
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BETAGAN 0,5 % Liquifilm, levobunolol hydrochloride 5 mg/ml sterile eye drops

Read all of this leaflet carefully before you start using BETAGAN 0,5 %

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or pharmacist.
- BETAGAN 0,5 % has been prescribed for you personally and you should not share medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT BETAGAN 0,5 % CONTAINS

The active substance of BETAGAN 0,5 % is levobunolol hydrochloride 5 mg/ml.

The other ingredients are polyvinyl alcohol, sodium chloride, disodium edetate, sodium phosphate dibasic heptahydrate, potassium dihydrogen phosphate, purified water, sodium metabisulphite (E223).

Benzalkonium chloride 0,004 % m/v as preservative.

2. WHAT BETAGAN 0,5 % IS USED FOR

Levobunolol, the active ingredient of BETAGAN 0,5 %, belongs to a group of medicines called beta-blockers.

BETAGAN 0,5 % is an eye drop. It is used to treat glaucoma by lowering the pressure that builds up in the eye.

3. BEFORE YOU USE BETAGAN 0,5 %

Do not use BETAGAN 0,5 %:

- if you are allergic (hypersensitive) to levobunolol, benzalkonium chloride or other ingredients (see “What BETAGAN 0,5 % contains”)
- if you have or have had asthma or other lung diseases where you have difficulty breathing, wheezing or a chronic cough
- if you have or have had heart problems such as heart weakness or heart beat disorders (unless controlled by a pacemaker)

BETAGAN 0,5 % is not recommended for use in children.

Take special care with BETAGAN 0,5 %

Talk to your doctor before using BETAGAN 0,5 % if you suffer from, or have in the past suffered from:

- asthma or other breathing problems or are currently on medicine treatment for asthma or tight chest (also see “Using other medicines with BETAGAN 0,5 %”)
- heart problems (including cardiac failure and slow heart beat) or are currently on medicine treatment for a heart condition (also see “Using other medicines with BETAGAN 0,5 %”)
- blood pressure problems (drop of blood pressure on standing up) or if you are currently on medicine treatment for blood pressure (also see “Using other medicines with BETAGAN 0,5 %”)
- chest pain when resting (Prinzmetal’s angina)
- kidney or liver problems
- poor blood circulation, especially to the brain, legs, arms and hands
- diabetes or a sudden bout of low blood sugar (hypoglycaemia) or if you are currently on medicine treatment for blood sugar levels (also see “Using other medicines with BETAGAN 0,5 %”)
- too much acid in your blood
- thyroid problems
- depression
- any allergies (especially if any of the allergies are severe)
- chronic eye inflammation or if the surface of the eye is unhealthy
- skin rashes
- dry eyes
- eye surgery to lower the pressure in your eyes

Regular eye examination is required during prolonged and repeated use as the preservative benzalkonium chloride can cause damage to your eyes.

Patients with extensive eye surface diseases should take special care during long term use due to the preservative benzalkonium chloride.

If you have a history of breathing problems or heart disease your doctor may monitor you more closely as in rare cases death has been reported following taking levobunolol.

If you suffer from allergies, or have a severe allergic reaction be aware that the usual dose of epinephrine (adrenaline) may need to be increased.

If your eye(s) become irritated or any new eye problems occur, tell your doctor immediately. Eye problems may include redness or itching of the eye(s).

If you need to have a general anaesthetic, tell your doctor or dentist that you are using BETAGAN 0,5 %.

Please be aware that BETAGAN 0,5 % contains levobunolol (the active ingredient) which may lead to a positive result in anti-doping tests.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking BETAGAN 0.5 %.

Safety and efficacy during pregnancy has not been established.

Levobunolol is excreted in breast milk. BETAGAN 0,5 % should not be used by women breastfeeding their infants.

Driving and using machines

BETAGAN 0,5 % may cause tiredness, dizziness or blurred/abnormal vision. Do not drive or use machinery until these symptoms have cleared.

