

**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 because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mizollen is and what it is used for.
2. What you need to know before you take Mizollen.
3. How to take Mizollen.
4. Possible side effects.
5. How to store Mizollen.
6. Contents of the pack and other 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. What you need to know before you take Mizollen.



Do not take Mizollen

- × if you are allergic to mizolastine or any of the other ingredients of this medicine (listed in section 6)
- × if you are taking a macrolide antibiotic (such as erythromycin, clarithromycin, azithromycin)
- × if you are taking an imidazole antifungal medicine (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.



Warnings and precautions

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).



Other medicines and Mizollen

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

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

These medicines 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.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 medicines, Mizollen should be avoided in pregnancy, particularly during the first three months.

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



Driving and using machines

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

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.

**Turn
Over**

3. How to take Mizollen.

Always take this medicine 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 medicine, ask your doctor or pharmacist.

4. Possible side effects.

Like all medicines, this medicine 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 (may affect up to 1 in 10 people):

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

Uncommon side effects (may affect up to 1 in 100 people):

- 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 (may affect up to 1 in 10,000 people):

- 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.

Other side effects with frequency not known (frequency cannot be estimated from available data):

- vomiting.

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 medicines) have been associated with an abnormality in the electrical recording of the heart beat, increasing the risk of an irregular heartbeat.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mizollen.

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Refer to the storage conditions on the carton.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other 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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