

BETAGAN[®] EYE DROPS 0.25% and 0.5%

(levobunolol hydrochloride 2.5 and 5 mg per mL)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BETAGAN[®] eye drops, including how to use the eye drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using BETAGAN[®] eye drops 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 BETAGAN[®] eye drops are used for

BETAGAN[®] eye drops are a beta blocking agent used to lower increased pressure in the eye.

Your doctor has prescribed BETAGAN[®] eye drops to control increased pressure in the eye or to treat an acute increase in pressure that can occur after eye operations. Sometimes your doctor may give you another medicine or eye drop as well as BETAGAN[®] eye drops to help you.

Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of

sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that 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, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

BETAGAN[®] eye drops lower the pressure in the eye by decreasing the production of fluid in the eye chamber.

BETAGAN[®] eye drops can be used alone or together with other eyedrops/medicines to lower raised pressure within your eyes.

Although BETAGAN[®] eye drops help control your condition, they will not cure it.

BETAGAN[®] eye drops are only available with a doctor's prescription from pharmacies. Your doctor may have prescribed BETAGAN[®] eye drops for another reason. Ask your doctor if you have any questions about why BETAGAN[®] eye drops have been prescribed for you.

For more information about glaucoma, contact Glaucoma Australia Inc (telephone 1800 500 880) or Glaucoma NZ (telephone 64 9373 8779).

Before you use BETAGAN[®] eye drops

When you must not use it

Do not use BETAGAN[®] eye drops if:

- you are allergic or very sensitive (hypersensitive) to any of its

ingredients listed at the end of this leaflet especially sodium metabisulfite

- you suffer from asthma or have a history of asthma disease
- you have heart or lung disease
- the seal around the cap is broken
- the bottle/packaging shows signs of tampering
- the product does not look quite right.
- the expiry date on the bottle or carton has passed.

If you use this medicine after the expiry date has passed, it may not work effectively.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in BETAGAN[®] eye drops (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used BETAGAN[®] eye drops.

If you are not sure whether you should start using BETAGAN[®] eye drops, talk to your doctor.

It is not known if BETAGAN[®] eye drops are safe and useful for children and adolescents under 18 years.

These drops are for topical use only.

Before you start to use it

Tell your doctor if:

1. you have difficulty in breathing
2. you suffer from diabetes or have low blood sugar
3. you have an overactive thyroid gland

4. you are allergic to other beta-blockers
5. you are scheduled to have surgery using a general anaesthetic
6. you are pregnant or intend to become pregnant
7. you are breast-feeding or intend to breast-feed.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

BETAGAN[®] eye drops can increase the effect of beta-blockers which are taken orally.

When BETAGAN[®] eye drops are taken with adrenaline, enlargement of the pupils may occur.

Beta-blockers and catecholamine depleting drugs taken together may cause dizziness or fainting.

How to use BETAGAN[®] eye drops

How much to use

Your doctor will tell you how many drops you need to use each day. Use BETAGAN[®] eye drops only as prescribed by your doctor.

The usual dose of BETAGAN[®] eye drops is one drop in the affected eye(s) twice a day.

Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.

Use BETAGAN[®] eye drops every day, at about the same time each day, unless your doctor tells you otherwise. 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.

If you are using more than one eye drop product, wait 5 minutes before using the second product.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How to use it

You may find it easier to put drops in your eye while you are sitting or lying down.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

To open a new bottle of BETAGAN[®] eye drops first tear off the protective seal from the bottle. The contents are sterile if the seal is intact.

The seal will break and you can pull it off and then throw it away.

1. Wash your hands well with soap and water.
2. Remove the lid/cap.
3. Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
4. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
5. Tilt your head back and look up.
6. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
7. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
8. Close your eye. Do not blink or rub your eye.
9. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.
10. Replace the lid/cap, sealing it tightly.
11. Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.

