



## PACKAGE LEAFLET

### **ZOMRANIP-T 1% + 0.5% Eye Drops, Suspension**

**Instilled into the eye(s).**

**Sterile**

**Active substance(s):** 10 mg/ml brinzolamide and 5 mg/ml timolol (equivalent to 6.8 mg timolol maleate)

**Excipient(s):** Benzalkonium chloride, mannitol, carbomer 974 P, tyloxapol, disodium EDTA, sodium chloride, hydrochloric acid and sodium hydroxide (for pH adjusting), water for injection.

**Read all of this LEAFLET carefully before you start using 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you visit a doctor or hospital while using this medicine, tell them that you are using this medicine.*
- *Please, follow the instructions in this leaflet. Do not use any **higher** or **lower** doses than the recommended dose of this medicine.*

#### **What is in this leaflet:**

- 1. What ZOMRANIP-T is and what it is used for***
- 2. What you need to know before you use ZOMRANIP-T***
- 3. How to use ZOMRANIP-T***
- 4. Possible side effects***
- 5. How to store ZOMRANIP-T***

#### **1. What is ZOMRANIP-T and what it is used for**

ZOMRANIP-T is a white to off-white suspension. It is available in a package of 5 ml eye drops with a screw cap.

ZOMRANIP-T is used to treat high pressure within the eyes in adult patients. This pressure can cause a condition called glaucoma or ocular hypertension.

ZOMRANIP-T is a combination drug for the treatment of glaucoma. The active substances of the drug (brinzolamide and timolol) reduce pressure within the eye.

#### **2. What you need to know before you use ZOMRANIP-T**

**DO NOT use ZOMRANIP-T in the following conditions:**

- If you are allergic to any of the ingredients of ZOMRANIP-T. Please see the active substances and excipients section for the full list of ingredients.
- If you have now or have had in the past respiratory problems such as asthma, long lasting obstructive bronchitis (severe lung condition which may cause difficulty in breathing and/or long standing cough) or other types of breathing problems.



- If you have severe allergic rhinitis, overactivity of the bronchi.
- If you have a slow heartbeat, overt heart failure, heart block, disorders of heart rhythm or cardiogenic shock.
- If you have too much acidity in your blood (a condition called hyperchloremic acidosis).
- If you have severe kidney failure.
- If you are hypersensitive to sulfonamides. Examples include medicines to treat diabetes and infections, and also diuretics (water tablets). ZOMRANIP-T may cause a similar allergy.
- If you are hypersensitive to other beta-blockers.
- If you have severe hay fever.

**Use ZOMRANIP-T with SPECIAL CARE in the following conditions:**

- If signs of serious reactions or hypersensitivity occur, discontinue the use of this product and talk to your doctor.
- If you have coronary artery disease (symptoms include chest pain or tightness, breathlessness or shock), heart failure, tell your doctor before starting ZOMRANIP-T treatment.
- If you have disturbances of heart rate such as slow heart beat
- If you have breathing difficulties due to narrowing of the airways, such as asthma or chronic obstructive pulmonary disease, tell your doctor before starting ZOMRANIP-T treatment.
- If you have chest pain (angina), blood circulation disease (such as Raynaud's disease or Raynaud's syndrome), or low blood pressure, ZOMRANIP-T may make these worse. If you notice any change in these symptoms, tell your doctor as soon as possible.
- If you have diabetes. ZOMRANIP-T can mask symptoms of low blood sugar (hypoglycemia), such as tremors and dizziness, so you should use it with caution.
- ZOMRANIP-T may mask the signs of overproduction of thyroid hormone in the body. Talk to your doctor if you have such a condition.
- If you have myasthenia gravis (a muscle weakness disease)
- If you have liver failure, talk to your doctor.
- If you have dry eyes or problems with the clear layer at the front of the eye, tell your doctor.
- If you have a severe allergic reaction while using ZOMRANIP-T for any reason, adrenaline treatment may not be effective. When receiving any other treatment please tell the doctor or nurse that you are taking ZOMRANIP-T.
- Because it may weaken the ability to perform tasks that require mental alertness and/or physical coordination in the elderly, be careful in performing tasks that require care while using ZOMRANIP-T.
- If you have kidney failure, use it with caution.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using ZOMRANIP-T or other related medicines, use it with caution.
- Tell your doctor before you have an operation that you are using ZOMRANIP-T as timolol may change effects of some medicines used during anesthesia.



