Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

Tesalin

Film-coated tablets

Active ingredient:
Each tablet of Tesalin contains: 8 mg petasins. The extract is produced from the leaves of the *Petasites hybridus (L.)* plant.

For the list of the other ingredients, please see section 6.
See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have any further questions, refer to your doctor or pharmacist.
This medicine was prescribed for treating your condition. Do not pass it on to others. It may harm them, even if you think their illness/medical condition is similar to yours.

1. What is the medicine intended for?

The medicine is intended for the treatment of symptoms of allergic rhinitis (hay fever) and related symptoms in eyes, nose and throat.

Therapeutic group:

Herbal medicine for treatment of hay fever symptoms.

2. Before using the medicine

Do not use the medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (for the list of the other ingredients, please see section 6.)

Special warnings regarding the use of this medicine:

Before starting the treatment with Tesalin, tell your doctor:

- If you suffer or have suffered in the past from liver problems.
- If you suffer or have suffered in the past from kidney problems.
- If you suffer from any allergies.
- If you suffer from other illnesses or any medical problem.

Additional warnings:

Very rare cases of liver damage (including serious damage), related to use of the plant root extracts have been reported. Tesalin contains an extract from the plant's leaves, but a possible negative effect on the liver (liver damage) cannot be ruled out. Therefore, if there is an existing liver problem, use with caution and according to your doctor's instructions. See 'Side effects' section.

Children and adolescents

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

Drug interactions:
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements.

Use of this medicine and food:
This medicine may be taken with or without food.

Pregnancy and breastfeeding:
The risk in taking the medicine during pregnancy and breastfeeding is unknown and therefore the use of the medicine during pregnancy and breastfeeding is not recommended.

Driving and use of machinery:
There is no information on the possible effect of the medicine, on driving or use of machinery.

Important information about some of the medicine's ingredients:
The tablet contains less than 0.2 mg of digestible carbohydrates.

3. How to use this medicine?
Always use according to the doctor's instructions. You should check with your doctor or pharmacist if you are not sure regarding the dosage and the manner of treatment with the medicine.
The dosage and the manner of treatment will be determined by the doctor only.
The standard dosage is usually: one tablet twice a day. In cases of high exposure to allergens the dosage may be increased to 3 tablets a day.
Do not exceed the recommended dose.
Swallow the tablet whole with water.

Crushing/halving/chewing:
There is no information on crushing/chewing/halving of the tablets.

If you have accidentally taken a higher dosage: there is no information on taking an overdose of the medicine. If you have taken an overdose or if a child has accidentally swallowed the medicine, consult a doctor and bring the medicine package with you.

If you forgot to take the medicine at the proper time, do not take two doses together.

Continue with the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

4. Side effects
Like any medicine, the use of Tesalin may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop the treatment and refer to the doctor if you experience symptoms that might indicate liver damage (very rare - appear in less than 1 user out of 10,000). These symptoms may include: impairment of daily functioning (e.g. abnormal fatigue, weakness), loss of appetite,

yellowing of the skin and/or the conjunctiva of the eyes (jaundice), dark urine, pains in upper abdomen, pale stools. See also 'Special warnings regarding the use of the medicine' section.

Additional side effects:
Common side effects (appear in 1-10 users out of 100):
Gastrointestinal discomfort, e.g. abdominal pain, diarrhea, nausea.
Uncommon side effects (appear in 1-10 users out of 1,000):
Skin hypersensitivity reactions, e.g. redness, edema, itchiness.
Side effects of unknown frequency (effects whose frequency has not been determined yet):
Headache, hypersensitivity reactions (allergy).

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, 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 a doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C, in the original package.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Silica colloidal anhydrous, cellulose microcrystalline, magnesium stearate, sodium starch glycolate type A, stearic acid, hypromellose, titanium dioxide (E 171), macrogol 20,000

What does the medicine look like and what does the package contain?
Round, convex, white to off-white tablets.
The tablets are packed in blisters, in packs of 20 or 60 tablets per box.
Not all pack sizes may be marketed.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.
Manufacturer: Max Zeller Söhne AG, Switzerland.
Medicine registration number in the National Medicines Registry of the Ministry of Health: 162-17-35348

This leaflet was checked and approved by the Ministry of Health in May 2019.
653001-MZ