Important information about some of the ingredients of BETAGAN 0,5 %

- A preservative in BETAGAN 0,5 % (called benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses. Therefore, do not use the drops while your contact lenses are in your eyes. Wait at least 15 minutes after using the eye drops before putting your lenses back in your eyes.
- BETAGAN 0,5 % contains sodium metabisulphite which may rarely cause allergic reactions, difficulty in breathing or wheezing.

Using other medicines with BETAGAN 0,5 %

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

It is important to tell your doctor before using BETAGAN 0,5 % if you are taking oral beta-blockers to lower blood pressure. BETAGAN 0,5 % is also a beta-blocker. Therefore your doctor needs to know whether there is likely to be a risk of having too much beta-blocker in your system.

The following symptoms could result from such a risk:

- Low blood pressure (for example, upon standing)
- Slow heart beat
- Dizziness/temporary loss of consciousness
- Low pressure in the eye ball

BETAGAN 0,5 % may also interact with the following medicines:

- medicines to help you sleep, treat anxiety or epileptic fits, certain pain killers or alcohol may interact with beta-blockers and increase the effect of the medicines taken
- medicines to control muscle activity, for example baclofen
- medicines to treat high blood pressure (hypertension)
- medicines for heart conditions (for example irregular heartbeat) such as other beta blockers, anti-dysrhythmic medicine (such as digoxin)
- another eye drop to lower pressure in the eye (glaucoma)
- medicines to dilate your pupil, for example epinephrine (adrenaline)
- medicines to treat diabetes or high blood pressure
- medicines to treat heartburn or stomach ulcers
- medicines that affect some of the hormones in your body, like epinephrine (adrenaline) and dopamine
- other beta blockers by mouth or as an eye drop

If you need to have an X-ray, tell your doctor or dentist that you are using BETAGAN 0,5 %.

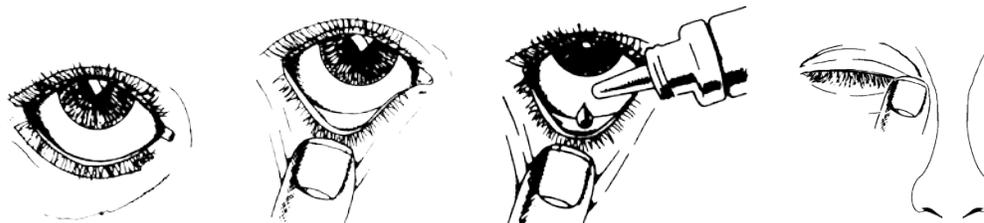
4. HOW TO USE BETAGAN 0,5 %

Always use BETAGAN 0,5 % exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 1 drop into the affected eye(s), twice daily.

Instructions for use

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it. Apply your eye drops in the following way:



1. 2. 3. 4.

1. Wash your hands. Tilt your head back and look up.
2. Gently pull the lower eyelid down until there is a small pocket.
3. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment.
4. Whilst keeping the treated eye closed, press your finger against its corner (where the eye meets the nose) and hold for one minute.

If a drop misses your eye, try again.

To avoid contamination, do not let the tip of the dropper touch your eye or anything else.

Replace and tighten the cap straight after use.

Wipe off any excess liquid from your cheek with a clean tissue.

Do not swallow.

The proper application of your eye drops is very important.

If you have any questions please ask your doctor or pharmacist.

Your doctor will tell you how long your treatment with BETAGAN 0,5 % will last.

Do not stop treatment early.

If you have the impression that the effect of BETAGAN 0,5 % is too strong or too weak, talk to your doctor or pharmacist.

What if you have used more BETAGAN 0,5 % than you should?

Putting too many drops in your eye(s) is unlikely to lead to unwanted side-effects. If you have placed too many drops in your eye(s), wash your eyes with clean water. Put your next dose in at the usual time.