Take special care with ZOMRANIP-T:

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with sulfonamide drugs. Stop using ZOMRANIP-T and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If any of these warnings apply to you, even for a period in the past, please consult your doctor.

**Using ZOMRANIP-T with food and drinks**

When used as directed, the product does not interact with food or drink.

**Pregnancy**

*Ask your doctor or pharmacist before you start to use this medicine.*

You should not use ZOMRANIP-T if you are pregnant or might get pregnant, unless your doctor considers it necessary.

*Talk to your doctor or pharmacist immediately if you find out that you are pregnant during treatment.*

**Breastfeeding**

*Ask your doctor or pharmacist before you start to use this medicine.*

You should not use ZOMRANIP-T if you are breast-feeding. Timolol may pass into milk.

**Driving and using machines**

Do not drive or use machines until your vision is clear. You may find that your vision is blurred for some time just after using ZOMRANIP-T.

One of the active ingredients may impair the ability to perform tasks requiring mental alertness and/or physical coordination. If you have these symptoms and blurred vision, do not drive or use machines.

**Important information about some of the ingredients of ZOMRANIP-T**

ZOMRANIP-T contains a preservative (benzalkonium chloride) which may cause eye irritation. Avoid contact with soft contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. It is known to change the color of the soft contact lenses.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

**Using with other medicines**

ZOMRANIP-T can affect, or be affected by, other medicines you are taking, including other eye drops for the treatment of glaucoma.

Tell your doctor if you are taking or intend to take medicines to lower blood pressure like parasympathomimetics and guanethidine, or other heart medicines including quinidine (used to treat heart conditions and some types of malaria), amiodarone or other medicines to treat heart rhythm disorders and glycosides to treat heart insufficiency. Also tell your doctor if you are taking or intend to take medicines to treat diabetes, or to treat gastric ulcers, antifungal (ketoconazole, itraconazole, clotrimazole), antiviral (ritonavir) or antibiotic medicines (troleandomycin), or antidepressants such as fluoxetine and paroxetine.

If you are receiving another carbonic anhydrase inhibitor (acetazolamide or dorzolamide), speak to your doctor.

Increase in pupil size when taking brinzolamide/timolol and adrenaline (epinephrine) together has been reported occasionally.

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

### 3. How to use ZOMRANIP-T

#### Instructions for appropriate use and dose/frequency of administration

Always use ZOMRANIP-T exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure.

If you are changing from another eye drop medicine used to treat glaucoma to ZOMRANIP-T, you should stop using the other medicine and start using ZOMRANIP-T the following day.

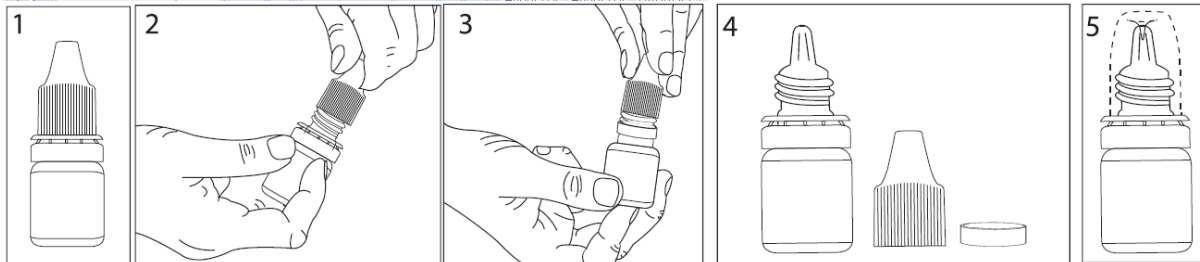
The usual dose for adults is 1 drop in the affected eye or eyes twice daily, morning and evening. Only use ZOMRANIP-T in your eyes if your doctor told you to.

Take it for as long as your doctor told you to. If a drop misses your eye, try again.

