

Patient Package Insert According with the Pharmacists' Regulations (Preparations) - 1986

This product can be sold without a physician's prescription

Alphosyl® "2 in 1" Medical Shampoo with Conditioner

Active Ingredient and its concentration:
Alcoholic extract of coal tar 5.0% w/w

Inactive ingredients and allergens in the product: see section 2 "Important information about some of the ingredients of this product" and section 6 in this leaflet.

Read this entire leaflet carefully before using this product. This leaflet contains concise information about the product. If you have any further questions, ask the physician or pharmacist.

Use this product according to the instructions in the dosage section in this leaflet. Contact a physician if the symptoms of your illness get worse or if they do not improve after 4 weeks.

1. What is the product intended for?

Alphosyl Shampoo is intended for the treatment of scalp disorders such as psoriasis, seborrhoeic dermatitis, scapling and itching (often associated with eczema) and dandruff.

Therapeutic group: topical antipsoriatics (tar).

The active ingredient is an alcoholic extract of coal tar, which relieves itching and is an anti-scaling agent that helps in the breakdown of keratin (part of the skin structure).

2. Before using the product

Do not use the product:

- if you are hypersensitive (allergic) to the active ingredient alcoholic extract of coal tar or to any of the other ingredients this product contains (see section 6 "Additional information").
- for the treatment of infected, open or damaged skin.
- for the treatment of sores or acute pustular psoriasis (skin redness covered by pus-filled blisters).

Special warnings regarding the use of the product:

- Consult a physician or pharmacist if your symptoms persist.
- Use Alphosyl Shampoo with caution in children under the age of 12 years and only upon recommendation from the physician or pharmacist.
- Stop using Alphosyl Shampoo if your scalp becomes irritated.
- Avoid contact of the shampoo with the eyes. If necessary, rinse with warm water.
- The shampoo may stain the clothes and skin and in rare cases has caused temporary changes in hair color. Skin stains will wear off after treatment is completed.
- The shampoo may cause sensitivity to sunlight. Avoid using sunlamps and spending a long time in the sun during the treatment.
- If you accidentally swallow any shampoo, contact the physician immediately.

Drug interactions

If you are taking or have recently taken other products including non-prescription medicines and nutritional supplements, tell the physician or pharmacist, especially inform the

physician or pharmacist if you are taking: Products known to increase sensitivity to light such as:

- Thiazides (diuretics)
 - Tetracyclines, fluoroquinolones, sulfonamides
 - Phenothiazines (for treating mental disorders)
- as these products may raise the possibility of increased sensitivity to light.

Pregnancy and breastfeeding

Consult a physician or pharmacist before starting treatment with Alphosyl Shampoo if you are pregnant, planning to become pregnant or are breastfeeding.

Do not use Alphosyl Shampoo in the first trimester of pregnancy. If you are breastfeeding, make sure you have washed off all shampoo residue.

Important information about some of the ingredients of this product

The product contains parahydroxybenzoate that may cause an allergic reaction, which could be delayed.

3. How to use the product

Check with the physician or pharmacist if you are not sure about the dosage and treatment regimen of the product.

The usual recommended dosage is:

For the treatment of dandruff: 1-2 times a week as needed, or according to instructions of a physician.

For the treatment of psoriasis, seborrhoeic dermatitis and itching: 2-3 times a week, or according to instructions of a physician. The recommended duration of treatment is 4 weeks. In order to improve your condition, adhere to the treatment. If there is no improvement after 4 weeks, contact a physician.

How to use:

1. Wet the hair thoroughly with water.
 2. Apply enough Alphosyl Shampoo so that the lather covers your scalp, hair and adjacent areas, if they are also affected.
 3. Massage the scalp well, and adjacent areas if necessary, with the fingertips for a few minutes until lather forms.
 4. Rinse your hair thoroughly.
 5. Repeat steps 2 to 4.
- The shampoo should be in contact with the scalp for a total time of 3-5 minutes over the two applications.

Do not exceed the recommended dose. Do not swallow.

For external use only.

If you have accidentally used a higher dosage

If you used more Alphosyl Shampoo than recommended or more often than recommended, you may be more likely to get skin irritation or skin sensitivity to sunlight.

If a child or anyone else has accidentally swallowed this product, proceed immediately to a physician or to a hospital emergency room and bring the product package with you.

If you forgot to use Alphosyl Shampoo at the designated time, apply the next day instead.

Do not take products in the dark! Check the label and the dose **each time** you take a product. **Wear glasses if you need them.**

If you have further questions on the use of this product, consult the physician or pharmacist.

4. Side effects

As with any product, the use of Alphosyl Shampoo may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop the treatment and contact a physician immediately if the following signs appear:

• **Allergic reactions** which may be severe such as raised and itchy skin rash (hives), swelling of the face or mouth, or difficulty breathing.

Some of the side effects noted below can also be symptoms of the conditions you are treating. However, if you experience any of these effects for the first time after starting the treatment, or if these effects get worse, **stop** using Alphosyl Shampoo and contact a physician or pharmacist:

- unusual hair loss or thinning
- eczema (itchy skin rash)
- abnormal hair texture
- skin irritation, the skin may be dry, red or itchy, a burning sensation of the skin
- skin pain, rash or swelling of the skin at the application site
- eye irritation
- hair color changes
- sensitivity to sunlight

If a side effect appears, if one of the side effects gets worse or if you suffer from a side effect which is not mentioned in this leaflet, consult the physician.

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: <https://sideeffects.health.gov.il> Additionally, side effects can be reported to Perrigo via the following address: www.perrigo-pharma.co.il

5. How to store the product

- Avoid poisoning! This product and any other product must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the product after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Can be used for 5 weeks after first opening, but not later than the expiry date.

6. Additional information

- **In addition to the active ingredient, the product also contains:**
Purified Water, Ammonium Lauryl Sulphate, Sodium Lauryl Sulphate, Lauramide DEA, Herbal Fragrance, Hydroxy Propyl Methyl Cellulose 2910, Citric Acid Anhydrous, Guar Hydroxy Propyl Trimonium Chloride, Methyl Parahydroxybenzoate, Propyl Parahydroxybenzoate, Patent Blue V (E 131).
- **What does the product look like and what are the contents of the package:** Alphosyl Shampoo is a green liquid packed in a reusable white plastic bottle of 250 ml.
- **Registration holder:** Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.
- **Manufacturer:** Purna Pharmaceuticals, Puurs, Belgium.
- Revised in April 2021 according to MOH guidelines.
- **Registration number of the product at the National Drug Registry of the Ministry of Health:** 060-84-27674.

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