AIM

0.5mL

Anme Eye Drops 0.5%

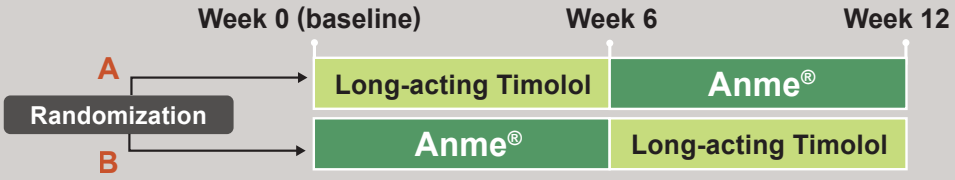
Composition	Each mL contains : Timolol 5mg (eq. to Timolol Maleate 6.8mg)
Indication	Glaucoma
Pharmacological mechanism	It is a non-selective beta blockers that reduce aqueous humor production.
Usage	Administer one drop topically to the eye(s) two times a day.
Precautions	Please use caution in the following four patient groups : 1. Those allergic to Timolol eye drops. 2. Individuals with asthma or a history of asthma, or those with chronic obstructive pulmonary disease (COPD), should not use Timolol Maleate. 3. Patients with heart failure. 4. Those with sinus bradycardia (slow heart rate).
Storage	Store below 25℃. Avoid direct sunlight and direct light.

Regulations for the Use of Single-Dose Glaucoma Eye Preparations under National Health Insurance

High Intraocular Pressure and Glaucoma Eye Preparations
The dosage regimen for this category of drugs is as follows :
For single-use packaging (preservative-free), prescribed limits per eye or both eyes every 4 weeks are as follows :
(1) For once daily use, limited to 30 units or fewer.
(2) For twice daily use, limited to 60 units or fewer.

Anme Eye Drops 0.5% / 0.5mL	Long-acting glaucoma eye drops from other brands. / 2.5mL

Timolol 5mg/mL
Administer one drop topically to the eye(s) two times a day.



(At Taipei Veterans General Hospital was conducted a randomized, open-label, crossover study.)

The effectiveness comparison :

1. Intraocular Pressure（IOP）: The reduction in IOP in the Anme group is comparable to the control group.

When comparing the IOP between the two groups, the Anme group consistently showed a greater reduction than the control group, with an average difference ranging from 0.24 to 1.27 mmHg. However, there was no statistically significant difference between the Anme group and the control group, indicating that the effectiveness of Anme is not inferior to the control group.

2. Tear Film Break-up Time（BUT）: Anme provides better protection of the tear film compared to the control group.

The average increase in tear film break-up time for both left and right eyes in the Anme group was 1.3 seconds and 0.8 seconds, respectively. In contrast, the tear film break-up time decreased on average by 1.7 seconds and 1.5 seconds for the left and right eyes in the control group, suggesting that the tear film stability was negatively affected in the control group.

3. Anme significantly reduces the scores of corneal punctate keratitis (SPK) compared to the control group.

Both left and right eyes in the Anme group showed a reduction in SPK scores at the second follow-up assessment, with statistically significant differences observed in the SPK scores of the right eye compared to baseline. The average reduction in SPK scores for both left and right eyes in the Anme group was 0.4. In contrast, the average reduction in SPK scores for the left and right eyes in the control group was only 0.1 and 0.2, respectively.

Safety Comparison :

There was no statistically significant difference in the incidence rate of side effects between the two groups.

Overall Results Analysis :

The Anme group demonstrated comparable effectiveness in reducing intraocular pressure (IOP) to the control group, with some instances showing superior outcomes compared to the control group. Additionally, the reduction in IOP was more consistent in the Anme group. Furthermore, in terms of tear film break-up time (BUT) and corneal punctate keratitis (SPK), the Anme group outperformed the control group, clearly enhancing corneal protection.

Moreover, Anme exhibits advantages over the control group for the following reasons :
1) Single-dose packaging to mitigate the risk of eye infections.
2) Absence of preservatives in the medication, reducing the risk for patients.
The use of preservatives may increase the risk of allergic reactions among trial participants. Apart from reports in the Pharmacist's Association Journal on the impact of excipients, the Taiwan Food and Drug Administration has conducted research and analysis on international requirements and regulations concerning excipient contents. They have also addressed potential risks associated with preservatives. In 2019, under Announcement No. 1081406576 by the Ministry of Health and Welfare, amendments were made to the "Guidance for Drug Review - Ophthalmic Preparations," mandating the labeling of preservative types and the addition of warnings.

Anme has been unanimously recommended for use by all glaucoma specialists and the Pharmacy Committee within the Ophthalmology Department at Taipei Veterans General Hospital.