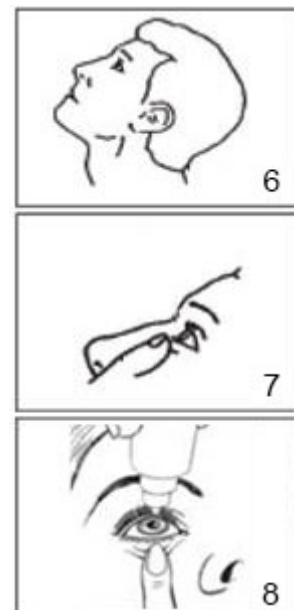
If you are using other eye drops, wait at least 5 minutes before using ZOMRANIP-T. Eye ointments should be administered last.

#### Route and method of administration

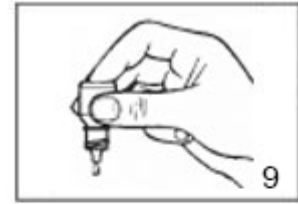
ZOMRANIP-T is instilled in eyes. Do not use the product in any other way.



- Get the ZOMRANIP-T bottle (see Figure 1).
- Wash your hands.
- Shake well the bottle before use.
- Twist off the bottle cap (see Figure 2). Remove the ring under the cap (see Figure 3 and Figure 4).
- Close the cap again without the ring. The plastic pin inside the cap will pierce the tip of the bottle (see Figure 5).
- Hold the bottle, pointing down, between your thumb and fingers.
- Move your head back. Tilt your head back and see the ceiling (see Figure 6).
- Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye (see Figure 7). The drop will go in here (see Figure 8).
- Bring the bottle tip close to the eye. Use the mirror if it helps.
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- Turn the bottle upside down and apply 1 drop into the affected eye (see Figure 8).



- Gently press on the base of the bottle to release 1 drop of ZOMRANIP-T at a time (see Figure 9).
- Release your lower eyelid and keep your eye closed for 30 seconds (see Figure 10).
- After using ZOMRANIP-T, press a finger into the corner of your eye, by the nose (see Figure 11). This helps to stop ZOMRANIP-T getting into the rest of the body.
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Use up a bottle before opening the next bottle.



### **Special age groups**

#### Use in children

ZOMRANIP-T is not recommended for children under 18 years.

#### Use in the elderly

No significant differences in safety and efficacy were observed between the elderly and other adult populations.

### **Special conditions for use**

None.

*If you think that the effect of ZOMRANIP-T is too strong or too weak, talk to your doctor or pharmacist.*

### **If you take more ZOMRANIP-T than you should**

Rinse your eye with warm water. In case of overdose with ZOMRANIP-T, you may experience a decreased heart rate, decreased blood pressure, heart failure, difficulty breathing and your nervous system may be affected. Do not put in any more drops until the next use.

*Talk to a doctor or pharmacist if you have used more ZOMRANIP-T than you should.*

### **If you forget to use ZOMRANIP-T**

*Do not use a double dose to make up for a forgotten dose.*

If you forget to use ZOMRANIP-T, continue with the next dose as planned.

Do not use more than 1 drop in the affected eye(s) twice daily.

### **Possible effects if you stop using ZOMRANIP-T**

If you stop using ZOMRANIP-T speaking to your doctor, the pressure in your eye will not be controlled which could lead to loss of sight.

### **4. Possible side effects**

As with all other medicines, ZOMRANIP-T may cause side effects in people with hypersensitivity to its ingredients.



**Stop using ZOMRANIP-T and IMMEDIATELY tell your doctor or refer to your nearest hospital emergency department if any of the following occurs:**

Severe redness and itching of the eye, reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

You can usually carry on using ZOMRANIP-T, unless the effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop using ZOMRANIP-T without speaking to your doctor first.

These are all very serious side effects.

- If you have any of them, you are severely allergic to ZOMRANIP-T. Urgent medical care or hospitalization may be needed.

However, there may be conditions where the medicine should be discontinued and urgent medical care is needed, other than some allergic side effects.

- If you have any of these conditions, you may need urgent medical care or hospitalization.

Side effects are listed as shown in the categories below:

Very common	: May affect more than 1 in 10 patients.
Common	: May occur in less than 1 in 10 but more than 1 in 100 patients.
Uncommon	: May occur in less than 1 in 100 but more than 1 in 1,000 patients.
Rare	: May occur in less than 1 in 1,000 but more than 1 in 10,000 patients.
Very rare	: May occur in less than 1 in 10,000 patients.
Unknown	: Frequency cannot be estimated from the available data.

