

timolo

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Nyogel.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-todate leaflet from

www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Nyogel against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Nyogel is used for

This medicine is used to lower the pressure in the eye and to prevent loss of vision in glaucoma.

It works by decreasing the formation of fluid which flows through the eye. The eye is filled with fluid which is constantly being replaced. If excessive amounts of fluid are produced or if it cannot drain away properly, the pressure inside the eye can damage the nerve cells that transmit information from the eye to the brain. This nerve cell damage is called glaucoma.

Glaucoma is often but not always associated with increased pressure in the eye. A reduction of the pressure inside the eye can prevent further nerve cell damage.

There are usually no symptoms of glaucoma. Damage can progress so slowly that you are not aware of a gradual loss of sight. The only way of knowing you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated, it can lead to serious problems. You may have no symptoms but eventually glaucoma can lead to total blindness.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 12 years.

Before you use Nyogel

When you must not use it

Do not use Nyogel if you have an allergy to:

- any medicine containing timolol
- any of the ingredients listed at the end of this leaflet
- any other similar medicines used to treat glaucoma or high blood pressure.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use this medicine if you have or have had:

- asthma or other lung disease
- slow heart rate
- some types of heart disease
- severe problems with the circulation in your arms and legs
- a type of angina called Prinzmetal's angina
- untreated phaeochromocytoma, a rare tumour of the adrenal gland
- some cases of low blood pressure
- diseases of the cornea of the eye
- · severe hay fever.

Do not breast-feed if you are using this medicine.

The active ingredient in Nyogel passes into breast milk and there is a possibility that your baby may be affected.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- · low blood pressure
- heart disease
- an overactive thyroid
- any other type of glaucoma than that for which you have been given this medicine
- diabetes.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you wear soft contact lenses.

The preservative in Nyogel (benzalkonium chloride) is known to discolour soft contact lenses. You should not wear soft contact lenses while using this medicine. You can put your contact lenses into your eyes 15 minutes after you have used Nyogel.

If you have not told your doctor about any of the above, tell him/her before you start using Nyogel.

Taking other medicines

Tell your doctor or pharmacist if you are taking or using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and Nyogel may interfere with each other. These include:

- medicines used to treat high blood pressure including a group of medicines called beta-blockers that are also used to treat heart problems and to prevent migraine
- other medicines used to treat glaucoma
- medicines used to treat heart disease or abnormal heart beat
- medicines used to treat depression or schizophrenia
- anaesthetics
- cimetidine used to treat stomach ulcers.

These medicines may be affected by Nyogel or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Nyogel

Follow the directions given to you by your doctor or pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to use

The usual dose is one drop in the affected eye(s) daily.

How to use it

To use this medicine:

- 1. First wash your hands and sit or stand comfortably.
- With your head tilted back, use your forefinger to gently pull down the lower lid of the eye to be treated.

- Hold the container upside down above your eye and place the dropper tip close to your eye but without touching the eye or lid.
- 4. Squeeze the bottle gently so that only one drops falls into the pouch between your lower lid and your eye, then release your lower lid.

To ensure you get the correct dose, keep the bottle vertical while putting in the drops.

- Close your eyelid and gently press the inner corner of your eye for one minute.
- 6. Treat your other eye in the same way if your doctor has told you to do this.
- 7. Put the cap back on the bottle.

 Discard the bottle and remaining gel four weeks after opening.

If you are using any other eye drops at the same time as Nyogel, leave an interval of at least 5 minutes between each eye drop to stop the drops being washed out of the eye. Use Nyogel last.

When to use it

Use your medicine at about the same time each day, preferably in the morning.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep using your medicine even if you feel well.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand) if you think that you or anyone else may have used too much Nyogel. Do this even if there are no signs of discomfort or poisoning.

You may need medical attention.

While you are using Nyogel

Things you must do

If you wear soft contact lenses, stop wearing them while you are using Nyogel.

If you are going to have surgery, tell the surgeon or anesthetist that you are using this medicine.

You may be advised to gradually stop using Nyogel prior to surgery.

If you have diabetes, you should monitor your blood sugar carefully, particularly when starting Nyogel.

Nyogel may mask the symptoms of low blood sugar.

If you are having an x-ray that requires you to have an injection of dye containing iodine, tell the person doing the x-ray that you are using Nyogel.

Nyogel and x-ray injections that contain iodine may interfere with one another.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Nyogel.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use Nyogel to treat any other complaints unless your doctor tells you.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Nyogel affects you.

This medicine may cause visual disturbances and dizziness or fatigue in some people. If you get these symptoms when you use it, do not drive, operate machinery or do anything else that could be dangerous until this effect has worn off.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Nyogel.

This medicine helps most people with increased pressure in the eye, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Irritation, pain or redness of the eye
- blurred vision or other vision changes
- dry eyes or dry mouth
- dizziness, tiredness or headache
- nausea, vomiting or diarrhoea.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- conjunctivitis or swollen eyelids
- fainting
- palpitations
- cold hands and feet, or tingling or numbness of the hands and feet
- chest pain
- allergic skin reactions including rash, redness, itching, thickened patches of skin, unusual hair loss or thinning
- shortness of breath, coughing, wheezing or difficulty breathing
- joint pain
- muscle weakness and tiredness, especially in the eyes, face, throat, arms and legs, which may cause drooping eyelids and difficulty in speaking and swallowing
- a butterfly-shaped red rash on face, exposed areas of neck, upper chest and elbows, often with swollen, painful joints
- a painful erection.

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Nyogel

Storage

Keep your eye gel in a cool dry place where the temperature stays below 25°C.

After opening, use the bottle of eye gel for four weeks and then get a new bottle of eye gel, even if there is some left in the old bottle.

Store the dropper bottle upside down in the carton to facilitate instillation of the eye gel.

Do not store Nyogel or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Nyogel is a clear colourless gel in a 5 g bottle.

Ingredients

Nyogel contains 1 mg/g of timolol (as timolol maleate) as the active ingredient. It also contains:

- · benzalkonium chloride
- carbomer 934 (974 P grade)
- lysine monohydrate
- polyvinyl alcohol
- · sodium acetate
- sorbitol

• water for injections.

Sponsor

Nyogel is supplied in Australia by:

Aspen Pharma Pty Ltd

34-36 Chandos Street St Leonards NSW 2065 Australia.

Date of preparation

This leaflet was prepared in May 2014

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AUST R 97737