

This medicine is marketed without prescription

Thio Gel

Composition:

Isothipendyl Hydrochloride 0.75%

Inactive ingredient list: see the chapter 6- other information.

Read this package insert carefully in its entirety before using this medicine. This leaflet contains essential information of this medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine is given without a prescription and is intended for adults and children aged 30 months and older.

Dosage for children under 6 years: will be determined by the doctor.

Contact a doctor if symptoms do not pass within 5 days despite the treatment.

If you notice side effects that not mentioned in this leaflet, or if you have any serious side effects, contact your doctor or pharmacist.

Take this medicine correctly. Consult your pharmacist if you need more information.

1. What is the medicine intended for?

Indications: This medicine is intended for temporary relief of itching due to minor disorders of the skin such as bites (non-toxic), irritation, sunburn and inflammation of the skin due to the sensitivity of ivy or oak.

Therapeutic group:

Antihistamine for external use.

2. Before use this medicine:

Do not take this medicine

- If you are sensitive to histamine or Isothipendyl or one of the other components of the medicine.
- On open wounds or inflamed

Do not take this medicine without consulting a doctor before starting treatment if you:

If you are pregnant or breastfeeding.

Special warnings concerning the use of this medicine:

Do not use this medicine frequently, without consulting a doctor.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Do not use on open wounds, cracked or inflamed skin, the presence of blisters or discharges, or chicken pox or measles.

Avoid continuous use or extensive preparation.

Do not use this medicine on the eyes.

Do not use on large surface areas, under bandage, on affected skin, or infants or premature infants because of the risk of transition of the active ingredient into the blood.

Do not use on mucosal membranes.

This medicine is not a cream to protect against the sun.

Do not use this medicine as care cream on healthy skin.

Itching is a symptom which may have many causes which requires the advice from your doctor especially in the case of continuous disturbance or exacerbations.

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplement and vitamins, inform the doctor or the pharmacist.

Pregnancy and breast-feeding:

This medicine must be used with caution during pregnancy and breastfeeding.

If you are pregnant or breastfeeding, consult your doctor or pharmacist before using this medicine.

Important information about some of the components of Thio Gel:

The medicine contains sorbic acid which may cause local skin reactions (such as eczema)

3. How to use this medicine?

Consult your doctor or your pharmacist if you are unsure.

Recommended dosage unless otherwise prescribed by your doctor:

Apply to the affected area 2-3 in the day.

This medicine is intended for adults and children over the age of 30 months.

Dosage for children under 6 years: will be determined by your doctor.

Do not exceed the recommended dose.

If no improvement in the condition is noted within 5 days, consult your doctor.

Note: Do not swallow! This medicine is for external use only.

Avoid contact with eyes, mucous membranes (such as the mouth and nose) in the case of contact with eyes, rinse them thoroughly with water.

If you forgot to use this medication at the specified time, never apply a double dose.

If you have accidentally taken an overdose, or if a child has accidentally swallowed the medicine, contact immediately the doctor or proceed immediately to a hospital emergency room and bring the package of the medicine with you.

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

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

4. Side Effects:

Like all medicines, **Thio Gel** use can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible events. You may not have any of them.

In case of these side effects, contact your doctor:

- Allergic reactions to Thio Gel

- Very occasional cases of photosensibilisation (skin reaction following exposure to sunlight or UV)

If one of the side effects gets worse, or in the event that you experience side effects not mentioned in this leaflet, consult your doctor immediately.

5. How to store this medicine?

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use this medicine after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Can be used for 8 weeks after first opening.

Store below 25°C.

6. Further information:

In addition of the active ingredient this medicine also contains:

Purified water, sorbitol solution 70%, Carboxymethylcellulose sodium, sorbic acid, edetic acid, sodium hydroxide

What does the medicine look like and looks contents of the package:

Transparent gel packaged in a tube of aluminum containing 40 grams.

Manufacturer and Holder:

Rekah Pharmaceutical Prod. Ltd., 30 Hamelacha St., Holon, Israel

This leaflet was checked and approved it in April 2014.

License number of the medicine in the Ministry of Health:

140 23 24394 00

For simplicity and easier to read, this leaflet is formulated male, however, the medicines is intended for members of both sex.