How long to use it

BETAGAN[®] eye drops help control your condition, but do not cure it. Therefore, BETAGAN[®] eye drops must be used every day. Continue using BETAGAN[®] eye drops for as long as your doctor prescribes.

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 the drops as soon as you remember, and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you use too much (overdose)

If you accidentally put several drops in your eyes, flush the eye(s) with water or saline solution.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of BETAGAN[®] eye drops, immediately telephone your doctor or the **Poisons Information Centre (Australia : telephone 13 11 26; New Zealand: telephone 0800 POISON or 0800 764 766)** for advice, or go to casualty at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

While you are using BETAGAN[®] eye drops

Things you must do

Have your eye pressure checked when your eye specialist says, to

make sure BETAGAN[®] eye drops are working.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of BETAGAN[®] eye drops because of possible contamination of the old one.

If you become pregnant while using BETAGAN[®] eye drops tell your doctor immediately.

If you wear soft contact lenses, remove them before using BETAGAN[®] eye drops. Leave your lenses out for at least 15 minutes after putting in the eye drops.

Tell your doctor if your condition gets worse or does not get better while using BETAGAN[®] eye drops.

If you are about to start any new medicine tell your doctor and pharmacist that you are using BETAGAN[®] eye drops.

Things you must not do

Do not give BETAGAN[®] eye drops to anyone else, even if they have the same condition as you.

Do not stop using BETAGAN[®] eye drops without first talking to your doctor. If you stop using your eye drops, your eye pressure may rise again and damage to your eye may occur.

Things to be careful of

BETAGAN[®] eye drops are not expected to cause any problems with your ability to drive a car or operate machinery. However, they may cause blurred vision/dizziness/tiredness in some people. As a general precaution be careful driving or operating machinery until you know how BETAGAN[®] eye drops affect you.

Side effects

Tell your optical practitioner, doctor or pharmacist as soon as possible if you do not feel well while you are using BETAGAN[®] eye drops.

BETAGAN[®] eye drops help most people with high eye pressure and glaucoma, 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 treatment if you get some of the side effects.

Check with your doctor as soon as possible if you have any problems while taking BETAGAN[®] eye drops, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Ask your optical practitioner, doctor or pharmacist any questions you may have.

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

- Stinging and burning feeling when it is instilled in the eye
- Inflammation of the eyelid

Rarely the following effects have been seen:

Headaches, tiredness, dizziness, itching, inflammation of the iris, clumsiness and lack of co-ordination, hives, decreased heart rate and blood pressure and decreased sensitivity of the front layer of the eyeball.

After using BETAGAN[®] eye drops

Storage

Keep your eye drops in a cool, dark place where the temperature stays below 25°C.

Keep the bottle where children cannot reach it.

Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops.

Disposal

Throw out any remaining solution after 4 weeks from the date of opening.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What BETAGAN[®] eye drops look like:

The eye drops are supplied in a 5mL sterile plastic bottle.

Ingredients

Active ingredient:
Levobunolol hydrochloride
2.5mg/mL; 5.0 mg/mL

Preservative:
Benzalkonium chloride

Inactive ingredients:
Polyvinyl alcohol
Disodium edetate
Sodium metabisulphite
Sodium phosphate
Potassium phosphate
Sodium chloride
Purified water

Manufacturer/Supplier

ALLERGAN AUSTRALIA PTY LTD
810 Pacific Hwy
Gordon NSW 2072
ABN 85 000 612 831

Toll free: 1800 252 224 (Australia)

ALLERGAN NEW ZEALAND
LIMITED
Cnr Manu Tapu Drive & Joseph
Hammond Place,
Auckland International Airport,
New Zealand
Freephone: 0800 659 912 (NZ)

BETAGAN[®] eye drops can be identified by registration number:

BETAGAN[®] 2.5 mg/mL
AUST R 45037;
BETAGAN[®] 5.0 mg/mL
AUST R 45043

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