If, by accident, anyone drinks BETAGAN 0,5 %, contact your doctor straight away. If neither is available, contact the nearest hospital or poison control centre immediately.

The following symptoms could result from such a risk:

- Low blood pressure (for example, upon standing)
- Slow heart beat
- Dizziness/temporary loss of consciousness

What if you forget to take or missed a dose of BETAGAN 0,5 %?

If you forget to use a dose, use it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and then go on as before. **Do not use two dosages at the same time.**

Effects when treatment with BETAGAN 0,5 % is stopped

Do not stop using BETAGAN 0,5 % or reduce the amount you are using until your doctor tells you to, since your symptoms may get worse.

BETAGAN 0,5 % should be used as advised by your doctor. If you have any further questions on the use of BETAGAN 0,5 %, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS

BETAGAN 0,5 % has side effects.

Not all side effects reported for BETAGAN 0,5 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BETAGAN 0,5 %, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking BETAGAN 0,5 % and tell your doctor immediately or go to casualty department at your nearest hospital:

- rash, swallowing or breathing difficulties, swelling of your lips, face, throat or tongue (these could be signs of a serious allergic reaction)
- breathing difficulties (including asthma)
- loss of consciousness (or feeling like this)
- unusual or slow heart beat
- low blood pressure

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BETAGAN 0,5 %. You may need urgent medical attention or hospitalisation.

Other side-effects may occur that usually do not need urgent medical attention, but please consult with your doctor as soon as possible.

The following side-effects have been reported:

Frequent side effects:

- eye irritation/eye pain
- irritation/redness of the outermost layer of the eye
- inflammation of the eyelids and outermost layer of the eye

Side effects with unknown frequency:

- depression
- worsening of lower leg cramp that affects walking, lack of coordination, confusion, dizziness, sleepiness, decreased energy, tiredness, headache, sleeplessness
- dry eye, decreased blinking, inflammation of the iris and inner eye or surface of the eye, trouble with your vision, itching of the eye/eye lids, eye and/or eyelid swelling/puffiness, eye discharge or tearing, foreign body sensation in the eye
- unusual, irregular or a fast heart beat or slow heart beat
- low blood pressure, fainting
- breathing difficulties or asthma
- throat irritation, nasal discomfort
- stomach ache, nausea, vomiting, diarrhoea
- hair loss, skin rashes, flaking and itching, rough patches of skin, redness of the skin
- swelling of the face
- sleep disturbances and nightmares, hallucinations
- erection problems
- tingling, cold, numbness or discolouration of the hands or feet
- low blood sugar

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF BETAGAN 0,5 %

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C.
- Do not use an unopened bottle of BETAGAN 0,5 % after the expiry date which is stated on the bottle label and the carton after “EXP”. The expiry date refers to the last day of that month.
- Store BETAGAN 0,5 % in the original carton to protect it from light.
- Do not use BETAGAN 0,5 % if you notice that the tamper-proof seal is broken.
- Once opened, solutions may become contaminated, which can cause eye infections. Therefore, you must throw away the bottle 4 weeks after you first opened it, even if some solution is left. To help you remember, write down the date that you opened it in the space on the carton.

- Please return all unused or expired medicines to your pharmacist.
- Do not dispose of these medicines in drains or sewerage systems (via wastewater or household waste).

7. PRESENTATION OF BETAGAN 0,5 %

BETAGAN 0,5 % Liquifilm Sterile Ophthalmic Solution is supplied in sterile dropper bottles containing 5 ml solution.

8. IDENTIFICATION OF BETAGAN 0,5 %

BETAGAN 0,5 % Liquifilm Sterile Ophthalmic Solution is a colourless to light yellow solution.

9. REGISTRATION NUMBER/REFERENCE NUMBER

S/15.4/0194

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

Allergan Pharmaceuticals (Pty) Ltd
30 New Road (entrance off Bavaria Road)
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11. DATE OF PUBLICATION

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