

Package leaflet: Information for the user

Brinzolamide/ Timolol Mylan 10 mg/ml + 5 mg/ml eye drops, suspension

brinzolamide/timolol

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, 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 illnesses 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. See section 4.

What is in this leaflet

1. What Brinzolamide/Timolol Mylan is and what it is used for
2. What you need to know before you use Brinzolamide/Timolol Mylan
3. How to use Brinzolamide/Timolol Mylan
4. Possible side effects
5. How to store Brinzolamide/Timolol Mylan
6. Contents of the pack and other information

1. What Brinzolamide/Timolol Mylan is and what it is used for

Brinzolamide/Timolol Mylan contains two active substances, brinzolamide and timolol, which work together to reduce pressure within the eye.

Brinzolamide/Timolol Mylan is used to treat high pressure in the eyes, also called glaucoma or ocular hypertension, in adult patients that are more than 18 years of age and in whom high pressure in the eyes cannot be controlled effectively by one medicine alone.

2. What you need to know before you use Brinzolamide/Timolol Mylan

Do not use Brinzolamide/Timolol Mylan:

- If you are allergic to brinzolamide, medicines called sulphonamides (examples include medicines used to treat diabetes, infections) and also diuretics (water tablets), timolol, beta-blockers (medicines used to lower blood pressure or to treat heart disease) or any of the other ingredients of this medicine (listed in section 6).
- If you have now or have had in the past respiratory problems such as asthma, severe long lasting obstructive bronchitis (severe lung condition which may cause wheezing, difficulty in breathing and/or long standing cough) or other types of breathing problems.
- If you have severe hay fever
- If you have a slow heart beat, heart failure or disorders of heart rhythm (irregular heartbeats).
- If you have too much acidity in your blood (a condition called hyperchloraemic acidosis).
- If you have severe kidney problems.

Warnings and precautions

Only use Brinzolamide/Timolol Mylan for dropping in your eye(s).

If signs of serious reactions or hypersensitivity occur, discontinue the use of this product and talk to your doctor.

Talk to your doctor or pharmacist before using Brinzolamide/Timolol Mylan if you have or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- disturbances of heart rate such as slow heart beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms of thyroid disease
- muscular weakness (myasthenia gravis)
- tell your doctor before you have an operation that you are using Brinzolamide/Timolol Mylan as timolol may change effects of some medicines used during anaesthesia.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using brinzolamide or other related medicines.
- if you have a history of atopy (a tendency to develop an allergic reaction) and severe allergic reactions you may be more sensitive to developing an allergic reaction whilst using Brinzolamide/Timolol Mylan and adrenaline may not be as effective to treat an allergic reaction. When receiving any other treatment please tell the doctor or nurse that you are taking Brinzolamide/Timolol Mylan.
- if you have liver problems.
- if you have dry eyes or cornea problems.
- if you have problems with your kidneys.

Take special care with Brinzolamide/Timolol Mylan

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with Brinzolamide/Timolol Mylan treatment. Stop using

brinzolamide and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children and adolescents

Brinzolamide/Timolol Mylan is not recommended for children and adolescents under 18 years.

Other medicines and Brinzolamide/Timolol Mylan

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Brinzolamide/Timolol Mylan 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 guanetidine, 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, antiviral or antibiotic medicines, or antidepressants such as fluoxetine and paroxetine.

If you are taking another carbonic anhydrase inhibitor (acetazolamide or dorzolamide), talk to your doctor. Increase in pupil size when taking Brinzolamide/Timolol Mylan and adrenaline (epinephrine) together has been reported occasionally.

Pregnancy and breast-feeding

You should not use Brinzolamide/Timolol Mylan if you are pregnant or might get pregnant, unless your doctor considers it necessary. Talk to your doctor before you use Brinzolamide/Timolol Mylan.

Do not use Brinzolamide/Timolol Mylan if you are breast feeding, timolol may get into your milk.

Ask your doctor for advice before taking any medicine during breastfeeding.

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 Brinzolamide/Timolol Mylan.

One of the active ingredients may impair the ability to perform tasks requiring mental alertness and/or physical coordination. If affected take care when driving or using machines.

Brinzolamide/Timolol Mylan contains benzalkonium chloride

This medicine contains 0.0033 mg benzalkonium chloride in each drop which is equivalent to 0.01% or 0.1 mg/ml.

Benzalkonium chloride is a preservative in Brinzolamide/Timolol Mylan that may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

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.

3. How to use Brinzolamide/Timolol Mylan

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

If you are changing from another eye drop medicine used to treat glaucoma to Brinzolamide/Timolol Mylan, you should stop using the other medicine and start using Brinzolamide/Timolol Mylan the following day. Check with your doctor or pharmacist if you are not sure

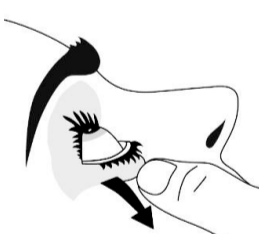
To prevent contamination of the dropper tip and the suspension, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip. Keep the bottle tightly closed when not in use.

The following measure is useful to limit the amount of medicine that will come into the blood after application of eye drops:

- Keep the eyelid closed, while simultaneously applying gentle pressure to the corner of the eye next to the nose with a finger for at least 2 minutes.

The recommended dose is one drop in the affected eye or eyes, twice a day. Only use Brinzolamide/Timolol Mylan in both eyes if your doctor told you to. Take it for as long as your doctor told you to.

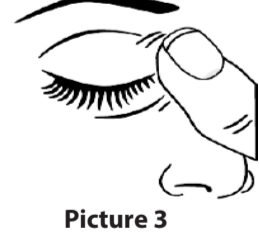
How to use:



Picture 1



Picture 2



Picture 3

- Get the bottle and a mirror.
- Wash your hands.
- Shake well before use.



VIATRIS		Description Brinzolamide/Timolol Mylan, 10 mg/ml+5 mg/ml, 5 ml		Date: 08 JUN 2023		Time: 11:00	
Component Type	Leaflet/IFU - Folded	Site Barcode/DataMatrix	108	No. of colours	1	Page Count	1 of 2
Affiliate Item Code	ART-170-03	Viatris SAP No.	400546982	Colours	Black		
Superseded Affiliate Item Code	ART-170-02	Vendor Job No.	N.A.	Non-Print Colours	Cutting Die		
TrackWise/GLAMS Job No.	ART-170-03	Artwork Proof No.	1	Equate CMYK with			
MA No.	PL 04569/1807	Client Market	United Kingdom	Main Font	Myriad Pro	Body Text Size	9 pt
Supplier SAP No.	N.A.	Barcode Info	N.A.	Dimensions	140 x 590 mm	Min Text Size used	9 pt
New Supplier Code	1609146C	3D Render ID	N.A.	Keyline/Drawing No.	N.A.		
Superseded Supplier Code	1609146B						
Packing Site/Printer	Lusomedicamenta (Povoa de Santo Adriaio - PT)						
Sign-offs							

