



**PATIENT PACKAGE INSERT  
IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS  
(PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription.

## Histazine

### Film-coated tablets/Syrup

Active ingredient:

**Histazine tablets:**  
Each film-coated tablet contains:  
Cetirizine Dihydrochloride 10 mg.

**Histazine syrup:**  
Each 5 ml syrup contains:  
Cetirizine Dihydrochloride 5 mg.  
For inactive ingredients in the preparation - see section 6 "Further Information".

**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 doctor or pharmacist.

**The syrup dosage form is not intended for children and infants below 2 years of age.** The tablet dosage form is not intended for children who do not know how to swallow tablets.

Use/swallow it properly. Consult a pharmacist if you need further information.

#### 1. WHAT IS THE MEDICINE INTENDED FOR?

An antihistaminic preparation for the treatment of allergic effects. For the treatment of seasonal and perennial allergic rhinitis and allergic skin effects in children aged 2 years and over (syrup treatment) and in adults.

**Therapeutic group** Antihistamine.

#### 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 contained in the medicine or to another antihistamine medicine that contains hydroxyzine.
- you are suffering from severe kidney disease.
- you are breastfeeding.

##### Special warnings regarding use of the medicine

- The use is not recommended in children below 6 years of age suffering from kidney and/or liver function problems, due to lack of preparation safety information in this population.
- Inform the doctor before taking this medicine if you are sensitive to any food or medicine.
- Before doing any test to diagnose allergy, inform the doctor that you are taking this medicine, since taking this medicine can affect the results.

##### ❗ Do not use this medicine without consulting a doctor before commencing treatment if:

- you are pregnant.
- you are suffering from impaired function of the kidney/urinary system.
- you are suffering from epilepsy or

are at increased risk for experiencing convulsions.

- you are suffering, or have suffered in the past, from impaired function of: the heart and/or blood vessels, the liver, the prostate, from emphysema or chronic bronchitis.

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

Medicines that affect the central nervous system such as: hypnotics and sedatives.

##### ❗ Pregnancy and breastfeeding

If you are pregnant, consult a doctor or pharmacist before using this medicine. Do not breastfeed while using this medicine.

##### ❗ Use of the medicine and alcohol consumption

Do not drink wine or alcoholic beverages during the course of treatment with this medicine.

##### ❗ Driving and use of machinery

During use with this medicine side effects may appear (such as: drowsiness and fatigue) requiring caution when driving a car and when engaging in any activity that requires alertness. Children should be warned against riding a bicycle or playing near the road and the like.

##### ❗ Important information regarding some of the ingredients of this medicine

The tablets contain lactose. If you have been told in the past by a doctor that you have an intolerance to certain sugars, consult a doctor before commencing treatment with this medicine.

#### 3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain regarding use. The usual dosage is generally:

**Tablets:**  
Children above 6 years of age and adults: one tablet once daily.

**Syrup:**  
Children 2-6 years of age: 2.5 ml once daily. A dosage of up to 5 ml once daily or 2.5 ml twice daily can be used.

Children above 6 years of age and adults: 10 ml once daily or 5 ml twice daily. If the symptoms do not pass, refer to a doctor.

**Do not exceed the recommended dose. This medicine is not intended for children and infants below 2 years of age.**

##### Mode of administration:

**Tablets:** Do not chew the tablet! Swallow the medicine with water.

##### Syrup:

1. For liquid medicines, you should use the measuring spoon, syringe or dropper designated for measuring the proper amount of medicine. If a measuring spoon or any other measuring device was not provided with the package, consult a pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in their sizes and you may not receive the appropriate amount of medicine.

2. Child-safety caps have significantly reduced the number of poisoning incidents caused by medicines each year. However, if you find it difficult to open the package, you can refer to a pharmacist to ask to have the safety mechanism removed and to turn the cap into a regular, easy to open cap.

**If you accidentally took a higher dosage, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.**

**If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult a doctor.**

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

#### 4. SIDE EFFECTS

As with any medicine, use of Histazine 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.

