

Drug Information Sheet("Kusuri-no-Shiori")

External

Revised: 11/2022

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Timoptol-XE Ophthalmic Solution 0.5%

Active ingredient: Timolol maleate

Dosage form: colorless to slightly white, slightly viscous, ophthalmic solution, 2.5mL, (bottle) clear and colorless, (cap) white [label of one vivid red purple line]

Imprint or print on wrapping:



Effects of this medicine

This medicine lowers pressure in the eye by reducing production of aqueous humor by blocking beta-receptor. It is usually used to treat glaucoma or ocular hypertension.

The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods. If you have: bronchial asthma/history of bronchial asthma, bronchospasm, chronic obstructive pulmonary disease, heart failure, sinus bradycardia, atrioventricular block, cardiogenic shock, right-sided heart failure secondary to pulmonary hypertension, congestive heart failure, diabetic ketoacidosis, metabolic acidosis, or diabetes. If you wear contact lenses.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, apply 1 drop of 0.25% preparation at a time, once a day. If there is not enough effect, apply 1 drop of 0.5% preparation at a time, once a day. This medicine is 0.5% preparation. Strictly follow the instructions.
- Before applying, wash your hands thoroughly with soap and running water. Next, shake the bottle once and open the cap (there is no need to shake many times). Pull down your lower eyelid and apply the medicine. Be careful not to touch the dropper tip to your eyelid, eyelashes, or eye. After applying, keep your eyes closed without blinking for a while (1 to 5 minutes), and apply gentle pressure to your tear ducts (located in the inner corners of the eyes) with your fingertips. Wipe off any excess liquid gently with clean gauze or a tissue. If you need to apply other eye drops at the same time, apply other eye drops first and wait more than 10 minutes before applying this medicine.
- If you miss a dose, apply 1 drop as soon as possible in case of the same day. If you notice on the next day, skip the missed dose and continue your regular dosing schedule. You should not apply twice a day or 2 drops at one time.
- If you accidentally apply more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop applying this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause blurred vision or leaving a greasy feeling in the eyes for a few minutes after applying.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include stinging eyes (burning sensation/ itch/ foreign body sensation). If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- bloodshot eyes, itchy eyes, foreign body sensation in eyes [ocular pemphigoid]
- shortness of breath, breathing difficulty, wheezing (whistling sound) [bronchospasm, respiratory distress, respiratory failure]
- respiratory distress, loss of consciousness, dizziness on standing up [heart block, congestive heart failure, cerebral ischemia, cardiac arrest, cerebrovascular disorder]
- fever, red rash, general malaise [systemic lupus erythematosus]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- The amount of contents seems to be insufficient because 2.5 mL of solution is packed in a 5 mL plastic bottle.
- Keep out of reach of children. Keep in a shading bag and store at room temperature (1 to 30 degrees Celsius) away from light and moisture and freezing.

•Discard the remainder. Do not store them. If you do not know how to discard of it, please ask your pharmacy or medical institution on how to discard them. Do not give it to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.