Package leaflet: Information for the patient

Taptiqom® 15 micrograms/ml + 5 mg/ml Eye drops, solution in single-dose container

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

1. What Taptiqom is and what it is used for

What kind of medicine is it and how does it work?
Taptiqom eye drops contain tafluprost and timolol. Tafluprost belongs to a group of medicines called prostaglandin analogues and timolol belongs to a group of medicines called beta blockers. Tafluprost and timolol work together and lower the pressure in the eye. Taptiqom is used when the pressure in the eye is too high.

What is your medicine for?
Taptiqom is used to treat a type of glaucoma called open angle glaucoma and also a condition known as ocular hypertension in adults. Both of these conditions are linked with an increase in the pressure within your eye and eventually they may affect your eyesight.

2. What you need to know before you use Taptiqom

Do not use Taptiqom:
- if you are allergic to tafluprost, timolol, beta blockers 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 chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- if you have a slow heartbeat, heart failure or disorders of the heart rhythm (irregular heartbeats).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Taptiqom.

Before you use this medicine, tell your doctor if you have now 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
- any allergies or anaphylactic reactions
- myasthenia gravis (a rare disease causing muscle weakness)
- other eye diseases; for example, disease of the cornea (the transparent tissue that covers the front of the eye) or a disease requiring eye surgery.

Tell your doctor if you have
- kidney problems
- liver problems.

Please note that Taptiqom may have the following effects and that some of them may be permanent:
- Taptiqom may increase the length, thickness, colour and/or number of your eyelashes and may cause unusual hair growth on your eyelids.
- Taptiqom may cause darkening of the colour of the skin around the eyes. Wipe off any excess solution from the skin. This will reduce the risk of skin darkening.
- Taptiqom may change the colour of your iris (the coloured part of your eye). If Taptiqom is used in one eye only, the colour of the treated eye may permanently become different from the colour of the other eye.
- Taptiqom may cause hair growth in areas where the solution comes repeatedly in contact with the skin surface.

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

Children and adolescents
Taptiqom is not recommended for children and adolescents below 18 years due to a lack of data on safety and efficacy in this age group.

Other medicines and Taptiqom
Tell your doctor or pharmacist if you are taking, have recently taken or might take other medicines. Taptiqom may affect or be affected by other medicines you are using.
In particular, tell your doctor if you are using or intend to use:
- other eye drops for the treatment of glaucoma
- medicines to lower blood pressure
- heart medicine
- medicines to treat diabetes
- quinidine (used to treat heart conditions and some types of malaria)
- antidepressants known as fluoxetine and paroxetine.

If you use other medicines **in the eye,** leave at least 5 minutes between putting in Taptiqom and the other medication.

Contact lenses
Remove contact lenses before putting in the drops and wait at least 15 minutes before putting the lenses back.

Pregnancy, breast-feeding and fertility
If you may become pregnant, you must use an effective method of birth control during Taptiqom therapy. Do not use Taptiqom if you are pregnant. You should not use Taptiqom if you are breast-feeding. Ask your doctor for advice.

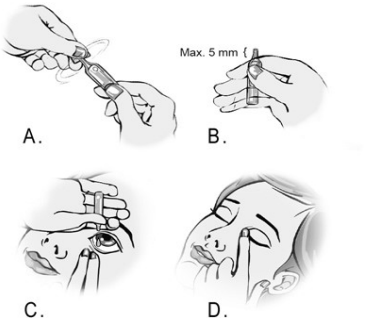
Driving and using machines
There are side effects associated with Taptiqom, such as blurred vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until you feel well and your vision is clear.

Taptiqom contains phosphate buffers
This medicine contains approximately 0.04 mg phosphates in each drop which is equivalent to 1.3 mg/ml. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Taptiqom

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 1 drop of Taptiqom in the eye or eyes, once daily. Do not instil more drops or use more often than as instructed by your doctor. This may make Taptiqom less effective.
Only use Taptiqom in both eyes if your doctor told you to. Discard the opened container with any remaining contents immediately after use.
For use as eye drops only. Do not swallow.
Do not allow the single-dose container to touch the eye or areas around the eye. It could cause injury to your eye. It may also become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the single dose container, keep the tip of the single dose container away from contact with any surface.

Instructions for use:
<u>When you start a new pouch:</u>
Do not use the single-dose containers if the pouch is broken. Open the pouch along the dashed line. Write down the date you opened the pouch in the space reserved for the date on the pouch.
<u>Every time you use Taptiqom:</u>



1. Wash your hands.
2. Take the strip of containers from the pouch.
3. Detach one single-dose container from the strip.
4. Put the remaining strip back in the pouch and fold the edge to close the pouch.
5. To open the container, twist off the tab. (Picture A)
6. Hold the container between your thumb and index finger. Note that the tip of the container must not show more than 5 mm above the edge of your index finger. (Picture B)
7. Tilt your head backwards or lie down. Place your hand on your forehead. Your index finger should be aligned with your eyebrow or resting on the bridge of the nose. Look up. Pull the lower eyelid downwards with the other hand. Do not allow any part of the container to touch your eye or any area around your eye. Gently squeeze the container to let one drop fall into the space between the lid and the eye. (Picture C)
8. Close your eye and press the inner corner of the eye with your finger for about two minutes. This helps prevent the eye drop from draining down the tear duct. (Picture D)
9. Wipe off any excess solution from the skin around the eye.

If a drop misses your eye, try again.
If your doctor has told you to use drops in both eyes, repeat steps 7 to 9 for your other eye.
The contents of one single-dose container are

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sufficient for both eyes. Discard the opened container with any remaining contents immediately after use.