**Discontinue use and refer to a doctor immediately if the following effects develop:**

- Sudden signs of allergy such as: rash, itching, fever, swelling of the throat, face, lips, eyelids, tongue and/or other parts of the body, shortness of breath/difficulty breathing, anaphylactic shock.
- Tendency to bruise and/or bleed more than usual.
- Convulsions/fits (occurs rarely).
- Restlessness, skin sensitivity to touch, drowsiness, stomach discomfort.
- Headache, fatigue, dry mouth, dizziness, diarrhea in children. These effects occur often.
- Weakness or malaise, diarrhea. These effects occur infrequently.

**Discontinue use and refer to a doctor if the following effects develop:**

- Hallucinations, confusion, abnormal liver function results, rapid heart rate (occur rarely), fainting.

##### Additional side effects

##### Occur frequently:

- Sore throat.
- Nausea, abdominal pain.
- Nosebleed.
- Soreness.
- Cold-like symptoms of the nose (children only).

##### Occur infrequently

- Nervousness.
- Insomnia.
- Numbness.
- Blistering of the skin.
- Rash and itching.
- Tingling in the hands and feet.

##### Occur rarely

- Edema.
- Tiredness in the morning.
- Depression, aggression.
- Weight gain.
- Tremor, tics, muscle stiffness.
- Changes in sense of taste.
- Vision problems, such as blurred vision.
- Difficulty/pain when passing urine, urinary incontinence.

If any of the side effects worsen or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.

##### Side effects and drug interactions in children:

Parents must report to the attending doctor all side effects and any additional medicine being given to the child!

#### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept 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 the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/label. The expiry date refers to the last day of that month.

- Contains 30 tablets.
- Contains 100 ml syrup.

احتفظ من متناول يدي الأطفال و/أو الرضع، وذلك لتفادي إصابتهم بالتسمم. لا تسبب القيء بدون تعليمات صريحة من الطبيب.

لا يجوز استعمال الدواء بعد انقضاء تاريخ الصلاحية (exp. date) الذي يظهر على ظهر العبوة/المصلحة.

يشير تاريخ الصلاحية إلى اليوم الأخير من نفس الشهر.

شروط التخزين:

أقراص: في مكان جاف، دون ٢٥ درجة مئوية.

شراب: في مكان بارد، دون ٢٥ درجة مئوية.

٦ معلومات إضافية

يحتوي الدواء بالإضافة للمادة الفعالة أيضاً - أقراص

• Storage conditions:  
Tablets: in a dry place, below 25°C.  
Syrup: in a cool place, below 25°C.

#### 6. FURTHER INFORMATION

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

**Tablets**  
Microcrystalline cellulose, lactose anhydrous, magnesium stearate, colloidal silicon dioxide, HPMC, titanium dioxide, polyethylene glycol 400.

Each tablet contains 35 mg lactose.

**Syrup**  
Purified water, sorbitol 2g/5ml, glycerin, propylene glycol, strawberry flavor, sodium citrate, citric acid anhydrous, methyl hydroxybenzoate, propyl hydroxybenzoate.

Each 5 ml of syrup contains 3.4 mg sodium.

**What does the medicine look like and what are the contents of the package?**

**Tablets:** Each package contains 10 or 20 white tablets with a score line on one side.

**Syrup:** The package contains 115 ml clear-pale yellow syrup.

**Manufacturer and license holder:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000 Israel.

This leaflet was checked and approved by the Ministry of Health in June 2014.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Histazine Tablets: 104.99.28579.00  
Histazine Syrup: 109.59.29304.00

• رجفان، خلجات، تصلب العظام.

• تغيرات في حاسة الذائق.

• مشاكل في الرؤية مثل تشوش الرؤية.

• صعوبة أ/م عند التبول، سلس البول.

إذا تفاقمت إحدى الأعراض الجانبية، أو عندما تعاني من عرض جانبي لم يذكر في هذه النشرة، عليك استشارة الطبيب.

الأعراض الجانبية والتفاعلات بين الأدوية لدى الأطفال:

على الوالدين إبلاغ الطبيب المعالج في أي عرض جانبي وكذلك عن كل دواء إضافي يعطى للطفل!

