PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Duelym®
0.1 mg/g + 1 mg/g
eye gel in single-dose container
bimatoprost/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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1.What Duelym is and what it is used for

Duelym contains two different active substances, bimatoprost and timolol, that both reduce pressure in the eye. Bimatoprost belongs to a group of medicines called prostamides, a prostaglandin analogue. Timolol belongs to a group of medicines called beta-blockers.

Duelym is used to treat high pressure in the eye in adults. Your doctor will prescribe you this medicine when other eye drops containing beta-blockers or prostaglandin analogues have not worked sufficiently on their own.

Your eye contains a clear, watery liquid that feeds the inside of the eye. Liquid is constantly being drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up. If the high pressure is not reduced, it could lead to a disease called glaucoma and eventually damage your sight. Duelym works by reducing the production of liquid and also increasing the amount of liquid that is drained. This reduces the pressure inside the eye.

2.What you need to know before you use Duelym

Do not use Duelym
- if you are allergic to bimatoprost, timolol, beta-blockers or any of the other ingredients of this medicine (listed in section 6).
- if you have, or have had, asthma, severe chronic obstructive lung (pulmonary) disease (COPD) also known as chronic bronchitis, or other diseases of the airways (which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- if you have certain conditions affecting (slowing down) the heart rate including some types of heart block, or an irregular heartbeat.
- if you have symptoms of heart failure.

Warnings and precautions
Talk to your doctor or pharmacist before using Duelym.
Before you use this medicine, tell your doctor 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
- a low heart rate (slow pulse)
- poor circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- breathing problems (such as asthma or chronic obstructive pulmonary disease, COPD, see also under **'Do not use'** above)
- diabetes (timolol may hide signs and symptoms of low blood sugar)
- an overactive thyroid gland (timolol may hide these signs and symptoms)
- any severe allergic reaction
- liver or kidney problems
- eye surface problems (e.g. dry eyes)
- separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye
- known risk factors for macular oedema (swelling of the retina within the eye leading to worsening vision), for example, cataract surgery
- viral infection or inflammation of the eye

Tell your doctor before you have an operation that you are using Duelym as timolol may change effects of some medicines used during anaesthesia.

During treatment, Duelym may cause a loss of fat around the eye, which may cause your eyelid crease to deepen, your eye to appear sunken, your upper eyelid to droop, the skin around your eye to tighten and the lower white part of your eye to become more visible. The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking Duelym.
Duelym may also cause your eyelashes to darken and grow, and cause the skin around the eyelid to darken too. The colour of your iris may also go darker. These changes may be permanent.
The change may be more noticeable if you are only treating one eye.
Duelym may cause hair growth when in contact with the skin surface.

Children and adolescents
Duelym has not been tested in children under the age of 18 and therefore should not be used by patients under 18 years.

Other medicines and Duelym
Duelym can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor or pharmacist if you are using, have recently used, or intend using any other medicines. In particular, it is important to mention medicines for high blood pressure, medicines for heart problems, diabetic medication, quinidine (used to treat some types of heart disease and malaria) or antidepressants (such as fluoxetine and paroxetine).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not use Duelym if you are pregnant unless your doctor considers it necessary.
Do not use Duelym if you are breast-feeding. Timolol may get into your milk.
Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines
Your sight may become blurred for a short time just after using Duelym. You should not drive or use machines until your sight is clear again.

3.How to use Duelym

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

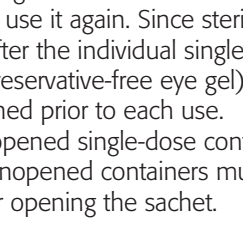
The recommended dose is one drop once a day, preferably in the evening, in each eye that needs treatment. Use at the same time each day.

If you use Duelym with another eye medicine, it should be administered at least 15 minutes before Duelym. Duelym should be used last. If you use another eye ointment or eye gel, check with your doctor.

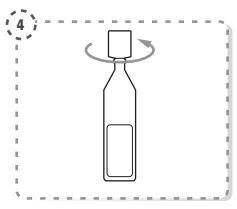
Contact lens wearers
If you wear contact lenses, you should remove them before using Duelym. After using Duelym you should wait 15 minutes before putting your contact lenses back in.

Instructions for use
This medicine is intended to be administered into the eye.

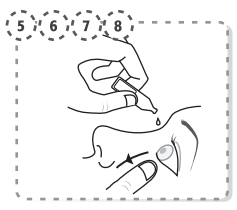
Please follow these instructions to use the drops:
1. Wash your hands and sit or stand comfortably.
2. Open the sachet containing 10 single-dose containers.
3. Break off one single-dose container from the strip.



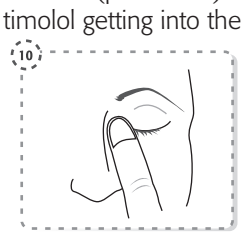
4. Twist open the top of the single-dose container as shown. Do not touch the tip after opening the container.