### **Common side effects**

**Effects in the eye:** Blurred vision, eye surface inflammation, eye pain, signs of eye irritation (burning, stinging, itching, tearing, redness)

**General side effects:** Taste disturbances, decreased heart rate

### **Uncommon side effects**

**Effects in the eye:** Corneal erosion (damage to the front layer of the eyeball), eye surface inflammation with surface damage, itchy eye, eye redness, eyelid redness, corneal staining, inflammation inside the eye, abnormal sensation in the eyes, eye discharge, dry eye, tired eyes.

**General side effects:** Decreased blood pressure, decrease in white blood cell count, blood in urine, body weakness, cough

### **Rare side effects**

**Effects in the eye:** Corneal disorder, sensitivity to light, increased tear production, eyelid crusting

**General side effects:** Difficulty sleeping (insomnia), throat pain, running nose



**Side effects with unknown frequency**

**Effects in the eye:** Disturbance of vision, damage to the optic nerve, increased eye pressure, deposits on the eye surface, corneal disorder, decreased eye sensation, inflammation or infection of the conjunctiva, abnormal, double or reduced vision, increased pigmentation of the eye, growth on surface of eye, increased tear production, eye swelling, sensitivity to light, decreased growth or number of eyelashes, drooping of the upper eyelids (making the eye stay half closed), inflammation of the eyelid and eyelid glands, inflammation in the cornea and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity

**General side effects:** Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

**Heart and circulation:** Changes in rhythm or rate of the heartbeat, slow heart rate, palpitations, a type of heart rhythm disorder, chest pain, reduced heart function, heart attack, increased blood pressure, reduced blood supply to the brain, stroke, edema (fluid build up), congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), swelling of the extremities, low blood pressure, discoloration of the fingers, toes, and occasionally other areas of the body (Raynaud's phenomenon), cold hands and feet.

**Respiratory:** Constriction of the airways in the lungs (predominantly in patients with pre-existing disease) shortness of breath or difficulty breathing, cold symptoms, chest congestion, sinus infection, sneezing, stuffy nose, dry nose, runny nose, nose bleeds, asthma, throat irritation.

**Nervous system and general disorders:** Depression, nightmares, memory loss, headache, nervousness, irritability, tiredness, shaking, feeling abnormal, fainting, dizziness, drowsiness, generalized or severe weakness, unusual sensations like pins and needles.

**Stomach and gut:** Nausea, vomiting, diarrhea, intestinal gas or abdominal discomfort, inflammation of the throat, dry or abnormal sensation in mouth, indigestion, stomach ache.

**Blood:** Abnormal liver function values, increased blood chlorine levels, or decreased red blood cell count as seen in a blood test.

**Skin:** Rash, skin redness or inflammation, abnormal or decreased skin sensation, hair loss, rash with white silvery colored appearance (psoriasiform rash) or worsening of psoriasis.

**Muscles:** Generalized back, joint, or muscle pain not caused by exercise, muscle spasms, pain in extremities, muscle weakness/tiredness, increases in the signs and symptoms of myasthenia gravis (muscle disorder).



**Ear:** Ringing in the ears, sensation of spinning or dizziness.

**Kidney:** Kidney pain such as lower back pain, frequent urination

**Reproduction:** Sexual dysfunction, decreased libido, male sexual difficulty

**Metabolism:** Low blood sugar levels.

*Please inform your doctor or pharmacist if any of the side effects listed in this leaflet get worse or if you experience another side effect not listed in this leaflet.*

#### Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. How to store ZOMRANIP-T**

*Keep ZOMRANIP-T out of the reach and sight of children, and in its package.*

Store at room temperature under 25°C.

After opening, use within 28 days and store at room temperature below 25°C.

#### **Use it in accordance with the expiry date.**

*Do not use ZOMRANIP-T after the expiry date, which is stated on the pack.*

The expiry date refers to the last day of that month.

Write down the first opening date of the bottle on carton in the space provided.

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.

#### ***Marketing authorization holder:***

DEVA Holding A.Ş.

Küçükçekmece - İSTANBUL / TÜRKİYE

#### ***Manufacturing site:***

DEVA Holding A.Ş.

Kartepe - KOCAELİ / TÜRKİYE

*This package leaflet was approved on 20/12/2023.*