

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

The medicine is dispensed according to a physician's prescription only

## Betacorten Scalp Solution

betamethasone (as valerate) 0.1% w/w  
Each 10 ml contains 0.01 ml of betamethasone valerate.

Inactive ingredients: The list of inactive ingredients is detailed in section 6 "Further information" and in section 2 "Important information about some of this medicine's ingredients".

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the physician 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. The medicine is not intended for children under 1 year of age.

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

Betacorten Scalp Solution contains a medicine called betamethasone valerate that is used to help reduce the redness and itchiness of certain scalp problems, such as psoriasis and skin inflammation (dermatitis) associated with dandruff.

**Therapeutic group:** corticosteroids.

### 2. Before using the medicine

**Do not use the medicine:**

- if you are sensitive (allergic) to betamethasone valerate or to any of the additional ingredients of Betacorten Scalp Solution (as listed in Section 6).
- if you have a skin infection on your scalp (viral, bacterial, or fungal).
- on children under 1 year of age.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your physician or pharmacist before using Betacorten Scalp Solution.

**Special warnings regarding use of the medicine**  
**Talk to your physician or pharmacist before you use this medicine if:**

- you have previously had an allergic reaction to another steroid.
- you are applying the solution under an airtight dressing. These types of dressings make the absorption of the active ingredient through the skin easier and it is possible to accidentally end up using too high a dosage of the solution.
- you have psoriasis; your physician will want to see you more often.
- you are applying the solution to broken skin or within the skin folds.
- you are applying to a large area of skin.
- you are applying to thin skin, or on children as their skin is thinner than that of adults and, as a result, may absorb larger amounts of the solution.
- In children, do not use a dressing where the scalp

solution is applied.

- Use on children should be limited to 5 days. Contact your physician if you experience blurred vision or other visual disturbances.

If you are not sure if any of the above apply to you, talk to your physician or pharmacist before using this medicine.

**Drug interactions:**

**If you are taking or have recently taken other medicines, including non-prescription medicines or nutritional supplements, tell the physician or pharmacist.** Especially if you are taking ritonavir or itraconazole medications.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to become pregnant, ask your pharmacist or physician for advice before taking this medicine.

**Important information about some of this medicine's ingredients**

Betacorten Scalp Solution contains chlorocresol, which can cause allergic reactions.

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

Always use according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about your dose or treatment regimen.

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

The usual dosage is generally:

- Application of Betacorten Scalp Solution in the morning and at night. The dose may be reduced as your scalp problem begins to get better.
- Do not use Betacorten Scalp Solution more often than prescribed for you.
- Do not use for a long time (such as every day for many weeks or months) without a physician's instruction.
- Be very careful not to get the solution into your eyes. Do not touch your eyes until you have washed your hands.
- If you wash or shampoo your hair, wait until your hair dries before applying the solution.
- If you are applying the solution on someone else, make sure you wash your hands after use or wear disposable plastic gloves.
- **Do not dry your hair with a hairdryer.**
- **Caution! Flammable substance! Avoid exposure of the solution to an open fire, flames, and any other source of ignition, including smoking when applying or immediately after applying the solution, until the preparation has fully dried.**

**Guidance on how to apply the solution**

1. Wash your hands.
2. Unscrew the bottle cap and place the nozzle on the scalp that needs treating.
3. Gently squeeze the bottle to cover the area with a thin and even layer of solution.
4. You can rub the solution in, but you do not have to.
5. Your scalp will feel cool until the solution has dried.
6. Wash your hands again.

**Do not exceed the recommended dose.**

Do not swallow

For external use only.

**If you have accidentally taken a higher dosage**

You might feel unwell if you apply too much or if you or a child accidentally swallows the medicine. Refer immediately to a physician or proceed to a hospital emergency room, and bring the package of the medicine with you.

**If you forget to take the medicine**

If you forget to apply Betacorten Scalp Solution, apply it as soon as you remember. If it is close to the time you are next meant to apply it, you can wait until this time.

Adhere to the treatment regimen as recommended by the physician.

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

**If you stop taking the medicine**

If you use Betacorten Scalp Solution regularly, talk to your physician before you stop using it. Your condition may worsen if the treatment is stopped suddenly.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions about using the medicine, consult the physician or pharmacist.**

### 4. Side effects

As with any medicine, use of Betacorten Scalp Solution may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

**Stop using Betacorten Scalp Solution and refer immediately to the physician if:**

- you find that your skin condition is getting worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to Betacorten Scalp Solution, have an infection, or need other treatment.
- you have psoriasis and get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

**Additional side effects you may notice when using Betacorten Scalp Solution include:**

**Common side effects** (may occur in up to 1 in 10 people):

- burning, pain, irritation or itching in the area where the solution is applied.

**Very rare side effects** (may occur in up to 1 in 10,000 people):

- an increased risk of infection
- an allergic skin reaction where the solution is applied
- rash, itchy bumpy skin or redness of the skin
- dryness and thinning of your skin which may also damage or wrinkle more easily
- stretch marks may develop

- veins under your skin may become more noticeable
- an increase or reduction in hair growth or hair loss and changes in skin colour
- weight gain, rounding of the face
- delayed weight gain or slowing of growth in children
- bones can become thin, weak and break easily
- cloudy lens in the eye (cataract) or increased pressure in the eye (glaucoma)
- increased blood sugar levels or sugar in the urine
- high blood pressure.

**Side effects of unknown frequency**

- blurred vision

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>  
You can also report by email: [safety@trima.co.il](mailto:safety@trima.co.il)

### 5. How should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

**Storage conditions:**

- Store in a cool place, below 25°C.
- Protect from light. Do not expose Betacorten Scalp Solution to direct sunlight.
- Keep the container tightly closed when not in use. Contents are flammable. Keep Betacorten Scalp Solution away from all sources of fire, flame, and heat.
- Use within 6 months of first opening, but not past the expiry date.

### 6. Further information

- In addition to the active ingredient, the medicine also contains: isopropyl alcohol, carbomer 940, chlorocresol, sodium hydroxide, purified water.
- What the medicine looks like and contents of the package  
Each carton contains a bottle with 30 ml of a colourless solution.
- Manufacturer and license holder: Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000.
- Revised in December 2021 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 050.46.23263.00

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Maabarot 4023000  
Israel Pharmaceutical Products  
Maabarot Ltd.