• كيفية تخزين الدواء؟

• تجنب التسمم! يجب حفظ هذا الدواء وكل دواء في مكان مغلق بعيداً عن متناول أيدي الأطفال و/أو الرضع، وذلك لتفادي إصابتهم بالتسمم. لا تسبب القيء بدون تعليمات صريحة من الطبيب.

• لا يجوز استعمال الدواء بعد انقضاء تاريخ الصلاحية (exp. date) الذي يظهر على ظهر العبوة/المصلحة.

يشير تاريخ الصلاحية إلى اليوم الأخير من نفس الشهر.

• شروط التخزين:

• أقراص: في مكان جاف، دون ٢٥ درجة مئوية.

• شراب: في مكان بارد، دون ٢٥ درجة مئوية.

٦ معلومات إضافية

• يحتوي الدواء بالإضافة للمادة الفعالة أيضاً - أقراص

• Storage conditions:  
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إذا تناولت بالخطأ جرعة دوائية أكبر أو إذا بلع الطفل

الخطأ من الدواء، توجه حالا إلى الطبيب أو إلى غرفة الطوارئ في المستشفى وأخضرو عبوة الدواء معك.

إذا نسيت تناول الدواء في الوقت المطلوب، لا يجوز تناول جرعة دوائية مضاعفة. تناول الجرعة الدوائية التالية في الوقت الإعتيادي واستشر الطبيب.

لا يجوز تناول الأدوية في المعتاد، يجب تشخيص طابع الدواء والتأكد من الجرعة الدوائية في كل مرة تتناول فيها الدواء. ضع النظارات الطبية إذا لزم الأمر ذلك.

إذا توفر لديك أسئلة إضافية حول استعمال الدواء، استشر الطبيب أو الصيدلي.

• الأعراض الجانبية

كما بكل دواء، إن استعمال هيمستازين قد يسبب أعراضاً جانبية عند بعض المستعملين. لا تتدهش من قائمة الأعراض الجانبية. من الجائز ألا تعاني أيًا منها.

يجب التوقف عن الاستعمال والتوجه فوراً للطبيب إذا تطورت الأعراض التالية:

• علامات فحائية لحساسية مثل: طفح، حكة، سخونة، إنفوخ في الحنجرة، في الوجه، في الشفتين، في الجفون، في اللسان و/أو في أجزاء أخرى من الجسم، ضيق/صعوبة في التنفس، صدمة إستهدافية.

• الميل للإصابة بجرح و/أو لحدوث نزف أكثر من المعتاد.

• إختلاجات/تشنجات (تظهر في أحيان نادرة).

• قلة راحة، حساسية الجلد للمس، نعاس، إزعاج في المعدة.

• صداع، إرهاق، جفاف الفم، دوار، إسهال لدى الأطفال. تظهر هذه الأعراض في أوقات متقاربة.

• ضعف أو الشعور بوعدة، إسهال. تظهر هذه الأعراض في أوقات متباعدة.

• يجب التوقف عن الاستعمال والتوجه للطبيب إذا تطورت الأعراض التالية:

• هذيان، إرتباك، نتائج غير سليمة لوظائف الكبد، نظم قلب متسارع (تظهر في أوقات نادرة)، إغماء.

• أعراض جانبية إضافية

تظهر في أوقات متقاربة:

• ألم في الحنجرة.

• غثيان، ألم في البطن.

• رعاف.

• الميل للنوم.

• أعراض مشابهة للزكام في الأنف (فقط لدى الأطفال).

• تظهر في أوقات متباعدة

• عصبية.

• آرق.

• تنمل.

• جويصلات في الجلد.

• طفح وحكة.

• وخز في راحتي اليدين والقدمين.

• تظهر في أوقات نادرة

• وذمة.

• شرى.

• إكتئاب، عداية.

• زيادة الوزن.

معبروت ٢٠٢٠٠٤  
منتجات طبية إسرائيلية  
معبروت، م.ض.

تريما  
TRIMA

Maabarot 4023000  
Israel Pharmaceutical Products  
Maabarot Ltd.