5. Use your finger to gently pull down the lower eyelid of your affected eye.
6. Tilt your head back and look at the ceiling.
7. Place the tip of the single-dose container close to, but not touching your eye.
8. Squeeze the single-dose container gently so that only one drop goes into your eye, then release the lower eyelid.



9. Wipe off any excess that runs down the cheek with a clean tissue. If a drop misses your eye, try again.
10. After using Duelym, press a finger into the corner of your eye, by the nose (picture 10) for 2 minutes. This helps to stop timolol getting into the rest of the body.



11. Repeat in your other eye if your doctor has told you to do this. Each single-dose container contains enough eye gel for both eyes.
12. Discard the single-dose container after use. Do not keep it to use it again. Since sterility cannot be maintained after the individual single-dose container is opened (preservative-free eye gel), a new container must be opened prior to each use.
13. Place the unopened single-dose containers back in the sachet. The unopened containers must be used within 1 month after opening the sachet.

If you use more Duelym than you should
If you use more Duelym than you should, it is unlikely to cause you any serious harm. Put your next dose in at the usual time. If you are worried, talk to your doctor or pharmacist.

If you forget to use Duelym
If you forget to use Duelym, carry on with the usual dosage at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop using Duelym
Duelym should be used every day to work properly. If you stop using Duelym the pressure inside your eye may go up, therefore talk to your doctor before stopping this treatment.

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

4.Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Duelym without speaking to your doctor.

The following side effects have been seen with Duelym:

Very common side effects
These may affect more than 1 in 10 people
Affecting the eye
- Red eye

Common side effects
These may affect up to 1 to 10 people
Affecting the eye
- Dry eyes
- Eye irritation
- A feeling that something is in your eye
- Itchy eyes

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Uncommon side effects
These may affect up to 1 in 100 people
Affecting the eye
- Darker eyelid colour
- Inflammation of the eyelid
- Cyst in the eyelid
- Red and itchy eyelids
- Increasing tears
- Eye pain
- Eyelid scales
- Longer eyelashes
- Redness and discomfort in the eye
- Impaired vision
- Discomfort in the eyelid
- Sensations like numbness, tingling, pins and needles in the eye
- Eye swelling
- Difficulty in seing clearly

Affecting the skin
- Itching

Affecting the body
- Hot flush
- Cold hands and feet
- Dizziness
- Headache
- Sensations like numbness, tingling, pins and needles
- Pain in the face

Other side effects
Other side effects have been reported in patients using different eye drops containing timolol and/or bimatoprost. These side effects may therefore also occur with Duelym. As with all medicines applied to the eye, some Duelym may be absorbed into the bloodstream and side effects can arise this way. However, the risk of such side effects is much lower than if the same medicines (bimatoprost and timolol) were to be given by a different route (e.g. by injection or by mouth). The following side effects include those reported with bimatoprost, timolol (and other beta-blockers) when used for treating eye conditions:
- Generalised allergic reactions including swelling beneath the skin, hives, localised and generalised rash, itchiness, severe sudden life-threatening allergic reactions
- Low blood glucose levels
- Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucination
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder)
- Inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, corneal erosion (damage to the front layer of the eyeball), double vision, loss of fat in the eye region which can lead to deepening of your eyelid crease, sunken eyes (enophthalmos), drooping eyelid (ptosis), tightening of the skin around your eye (involution of dermatochalasis), and the lower white part of your eye to become more visible (inferior scleral show), darker iris colour, loss of eyelashes, sensitivity to light, darker eyelashes, swelling of the eyelid, itchy, red and dry skin on eyelids
- Slow heart rate, chest pain, palpitations, oedema (fluid build up), changing in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), a type of heart rhythm disorder, heart attack, heart failure
- Low blood pressure, Raynaud's phenomenon
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting
- Muscle pain not caused by exercise
- Sexual dysfunction, decreased libido
- Muscle weakness/tiredness

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via The Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5.How to store Duelym

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

Do not use this medicine after the expiry date which is stated on the carton, sachet and single-dose container after EXP. The expiry date refers to the last day of that month.

Do not store above 25° C.

After first opening of the sachet: use the single-dose containers within 1 month.
To help you remember, write down the date you opened the sachet.
Keep the unused single-dose containers in the opened sachet in order to protect them from light.

After first opening of the single-dose container: use immediately and discard the single-dose container after use.

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.

6.Contents of the pack and other information

What Duelym contains
- The active substances are bimatoprost and timolol. Each g of eye gel contains 0.1 mg bimatoprost and 1 mg timolol (corresponding to 1.37 mg timolol maleate).
- The other ingredients are sorbitol, carbomer, lysine monohydrate, macrogol, sodium acetate trihydrate, water for injections.

What Duelym looks like and contents of the pack
Duelym is a colourless opalescent eye gel in single-dose container. It is presented in single-dose containers packed in a sachet of 10 units.
Each single-dose container holds 0.3 g of product.
A pack size contains 10, 30 (3 x 10) or 90 (9 x 10) single-dose containers.
Not all pack sizes may be marketed.

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Manufacturer
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This leaflet was last revised in 05/2025.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd, telephone number 0345 521 1290.

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