

BETOQUIN®

Eye Drops 0.5%

betaxolol hydrochloride

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you start to use Betoquin.

This leaflet answers some common questions about Betoquin. 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 to date leaflet from www.novartis.com.au.

The 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 Betoquin 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 your medicine.

You may need to read it again.

What Betoquin is used for

Betoquin contains the active ingredient betaxolol hydrochloride. Betaxolol hydrochloride belongs to a class of medicines known as "beta-adrenergic blocking agents".

Your doctor has prescribed Betoquin for you because the pressure within your eye(s), known as "intraocular pressure", is higher than normal. This raised pressure may damage your eyesight and lead to a condition known as glaucoma.

There are usually no symptoms of glaucoma. If glaucoma is not treated it can lead to serious problems, including total blindness. Untreated glaucoma is one of the most common causes of blindness.

Betoquin is used, either alone or in combination with other medicines, to lower the raised pressure within your eye(s). Betoquin does this by reducing the amount of fluid produced within your eye(s).

Although Betoquin helps control your glaucoma it does not cure it. So you must keep using it until your doctor tells you to stop.

For more information about glaucoma contact Glaucoma Australia (telephone 1800 500 880).

Ask your doctor if you have any questions about why Betoquin Eye Drops have been prescribed for you.

Your doctor may have prescribed Betoquin Eye Drops for another reason.

Betoquin Eye Drops are not addictive.

Use in Children

Betoquin is not recommended for use in children. The safety and effectiveness of Betoquin in children has not been established.

Before you use Betoquin

When you must not use it

Do not use Betoquin Eye Drops if you have an allergy to:

- Betaxolol or any of the ingredients listed at the end of this leaflet under "Product description".

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.

Tell your doctor if:

- You have a very slow or irregular heartbeat
- You have cardiac failure or any other serious heart conditions.

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

Do not use this medicine if the expiry date has passed, the packaging is torn or the safety seal around the closure and neck area is broken.

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

If you use your medicine after the expiry date has passed, it may not work as well.

Before you start to use it

Tell your doctor if:

- **You are pregnant, or intend to become pregnant.**

Your doctor will discuss the possible risks and benefits of using Betoquin during pregnancy.

- **You are breastfeeding or intend to breastfeed.**

Your doctor will discuss the possible risks and benefits of using Betoquin when you are breast-feeding.

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

- Any type of respiratory or breathing disorder (e.g. wheezing or asthma)
- Diabetes
- An overactive thyroid gland
- Any form of muscle weakness
- Any heart problems including heart failure, heart block or Prinzmetal's angina
- Severe circulation disorders e.g. Raynaud's disease or syndrome
- A condition called pheochromocytoma which is a tumour in the brain
- Metabolic acidosis where the body produces excessive acid that is not cleared by the kidneys.

Tell your doctor if you are about to have either major surgery or eye surgery.

This includes those doctors treating you in hospital or in a clinic. Your dose of Betoquin may need to be adjusted or gradually stopped prior to surgery.

Do not put Betoquin into your eye(s) while you are wearing soft contact lenses.

The preservative in Betoquin, benzalkonium chloride, may be deposited in contact lenses.

You can put your soft contact lenses back into your eyes 15 minutes after you have used Betoquin.

If you are not sure if you should start using Betoquin, talk to your doctor.

Taking or using other medicines

Tell your doctor or pharmacist if you are taking or using other medicines, including medicines that you get without a doctor's prescription from a pharmacy, supermarket or health food shop.

Some medicines and Betoquin interfere with each other. These include:

- other beta-blockers, calcium blockers, including amiodarone, and digitalis glycosides
- certain medicines used to treat lower blood pressure e.g. reserpine
- some medicines used to treat major mental illnesses.

These medicines may be affected by Betoquin or may affect how well it works. You may need different amounts of your medicines.

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

How to use Betoquin

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

They may differ from the information contained in this leaflet.

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

How to use it

The usual dose of Betoquin Eye Drops is one drop in the affected eye(s) two times each day. Your dosing instructions will be printed on the label your pharmacist put on the bottle or carton.

Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

Do not use Betoquin Eye Drops more often than your doctor or pharmacist has told you.

If you have been using any other eye drops for the treatment of raised intraocular pressure or glaucoma, it may take several days to change from the old drops to Betoquin Eye Drops. It is important that you follow your doctor's instructions for the changeover very carefully.

After using Betoquin Eye Drops, wait at least 5 minutes before putting any other eye drops in your eye(s).

How to use Betoquin

Follow these steps to use Betoquin Eye Drops:

1. Wash your hands thoroughly.
2. Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
3. Shake the bottle well.
4. Remove the cap from the bottle.
5. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

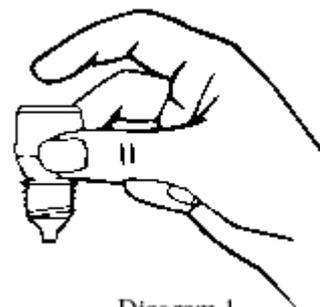


Diagram 1

6. While tilting your head back, gently pull the lower eyelid of your eye down using the forefinger of your other hand.
7. Place the dropper tip close to, but not touching, your lower eyelid and gently tap or press the base of the bottle with your

forefinger to release one drop (see Diagrams 2 and 3).

