

PACKAGE LEAFLET: INFORMATION FOR THE USER

MIOKARPIN

2% w/v Eye Drops, Suspension

PILOCARPINE HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 signs of illness 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 •

What is in this leaflet?

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

1. WHAT MIOKARPIN IS AND WHAT IS IT USED FOR

MIOKARPIN contains a miotic agent. It is used to make the pupil of the eye smaller.

Your doctor or eye specialist may use it to:

- reverse the effects of eye drops which cause the pupil to enlarge
- treat high pressure of liquid inside the eye (glaucoma) in emergency situation

This medicine is indicated for children, adults and the elderly.

2. BEFORE YOU TAKE MIOKARPIN

Do not use these drops if

- you are allergic to the active substance (pilocarpine hydrochloride).
- you have had an allergy to other miotic agents in the past
- you have some particular eye conditions where the constriction of the pupil should be avoided (e.g. inflammation of the iris, some forms of glaucoma)
- you wear soft contact lenses.

Take special care

Ask yourself the following questions:

- Do you have a heart disease (heart failure)?
- Do you have asthma?
- Do you have stomach ulcers?
- Do you have high blood pressure?
- Do you have problems with passing urine?
- Do you have Parkinson's disease?
- Do you have any other eye conditions?

If the answer to any of these questions is yes, tell your doctor or eye specialist.

Do you use any of these medicines

- creams or pills containing corticosteroids
- medicines belonging to a family called anticholinergics
- medicines used to treat allergic reactions (e.g. hayfever, hives) called antihistamines
- a pain killer called pethidine
- medicines used to treat depression
- any other medicine used to make the pupil of the eye smaller

If the answer to any of these questions is yes, tell your doctor or eye specialist

If you are pregnant, may be pregnant, or are breastfeeding

Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

Contact lenses

Do not use these eye drops if you wear soft contact lenses. Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore, do not wear your contact lenses until the effects of the drops have completely worn off.

Driving and using machines

These eye drops may affect your ability to focus and/or see in the dark.

As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

3. HOW TO TAKE MIOKARPIN

Dosage

Your doctor or eye specialist will decide the appropriate dosage of MIOKARPIN depending on the reason for which it has been prescribed. He/she will give you more detailed instructions. Make sure you follow these instructions carefully.

Method of administration

Make sure you follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue, and twist off the cap from the MIOKARPIN body of the unit.
4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid.
5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary.

If you use more MIOKARPIN than you should, an overdose is very unlikely to occur. If you suddenly feel unwell after receiving the drops, tell your doctor or eye specialist or contact your nearest emergency department immediately.

4. POSSIBLE SIDE EFFECTS

- Reactions in and around the eyes can occur: sensations of burning, itching, stinging, blurring of vision, discomfort in the eyes and red eyes.
- You may have difficulty to focus and/or adjust your eyes to the dark and experience bleeding in the main part of the eye.
- You may experience changes to your eyes when you use the product for a long period.
- Browache or headache may occasionally occur, especially in younger patients who have just started using this medicine.
- Other reactions have been rarely reported: low blood pressure, abnormally slow heart beat, wheezing and shortness of breath, salivation, sweating, sickness, diarrhoea and watering of the eyes.

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

5. HOW TO STORE MIOKARPIN

Keep out of the reach and sight of children.

Make sure the container is properly closed after each use.

Do not use the eye drops after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. Store in the original package in order to protect from light.

Dispose of this medicine four weeks after opening.

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.