

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

This medicine can be sold with a physician's prescription only

Esomed Gel

Active ingredients

hydroquinone 4% w/w
1 gram of the preparation contains 40 mg of hydroquinone.
Inactive and allergens: See section 6 "Additional information".

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It might harm them, even if you think that their medical condition is similar.

1. What is the medicine intended for?

The medicine is intended for lightening skin spots.

Therapeutic group: A topical agent for treatment of hyperpigmentation.

Mechanism of action of Esomed Gel

Hydroquinone reduces the synthesis of melanin, the substance responsible for skin pigmentation.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains.
- do not use to treat hyperpigmentation due to chemical ochronosis and colloid degeneration (colloid milium) due to either cosmetic or occupational cause.
- this medicine is not intended for children under 12 years of age.
- during pregnancy.

Special warnings regarding the use of this medicine

- Do not use the preparation on mucosal tissues, wounded skin, inflamed or irritated skin or in the area of sunburns or milium (sweat rash).
- Avoid contact with the eyes and mucous membranes. In case of accidental contact with the eyes, rinse immediately with plenty of water to prevent possible formation of cloudy spots on the cornea. In case of contact with the lips, you may notice a bitter taste and a mild anesthetic effect. If the area where there is pigmentation is very extensive, it should be treated in several cycles.
- During the treatment with hydroquinone, it is important to protect the treated area from sunlight since minimal sun exposure may renew melanin synthesis and lead to re-pigmentation. It is recommended to use a sunscreen with a high protection factor during the day.
- Wash your hands with soap after applying the preparation since hydroquinone may cause reversible brown stains on the nails.
- The product is not intended to prevent sunburn.
- In people with very dark skin, the effect of the medicine may be less visible.
- For some people, especially those with sensitive skin, hypersensitivity reactions may occur. Sensitivity should be tested as follows: Apply a small amount of the gel on the inside of the upper arm and wait 24 hours. In case of severe irritation, stop using the preparation.
- In some cases, temporary darkening or irritation of the skin may occur; if this effect persists, treatment should be discontinued.
- De-pigmentation (skin lightening) is not immediate, since hydroquinone interferes only with the synthesis of new melanin; this response is temporary and melanin synthesis is reactivated upon treatment discontinuation. De-pigmentation may persist between 2 and 6 months after

treatment discontinuation. The darker the lesions, the sooner will re-pigmentation occur.

Children and adolescents

The medicine is not intended for children under the age of 12.

Drug interactions

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

- If you are using or have recently used any other medicine in the area intended for treatment with Esomed Gel, including non-prescription medicines.
- Simultaneous use with peroxides, such as hydrogen peroxide or benzoyl peroxide, may cause temporary coloring of the skin due to hydroquinone oxidation. This temporary coloring disappears upon discontinuing the use of one of these preparations and washing the application area with mild soap.

Use of this medicine and food

Not applicable.

Pregnancy, breastfeeding and fertility

Esomed Gel is forbidden for use during pregnancy since sufficient data is not available about the use of hydroquinone in pregnant women.

Driving and use of machinery

There is no effect on the ability to drive and use machines.

3. How should you use this medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure. The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage:

Apply a thin layer of gel only to small areas of skin hyperpigmentation. It is recommended to start with application once a day for 10 to 15 days, and to continue the treatment with applications twice a day, one in the morning and one in the evening.

If there is no improvement after 2 months of treatment, stop using the medicine. The recommended treatment duration is 60 to 90 days.

Under no circumstances should this medicine be used for more than 6 months. **Do not exceed the recommended dose.**

Do not swallow! For external use only. Not for ophthalmic use.

If you have accidentally taken a higher dosage or an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. Accidental ingestion may lead to severe intoxication effects (tremors, seizures and anemia). Intoxication with external use is unlikely.

If you forgot to apply this medicine at the scheduled time, apply the dose as soon as you remember and the next dose at the regular time. Do not apply a double dose to make up for a forgotten dose. Continue with the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Esomed Gel may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

Stop the treatment and refer to a doctor as soon as possible if any of

the following side effects occur:

- Allergic reaction – hypersensitivity: Signs of hypersensitivity: swelling of the throat and face, lips and mouth, breathing or swallowing difficulties, itchy rash, pruritus or redness.
- Rare: long-term treatment with this medicine (more than 6 months) may cause gradual pigmentation of blue-black shade (exogenous ochronosis), mainly in people with a black skin tone.

Additional side effects

- Occasional: sensation of burning, rash, skin sensitivity, or dermatitis. If these side effects do not resolve within 1 week, stop the treatment.
- In long-term treatment, a hyperpigmentation reaction may occur. In long-term treatment, isolated cases of skin discoloration (depigmentation) have been reported.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) which directs to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

Additionally, you can report to Padagis via the following address: Padagis.co.il

5. How should the medicine be stored?

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 unless explicitly instructed to do so by the doctor. 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.

Even under the recommended packaging/storage conditions, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Store below 25°C.

Store in the original package.

Use within two months after first opening the tube, but no later than the expiration date.

Be sure to close the tube tightly after each use.

Do not use the medicine if you notice signs of medicine degradation.

6. Additional information

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

Purified water, Carbomer 940, Sodium Metabisulfite, Methylparaben, Sodium Hydroxide, Edetate Disodium.

What the medicine looks like and contents of the package

Clear, colorless homogeneous gel. Available in tubes of 30 grams and/or 60 grams.

Not all package sizes may be marketed.

Registration Holder and address:

Padagis Israel Agencies Ltd.,
1 Rakefet St., Shoham.

Manufacturer and address:

Ben Shimon Floris Ltd., Misgav Industrial Park (Teradion), 2017400 Israel.

Revised in January 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 132-93-30978

30.01.23

Esomed Gel PIL PB0223-03