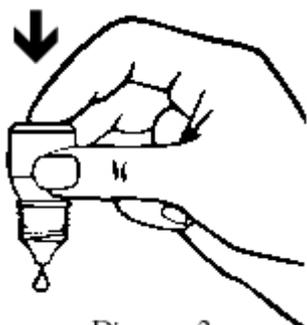


Diagram 2



Diagram 3

8. Close your eye gently without blinking and press on the inside corner of the eye with the pad of your index finger for two minutes.
9. If necessary, repeat the above steps for your other eye.
10. Place the cap on the bottle and close it tightly.
11. Wash your hands again.

You may feel a slight burning sensation in the eye shortly after using Betoquin Eye Drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Do not touch the tip of the dropper to your eye or to any other surface.

This will help to prevent your eye drops becoming dirty or contaminated.

How long to take it

Continue using Betoquin every day for as long as your doctor tells you.

Betoptic helps control your condition but it does not cure it.

If you are unsure about when, or how, to stop using Betoquin Eye

Drops, you should talk to your doctor.

If you forget to use Betoquin

If you forget to use Betoquin Eye Drops, you should put the drops that you missed in as soon as you remember and then go back to using them normally. If it is almost time for your next dose, skip the dose that you have missed and take your next dose when you are due to.

Never take a double dose to make up for the one that you missed.

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

If you use too much (overdose)

If you accidentally put too many drops in your eye(s), immediately rinse your eye(s) with warm water or normal saline.

If anyone accidentally swallows Betoquin Eye Drops, immediately telephone your doctor, the Poisons Information Centre on 13 11 26 or go to Accident and Emergency at the nearest hospital.

While you are using Betoquin

Things you must do

To make sure that Betoquin is working properly, have your eye pressure checked regularly by your doctor.

Have your eyes checked for any other changes you experience.

Tell your doctor immediately if you become pregnant while you are using Betoquin.

Tell your doctor and pharmacist that you are using Betoquin Eye Drops before you start taking any other medicines.

If you are going to have a general anaesthetic, tell your doctor that you are using Betoquin. Your

doctor may gradually stop your Betoquin treatment.

Things you must not do

Do not let children handle Betoquin Eye Drops. If a child accidentally swallows any of the drops, read the instructions under "If you use too much (overdose)".

Do not stop using Betoquin without first asking your doctor.

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

Things to be careful of

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

As with any eye medicines, temporary blurred vision or other visual disturbances may affect the ability to drive and use machinery in some people. If blurred vision occurs when you use your drops, wait until your vision is clear before driving.

Side effects

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

This medicine helps most people with glaucoma, but it may have unwanted effects in some 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.

Most side effects from Betoquin occur in, or around, the eye. These include:

- Discomfort or pain in your eye(s)
- A loss of feeling to the surface of your eye(s)
- Redness, inflammation, irritation and/or itching in your eye(s), eyelids or the surrounding lining of the eyelids

- Inflammation of the cornea (clear front portion of your eye) (punctate keratitis)
- Blurred vision and/or problems seeing clearly
- A feeling that something is in your eye(s)
- Eyelid spasms
- An increase in tearing or a discharge from the eye(s)
- A dry eye(s)
- Crusty eyelash(es) or eyelids
- Discomfort in the eye(s) due to a greater sensitivity to light
- Weakness or easily fatigued eyes.

Occasionally, some people notice unwanted effects in the rest of their body as a result of using Betoquin.

Tell your doctor immediately if you notice any of the following effects:

- Changes in breathing (e.g. wheezing or asthma)
- Cough
- Respiratory infection, sinusitis, runny nose
- Circulation problems
- Fast or slowing of heart beat, irregular heart beat
- Nausea
- Trouble sleeping
- Headache
- Dizziness
- Fainting
- Tiredness and/or depression
- Decreased libido
- Hives and more severe forms of skin rash
- Flaking skin and/or hair loss
- Sore tongue
- Altered taste sensation.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

After using Betoquin

Storage

Keep Betoquin Eye Drops in a cool place, where the temperature stays below 25°C. Do not freeze Betoquin Eye Drops.

Protect from light. Store the bottle in the outer carton.

Do not leave Betoquin Eye Drops 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-and-half metres above the ground is good place to store medicines.

Disposal

Discard each bottle of Betoquin Eye Drops 4 weeks after it has been opened.

Write the date the bottle was opened on the label to remind you when to discard the bottle.

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

Betoquin Eye Drops are a sterile isotonic solution supplied in a 5 mL Drop-Tainer®.

Active ingredients

The active ingredient in Betoquin Eye Drops is betaxolol HCl equivalent to betaxolol 5 mg in 1 mL.

Betoquin Eye Drops also contain:

- Benzalkonium chloride 0.1 mg in 1 mL as a preservative
- Disodium edetate
- Sodium chloride
- Purified water.

Supplier

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited
 ABN 18 004 244 160
 54 Waterloo Road
 Macquarie Park NSW 2113
 Telephone: 1-800-671-203
 Web site: www.novartis.com.au

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