

This patient package insert was reviewed and approved by the Ministry of Health in February 2015, and revised in May 2019 in accordance with Ministry of Health guidelines.

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

The medicine is dispensed with a doctor's prescription only

## MIZOLLEN TABLETS 10 mg

Film-coated tablets

SANOFI 

**Active ingredient:** Mizolastine 10 mg.

Inactive ingredients: See Section 6.

**Read this leaflet carefully in its entirety before using the medicine.** Keep this leaflet as you may need to read it again.

This leaflet contains concise information about the medicine.

If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is intended for adults and children above the age of 12.

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

Mizollen is intended for treatment of symptoms of:

- Runny nose and conjunctivitis due to seasonal allergy (hay fever).
- Runny nose and conjunctivitis due to a chronic allergy.
- Urticaria (an itchy skin rash).

**Therapeutic group:** Antihistamine.

### 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient mizolastine or to any other ingredient of the medicine (see Section 6).
- You are taking a macrolide antibiotic, such as erythromycin, clarithromycin, azithromycin.
- You are taking an imidazole antifungal preparation, such as ketoconazole, fluconazole, itraconazole.
- You suffer from liver problems.
- You suffer from heart problems.
- You have a history of irregular heartbeat or a slow heart rate.
- Your ECG (electrical recording of cardiac activity) test results are abnormal.
- You are being treated with medicines for heart rhythm disorders.
- You suffer from electrolyte imbalance, particularly a low blood level of potassium (hypokalaemia).

### Special warnings regarding use of the medicine:

**In the elderly** - Mizollen can make some people feel drowsy and cause a fast heartbeat or heart rhythm disturbances. These effects are more common in the elderly.

### Tests and follow-up

During the course of treatment you may be referred for blood tests and other tests to check how the medicine is affecting you.

This is more likely if:

- You suffer from diabetes (your blood sugar levels are not in order).
- The levels of salt substances in your blood sometimes change (electrolyte imbalance).
- You have problems with your heart beat (cardiac arrhythmias).

### Drug interactions:

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

Do not take the following medicines together with Mizollen:

- Macrolide antibiotics such as erythromycin, clarithromycin, azithromycin.
- Antifungals from the imidazole group such as ketoconazole, fluconazole, itraconazole.

Especially inform the doctor or pharmacist if you are taking or have recently taken:

- cimetidine (for stomach ulcer).
  - ciclosporin (an immunosuppressant).
  - nifedipine (for treatment of high blood pressure or heart conditions).
- Since these drugs can affect the levels of Mizollen (mizolastine) in your blood.

### Using the medicine and food

Mizollen can be taken with food or between meals.

### Use of the medicine and alcohol consumption

Mizollen does not change the effect of alcohol. However, as with any other medicine, you should not consume alcohol in excessive quantities when taking the medicine.

### Pregnancy, breastfeeding, and fertility

Consult your doctor or pharmacist before you take any medicine.

#### Pregnancy

The safety of taking Mizollen during pregnancy is not known.

As with any medicine, you should avoid taking Mizollen during pregnancy, particularly during the first three months of pregnancy.

#### Breastfeeding

Mizolastine passes into breast milk, therefore, Mizollen should not be used during breastfeeding.

### Driving and using machines

You may feel sleepy after taking the medicine. If this happens, do not drive or use machines.

### Important information about some of the ingredients in the medicine:

- Mizollen contains lactose - If your doctor has told you that you are sensitive to some sugars, consult your doctor before taking this medicine.
- Mizollen also contains hydrogenated castor oil, which may cause abdominal pain and diarrhea.

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

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about your dose and how you should take this medicine.

The dosage and manner of use will be determined by the doctor only. The usual dosage is generally:

Adults, including the elderly, and children above 12 years of age: one 10 mg tablet per day.

Swallow the medicine with a lot of water. Do not exceed the recommended dose.

Do not crush/halve/chew the tablets because they are film-coated.

#### If you have accidentally taken too high dosage

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

#### If you forgot to take the medicine

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult with the doctor. Be sure to adhere to the treatment as recommended by the doctor.

#### If you stop taking the medicine

Inform your doctor if you intend to stop taking Mizollen before completion of the recommended course of treatment.

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

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

### 4. SIDE EFFECTS

As with any medicine, use of Mizollen may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

**Stop treatment with Mizollen and contact the doctor immediately if you experience any of the following side effects:** Dizziness, swelling of the face, lips, tongue or throat and difficulty breathing - these may be symptoms of a serious allergic reaction.

**Common side effects** (occurring in 1 to 10 patients in 100):

- dry mouth, headache, dizziness, drowsiness, weakness.
- diarrhea, nausea.
- abdominal pain, indigestion.
- increased appetite associated with weight gain.

**Uncommon side effects** (occurring in 1 to 10 patients in 1,000):

- anxiety, depression.
- changes in the results of blood tests for liver function (increased liver enzymes).
- low blood pressure, rapid or irregular heartbeat.
- joint and muscle pain.

**Very rare side effects** (occurring in less than 1 in 10,000 patients):

- decreased white blood cell count, which increases the risk of

infections.

- serious allergic reaction, which can cause dizziness, swelling of the face, lips, tongue or throat, and difficulty breathing.
- generalized skin rash (urticaria), itching.
- fainting.

**Side effects of unknown frequency** (effects whose frequency has not been established yet):

- vomiting.

Patients having taken Mizollen have also reported: difficulty in breathing or wheezing, worsening of their asthma or slight changes in blood sugar and salts levels. Your doctor may order blood tests to monitor your condition.

Some antihistamines (anti-allergy medicines) have been associated with abnormal ECG results (electrical recording of cardiac activity), and increased risk of irregular heart rhythm.

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

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

## 5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of sight and reach of children and/or infants in order 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) appearing on the package/blister tray. The expiry date refers to the last day of that month.

Storage: At a temperature not above 25°C.

Do not use Mizollen if you notice that the tablets are discolored.

## 6. FURTHER INFORMATION

In addition to the active ingredient, Mizollen also contains:

- In the tablets: lactose monohydrate, hydrogenated castor oil, microcrystalline cellulose, tartaric acid, povidone, magnesium stearate, anhydrous colloidal silica, purified water.
- In the coating: hypromellose, titanium dioxide (E171), propylene glycol.

### **What the medicine looks like and the contents of the package:**

White, oblong, film-coated tablets with a score line on one side and a mark "MZI10" on the reverse side.

The tablets are packed in trays (blisters) made of aluminum/(oPA/Al/PVC). Each package contains 15 tablets.

**This leaflet does not contain all the information about the medicine. If you have any questions or are not sure about anything, please ask your doctor.**

**License holder and address:** Sanofi-Aventis Israel Ltd., 10 Benny Gaon Street, Netanya.

**Manufacturer and address:** Sanofi-Winthrop Industrie, France.  
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 114-94-29697-00