If you use other medicines in the eye, leave at least 5 minutes between putting in Taptiqom and the other medication.

If you use more Taptiqom than you should, you may feel dizzy or have headache, heart symptoms or breathing problems. If necessary, contact a doctor for advice.

If the medicine is accidentally swallowed, contact a doctor for advice.

If you forget to use Taptiqom, use a single drop as soon as you remember, and then go back to your regular routine. However, if it is nearly time for the next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

Do not stop using Taptiqom without asking your doctor. If you stop using Taptiqom, the pressure in the eye will increase again. This may cause a permanent injury to your eye.
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. Most side effects are not serious.

You can usually carry on using the drops, unless the effects are serious. If you are worried, talk to a doctor or pharmacist.

The following are known side effects of using Taptiqom:

Common side effects
The following may affect up to 1 in 10 people:
Eye disorders
Itching of the eye. Irritation in the eye. Eye pain. Redness of the eye. Changes in the length, thickness and number of eyelashes. Foreign body sensation in the eye. Discolouration of eyelashes. Sensitivity to light. Blurred vision.

Uncommon side effects
The following may affect up to 1 in 100 people:
Nervous system disorders
Headache.
Eye disorders
Dry eye. Redness of the eyelids. Small spotlike areas of inflammation on the surface of the eye. Watery eyes. Puffy eyelids. Tired eyes. Inflammation of the eyelids. Inflammation inside the eye. Discomfort in the eye. Eye allergy. Inflammation of the eye. Abnormal sensation in the eye.

The following additional side effects have been seen with the medicines in Taptiqom (tafluprost and timolol) and therefore might occur when you use Taptiqom:

The following side effects have been seen with tafluprost:
Eye disorders
Reduction in the eye's ability to see details. Change of colour of the iris (may be permanent). Change of colour of the skin around the eyes. Swelling of the eye's surface membranes. Eye discharge. Pigmentation of the eye's surface membranes. Follicles in the surface membranes of the eye. Sunken eye. Iritis/uveitis (inflammation of the coloured part of the eye). Macular oedema/ Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision).
Skin disorders
Unusual hair growth on eyelids.
Effects on the respiratory system
Worsening of asthma, shortness of breath.

The following side effects have been seen with timolol:
Immune system disorders
Allergic reactions, including swelling beneath the skin, hives, rash. Severe sudden life-threatening allergic reaction. Itching.
Metabolism and nutrition disorders
Low blood sugar.
Psychiatric disorders
Depression. Difficulty sleeping. Nightmares. Memory loss. Nervousness. Hallucination.
Nervous system disorders
Dizziness. Fainting. Unusual sensations (like pins and needles). Increases in signs and symptoms of myasthenia gravis (muscle disorder). Stroke. Reduced blood supply to the brain.
Eye disorders
Inflammation of the cornea. Decreased corneal sensitivity. Visual disturbances including refractive changes (sometimes due to withdrawal of miotic therapy). Drooping of the upper eyelid. Double vision. Blurred vision and detachment of the layer below the retina that contains blood-vessels following filtration surgery which may cause visual disturbances. Corneal erosion.
Ear disorders
Tinnitus (ringing in the ears).
Heart disorders
Slow heart rate. Chest pain. Palpitations. Oedema (fluid build-up). Changes 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.
Vascular disorders
Low blood pressure. Limping. Raynaud's phenomenon, cold hands and feet.
Breathing disorders
Constriction of the airways in the lungs (predominantly in patients with pre-existing disease). Difficulty breathing. Cough.
Gastrointestinal disorders
Nausea. Indigestion. Diarrhoea. Dry mouth. Taste disturbances. Abdominal pain. Vomiting.
Skin disorders
Hair loss. Skin rash with white silvery-coloured appearance (psoriasiform rash) or worsening of psoriasis. Skin rash.
Muscle and skeletal disorders
Muscle pain not caused by exercise. Joint pain.
Reproductive system and breast disorders
Peyronie's disease (which may cause a curvature of the penis). Sexual dysfunction. Decreased libido.
General disorders
Muscle weakness/tiredness. Thirst.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
United Kingdom: Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store
Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Taptiqom

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 single-dose container, pouch and the carton after 'Exp'. The expiry date refers to the last day of that month.

Store the unopened foil pouches in a refrigerator (2°C - 8°C). Do not open the pouch until you are about to start using the eye drops as unused containers in an open pouch must be discarded 28 days after first opening the pouch.

After opening the foil pouch:
- Keep the single-dose containers in the original foil pouch in order to protect from light.
- Do not store above 25°C
- Discard unused single-dose containers after 28 days from date of first opening of the foil pouch
- Discard an opened single-dose container with any remaining solution immediately 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 Taptiqom contains
- The active substances are tafluprost and timolol. 1 ml of solution contains 15 micrograms of tafluprost and 5 mg of timolol.
- The other ingredients are glycerol, disodium phosphate dodecahydrate, disodium edetate, polysorbate 80, hydrochloric acid and/or sodium hydroxide (to adjust pH), and water for injections.

What Taptiqom looks like and contents of the pack
Taptiqom is a clear, colourless liquid (solution) supplied in single-dose plastic containers, each containing 0.3 ml of solution. Ten single-dose containers are provided in one pouch. Taptiqom is supplied in packs containing 30 or 90 single-dose containers.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Santen Oy
Niittyhaankatu 20
33720 Tampere
Finland

Manufacturer
Santen Oy
Kelloportinkatu 1
33100 Tampere
Finland

This medicinal product is authorised in the following Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the name Taptiqom:
Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)

Loyada: Italy

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Panel info

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