidil/Target [®] needs time to act. Results may be seen after 2-4 months daily use twice a day. The number of the hair that are regenerated is different for each person. The effect of Minoxidil/Target [®] cannot be predicted. Based on clinical efficacy during clinical trials and safety studies, the majority of the patients that used Minoxidil/Target [®] showed significant decrease of hair loss during the first 4 months of treatment. |

To experience better results with **Minoxidil/Target**[®] use it according to the instructions, twice daily, every day, directly on your scalp.

If you use more Minoxidil/Target[®] than you should

Follow the given instructions of use. Do not exceed 2ml of the product daily and do not use it more than twice a day. Your hair will not grow faster and you will not see better result if you use more product or more often. In case of accidental ingestion you may experience adverse events like fluid retention, lowered blood pressure or tachycardia.

Poison Center Athens: +30 210 7793777

If you forget to use Minoxidil/Target[®]

Do not be disturbed if you miss one or two administrations of the solution, simply, continue using the product as if you have not forgot these doses.

If you stop using Minoxidil/Target[®]

If you stop using the solution, the regrown hair may fall out and your scalp may revert to the previous condition within 3-4 months.

If you have further questions on the use of the product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

| Organic System | Incidence | Side effect |
|--|-----------|---|
| Vascular disorders | Rare | Hypotension |
| Cardiac disorders | Rare | Rapid heartbeat (tachycardia) |
| Respiratory disorders | Rare | Chest pain |
| Skin and subcutaneous tissue disorders | Common | Local irritation, scalling, redness, skin rash, dry skin, hypertrichosis (unwanted non-scalp hair), burning sensation, τριχοφυΐα εκτός του κεφαλιού), κάψιμο, hives |
| | Rare | Alopecia, irregular hair growth, allergic reactions, hypersensitivity, generalized rash. |
| Sensation disorders | Rare | Ocular irritation, visual disturbances, taste alterations, rhinitis, ear infection (external otitis) |
| Nervous system disorders | | Headache, neuritis, tingling sensation |
| General disorders | | Dizziness, facial edema, weakness, pruritus (itching) |
| Other systems | Rare | Hepatitis, nephrolithiasis |

It is recommended that **Minoxidil/Target**[®] 5% should be used with caution by women due to the higher frequency of hypertrichosis versus **Minoxidil/Target**[®] 2%.

If you get any side effects, please talk to you doctor or pharmacist or other health care professional or directly to the National Medicines Agency (Mesogion 284, 15562, Cholargos, www.eof.gr).

5. HOW TO STORE MINOXIDIL/TARGET®

Keep out of reach and sight of children.

Do not use this product after the expiry date that appears on the label and outer carton after the indication marked as EXP. Expiry date refers to the last day of the month.

Medicines should not be disposed via wastewater or household water. Ask your pharmacist how to dispose the medicines that you no longer use. These measures will help to protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Minoxidil/Target® contains

Active substance: Minoxidil.

Excipients: Alcohol, Propylene glycol, Water purified

What Minoxidil/Target® looks like and contents of the pack

Bottle that contains 60 ml of cutaneous solution and pump spray applicator.

Marketing Authorization Holder

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