

# GLAALPHA combination ophthalmic solution (4.0 mg/mL ripasudil and 1.0 mg/mL brimonidine tartrate)

Ripasudil (4.0 mg/mL) and Brimonidine tartrate (1.0 mg/mL)

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## What GLAALPHA is used for

GLAALPHA is used to treat patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to monotherapy.

## How GLAALPHA works

GLAALPHA contains two active substances: ripasudil (Rho kinases inhibitor) and brimonidine tartrate ( $\alpha_2$ -adrenergic receptor agonist). These two components decrease elevated intraocular pressure (IOP) by complementary mechanisms of action and the combined effect results in additional IOP reduction compared to either compound administered alone.

GLAALPHA is used to reduce the pressure in your eye if you have conditions known as glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will prescribe you GLAALPHA when other medicines have not worked adequately.

## Before you use GLAALPHA

GLAALPHA can be used in adult, including the elderly.

### - When you must not use it

Do not use GLAALPHA:

- if you are allergic to ripasudil and brimonidine tartrate or any of the other

ingredients of this medicine (see "Product Description").

- GLAALPHA is contraindicated for low birth weight infants, newborns, infants, and children under 2 years of age.

### - Before you start to use it

Warnings and precautions:

Talk to your doctor or pharmacist before using GLAALPHA and during treatment, if you have any of the following signs or symptoms:

- Eye redness (conjunctival hyperaemia) Conjunctival hyperaemia after instillation is usually transient. Tell your doctor or pharmacist if it persists for a long time.

Talk to your doctor or pharmacist before using GLAALPHA if you have now or have had in the past:

- You have cerebrovascular disorders or orthostatic hypotension.
- You have cardiovascular diseases.
- You are or may be pregnant.
- You are breastfeeding.
- You wear contact lenses. Follow the instructions for contact lens wearers (see "Contact lenses wearers")

### - Taking other medicines

It is known that caution is required in case of co-administration of brimonidine tartrate ophthalmic solution with antihypertensives, central nervous system depressants (e.g., barbiturates, opioid analgesics, sedatives, and anesthetics), alcohol, and monoamine oxidase inhibitors. Although specific medicinal product interaction studies have not been performed with GLAALPHA, concomitant administration of GLAALPHA with the above should be avoided because it contains brimonidine.

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

medicines obtained without a prescription.

## How to use GLAALPHA

### - How much to use

The usual dosage for adults (including the elderly) is one drop in the affected eye(s), twice a day.

Usually, this means one drop in the morning and one drop in the evening.

For the instillation, you should tilt your head backwards, open the affected eye, pull the lower eyelid down to form a small pocket, instil GLAALPHA into the pocket, close the eyelid for 1 to 5 minutes while pressing a finger into the corner of your eye by nose, and open the eye.

Be careful not to touch the tip of the bottle against your eye, eyelid, eyelashes or anything else during the instillation in order to prevent contamination of the medicine.

Instil with an interval of at least 5 minutes when using the medicine in combination with other ophthalmic solutions.

### - Contact lenses wearers

If you wear contact lenses, you should remove them before using GLAALPHA. After using GLAALPHA you should wait at least 5 minutes before putting your contact lenses back in. Avoid instillation while wearing a soft contact lens. (Benzalkonium chloride contained in GLAALPHA may be adsorbed by the soft contact lens.)

### - When to use it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### - How long to use it

Use GLAALPHA as instructed by your doctor until your doctor tells you to stop.

### - If you forget to use it

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If you miss a dose of GLAALPHA, take it as soon as you remember and then go back to your regular routine.

If, however, it is almost time for your next dose, skip the dose you missed and take your next dose at usual time.

Do not take a double dose to make up to the dose you missed.

If you are unsure about anything, talk to your doctor or pharmacist.

### - If you use too much (overdose)

No case of overdose of GLAALPHA has been reported and is unlikely to occur after ocular administration. If overdose occurs, treatment should be symptomatic and supportive.

### - If you swallow it

If GLAALPHA is accidentally swallowed, you should immediately contact your doctor for advice.

### **While you are using GLAALPHA**

#### - Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the healthcare professionals treating you that you are taking GLAALPHA.

Tell your doctor immediately if you become pregnant while taking GLAALPHA.

#### - Things you must not do

Do not stop taking GLAALPHA without the advice of your doctor even if you feel better.

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

Do not take any new medicines without consulting your doctor.

Do not give GLAALPHA to anyone else, even if they have the same symptoms or condition as you.

#### - Things to be careful of

Driving and using machines:

If you feel sleepy, dizzy and blurred vision, do not drive or operate machines until these side effects have gone away.

### **Side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effects, talk to your doctor or pharmacist.

The following side effects may be seen with GLAALPHA:

- Eye problems, such as eye redness, eye inflammation (including conjunctivitis allergic), eyelid inflammation (including blepharitis allergic), eye irritation, eye surface disorder, corneal inflammation (keratitis), itchy eye, eyelid redness, eyelid swelling, eye swelling (conjunctival oedema), follicles or white spots on eye (conjunctival follicles), eye haemorrhage (conjunctival haemorrhage), dry eye (keratoconjunctivitis sicca), eye discharge, eye pain, foreign body sensation in eyes, blurred vision, eyestrain (asthenopia), increased tear shedding, abnormal sensation in eye
- Hypersensitivity (skin rashes)
- Cardiovascular disorders (low blood pressure, high blood pressure, rapid heartbeat)
- Cough, vertigo, drowsiness
- Dry mouth, thirst, taste abnormality
- Lack of energy

Eye redness usually occurs transiently at the time of instillation. The incidence of conjunctivitis allergic and blepharitis allergic tends to be high in patients with long-term instillation. If it continues, talk to your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

### **Storage and Disposal of GLAALPHA**

#### - Storage

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

Do not store above 30°C.

#### - Disposal

Discard four weeks after first opening.

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.

### **Product Description**

#### - What it looks like

GLAALPHA is a pale yellow-green, clear liquid sterile aqueous ophthalmic solution.

It is packed in a bottle of 5mL.

#### - Ingredients

- Active ingredients

- Ripasudil hydrochloride hydrate

- Brimonidine tartrate

- Other ingredients

Sodium dihydrogen phosphate, sodium chloride, Sodium hydroxide, Benzalkonium chloride concentrated solution 50, Purified water

#### - MAL number:

MAL25076011AZ

### **Manufacturer**

Kowa Company, Ltd., Mohka Factory  
21-1, Matsuyama-Cho, Mohka, Tochigi,  
JAPAN

### **Product Registration Holder**

DKSH Malaysia Sdn Bhd  
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### **Date of revision**

16/07/2025

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