

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Mizollen® 10 mg modified-release tablets

Mizolastine

SANOFI 



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- 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 may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Mizollen is and what it is used for
2. Before you take Mizollen
3. How to take Mizollen
4. Possible side effects
5. How to store Mizollen
6. Further information

1. WHAT MIZOLLEN IS AND WHAT IT IS USED FOR



The active ingredient in Mizollen is mizolastine. Mizolastine is an antihistamine.

Mizollen is used to reduce the symptoms of:

- hay fever (seasonal allergic rhinoconjunctivitis)
- other allergic reactions causing irritation of the eyes and nose (perennial allergic rhinoconjunctivitis)
- urticaria (an itchy skin rash, like nettle rash).

2. BEFORE YOU TAKE MIZOLLEN



Do not take Mizollen

- × if you are allergic (hypersensitive) to mizolastine or any of the other ingredients of Mizollen (see section 6)
- × if you are taking a macrolide antibiotic (such as erythromycin, clarithromycin, azithromycin)
- × if you are taking an imidazole antifungal drug (such as ketoconazole, fluconazole, itraconazole, used to treat fungus infections)
- × if you have liver problems
- × if you have heart problems
- × if you have ever had an irregular heart beat or a slow heart rate
- × if you have an abnormal ECG (electrical recording of your heart beat)
- × if you are already taking medicines for an irregular heart beat
- × if you have abnormal levels of salts in the blood, in particular low potassium levels.

If any of these apply to you, or if you are not sure, talk to your doctor or pharmacist before you take this medicine.



Take special care with Mizollen

In the elderly - Mizollen can make some people feel drowsy and cause a fast or irregular heart beat
- these effects are more likely in the elderly.

Blood tests

Your doctor may carry out regular blood tests and other tests to check how well the medicine is working for you. This is more likely if:

- You have diabetes (your blood sugar level is uncontrolled)
- The levels of salt substances in your blood sometimes change (electrolyte imbalance)
- You have problems with your heart beat (cardiac arrhythmias)



Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken:

- a macrolide antibiotic such as erythromycin, clarithromycin, azithromycin
- an imidazole antifungal drug, such as ketoconazole, fluconazole, itraconazole.

These drugs should not be taken with Mizollen.

You should also tell your doctor or pharmacist if you are taking:

- cimetidine (used to treat stomach ulcers)
- ciclosporin (an immunosuppressant)
- nifedipine (used to treat high blood pressure or heart disease)

because these drugs can affect the levels of Mizollen (mizolastine) in your blood.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Mizollen with food and drink

Mizollen can be taken with food or in between meals. Mizollen does not alter the effects of alcohol. However, just like with any other medicine, you should not drink alcohol in excess when taking Mizollen.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

The safety of Mizollen in human pregnancy has not been established. As with all drugs, Mizollen should be avoided in pregnancy, particularly during the first three months.

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



Driving and using machines

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

Important information about some of the ingredients of Mizollen

Mizollen contains lactose - if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Mizollen.

Mizollen contains hydrogenated castor oil which can cause stomach upset and diarrhoea.



3. HOW TO TAKE MIZOLLEN

Always take Mizollen exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For adults, including the elderly and children aged 12 years and over.

The usual dose is one tablet (10 mg) daily.

The tablets should be taken with plenty of water.

If you take more Mizollen than you should

If you think you have taken too many tablets of Mizollen contact your doctor or nearest hospital emergency department immediately.

If you forget to take Mizollen

If you have forgotten to take a tablet of Mizollen, take the next tablet at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Mizollen

Inform your doctor if you wish to stop your treatment before finishing the course of treatment.



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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mizollen can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking Mizollen if you experience dizziness, swelling of the face, lips, tongue or throat and difficulty in breathing, as these may be signs of a serious allergic reaction.

Common side effects (occurring in more than 1 in 100 patients and less than 1 in 10 patients):

- dry mouth, headache, dizziness, drowsiness, lack of energy
- diarrhoea, nausea
- stomach pain, indigestion
- increased appetite associated with weight gain.

Uncommon side effects (occurring in more than 1 in 1000 patients and less than 1 in 100 patients):

- anxiety and depression
- changes in blood tests which show how the liver is working
- low blood pressure, fast or irregular heart rate
- joint and muscle pains.

Very rare side effects (occurring in less than one in 10 000 patients):

- low numbers of white blood cells which make infections more likely
- serious allergic reaction which can cause dizziness, swelling of the face, lips, tongue or throat and difficulty breathing
- generalised skin rash (nettle rash), itching
- fainting.

Some people taking Mizollen have also experienced: difficulty in breathing or wheezing, worsening of their asthma or small changes in blood sugar levels and blood salts. Your doctor may organise blood tests to monitor your progress.

Some antihistamines (anti-allergy drugs) have been associated with an abnormality in the electrical recording of the heart beat, increasing the risk of an irregular heartbeat.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MIZOLLEN

Keep out of the reach and sight of children.

Do not use Mizollen after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

This medicinal product does not require any special temperature storage conditions.

Refer to the storage conditions on the carton.

Do not use Mizollen if you notice that the tablets become discoloured.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Mizollen contains

- The active substance is mizolastine
- Each tablet contains 10mg of mizolastine
- The other ingredients are:
 - Core: hydrogenated castor oil, lactose monohydrate, microcrystalline cellulose, tartaric acid, povidone, anhydrous colloidal silica, magnesium stearate
 - Film-coating: hypromellose, titanium dioxide (E171), propylene glycol.

What Mizollen looks like and contents of the pack

The tablets are oblong, white with a scored line on one side and a mark "MZI 10" on the reverse side.

It is presented in boxes of 4, 7, 10, 15, 20, 30, 50, or 100 in Aluminium (oPA/Aluminium/PVC) blisters, in Aluminium/PVC blisters or in polypropylene tablet container with polyethylene caps.

Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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