

Package leaflet: Information for the user

Bondulc 40 micrograms/ml eye drops, solution Travoprost

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Bondulc is and what it is used for

Bondulc **contains travoprost**, one of a group of medicines called **prostaglandin analogues**. It works by reducing the pressure in the eye. It may be used on its own or with other drops e.g. beta-blockers, which also reduce pressure.

Bondulc **is used to reduce high pressure in the eye in adults, adolescents and children from 2 months old onward**. This pressure can lead to an illness called **glaucoma**.

2. What you need to know before you use Bondulc

Do not use Bondulc

- **If you are allergic** to travoprost or any of the other ingredients of this medicine (listed in section 6).

Ask your doctor for advice if this applies to you.

Warnings and precautions Bondulc

- Bondulc **may increase** the length, thickness, colour and/or number of your **eyelashes**. Changes in the eyelids including unusual hair growth or in the tissue around the eye have also been observed.
- Bondulc may **change the colour of your iris** (the coloured part of your eye). This change may be permanent. A change in the colour of the skin around the eye may also occur.
- If you have had **cataract surgery**, talk to your doctor before you use Bondulc.
- If you have current or previous history of an **eye inflammation** (iritis and uveitis), talk to your doctor before you use Bondulc.
- Bondulc may rarely cause **breathlessness** or **wheezing** or increase the symptoms of asthma. If you are concerned about changes in your breathing pattern when using this medicine talk to your doctor as soon as possible.

- Bondulc may be **absorbed through the skin**. If any of the medicinal product comes into **contact with the skin**, it should be **washed off** straight away. This is especially important in women who are pregnant or are attempting to become pregnant
- If you wear soft contact lenses, do not use the drops with your lenses in. After using the drops wait 15 minutes before putting your lenses back in.

Children and adolescents

Bondulc can be used in children from 2 months to < 18 years at the same dose as for adults. Use of Bondulc is not recommended to those children under 2 months of age. Bondulc

Other medicines and Bondulc

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

Do not use Bondulc if you are pregnant. If you think that you may be pregnant speak with your doctor right away. If you could become pregnant you must use adequate contraception whilst you use this medicine.

Do not use Bondulc if you are breast feeding. Bondulc may get into your milk.

Ask your doctor for advice before taking any medicine.

Driving and using machines

You may find that your vision is blurred for a time just after you use Bondulc. Do not drive or use machines until this has worn off.

Bondulc contains benzalkonium chloride

May cause eye irritation.

Avoid contact with soft contact lenses.

Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

Know to discolour soft contact lenses.

Bondulc contains macrogol glycerol hydroxy stearate 40

This medicine contains macrogol glycerol hydroxy stearate 40, which may cause skin reactions.

3. How to use Bondulc

Always use this medicine exactly as your doctor or the doctor treating your child has told you. Check with your doctor, the doctor treating your child or pharmacist if you are not sure.

The recommended dose is

One drop in the affected eye or eyes, once a day – in the evening.

Only use Bondulc in both eyes if your doctor told you to. Use it for as long as your doctor or the doctor treating your child told you to.

Only use Bondulc for dropping in your or your child's eyes.



- Immediately before using a bottle for the first time, tear-off the overwrap pouch (**picture 1**). Take out the bottle and write the date of opening on the label in the space provided.
- Get the medicine bottle and a mirror
- Wash your hands.
- Twist off the cap.

<p>1</p> 	<ul style="list-style-type: none"> • Hold the bottle, pointing down, between your thumb and fingers. • Tilt your head or your child's head gently back. Pull down the eyelid with a clean finger, until there is a 'pocket' between the eyelid and the eye. The drop will go in here (picture 2). • Bring the bottle tip close to the eye. Use the mirror if it helps.
<p>2</p> 	<ul style="list-style-type: none"> • Do not touch the eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops. • Gently squeeze the bottle to release one drop of medicine at a time (picture 3). • After using the medicine, keep the eyelid closed, apply gentle pressure by pressing a finger into the corner of the eye, by the nose (picture 4) for at least 1 minute. This helps to stop the medicine getting into the rest of the body.
<p>3</p> 	<ul style="list-style-type: none"> • If you use drops in both eyes, repeat these same steps for the other eye. • Close the bottle cap firmly immediately after use. • Only use one bottle of medicine at a time. Do not open the pouch until you need to use the bottle.

If a drop misses your eye, try again.

If you or your child are using other eye preparations such as eye drop or eye ointment, wait for at least 5 minutes between putting in Bondulc and the other eye preparations.

If you or your child receive more Bondulc than you should

Rinse all the medicine out with warm water. Do not put in any more drops until it is time for your next regular dose.

If you forget to use Bondulc

Continue with the next dose as planned. **Do not use a double dose** to make up for a forgotten dose. Never use more than one drop in the affected eye(s) in a single day.

If you stop using Bondulc

Do not stop using this medicine without first speaking to your doctor or the doctor treating your child, the pressure in your eye or your child's eye will not be controlled which could lead to loss of sight.

If you have any further questions on the use of this medicine, ask your doctor, the doctor treating your child or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

You can usually carry on using the drops, unless the side effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop taking Bondulc without speaking to your doctor.

The following side effects have been seen with Bondulc

Very common side effects: may affect more than 1 in 10 people

Effects in the eye: eye redness.

Common side effects: may affect up to 1 in 10 people

Effects in the eye: changes in the colour of the iris (coloured part of the eye), eye pain, eye discomfort, dry eye, itchy eye, eye irritation.

Uncommon side effects: may affect up to 1 in 100 people

Effects in the eye: corneal disorder, eye inflammation, iris inflammation, inflammation inside the eye, eye surface inflammation with/out surface damage, sensitivity to light, eye discharge, eyelid inflammation, eyelid redness, swelling around the eye, eyelid itching, reduced vision, blurred vision, increased tear production, infection or inflammation of the conjunctiva (conjunctivitis), abnormal turning outward of the lower eyelid, clouding of the eye, eyelid crusting, growth of eyelashes, discolouration of the eyelashes, tired eyes.

General side effects: increased allergic symptoms, headache, dizziness, irregular heartbeat, shortness of breath, asthma, stuffy nose, throat irritation, darkening of skin around the eye(s), skin darkening, abnormal hair texture, excessive hair growth.

Rare side effects: may affect up to 1 in 1,000 people

Effects in the eye: perception of flashing lights, eczema of the eyelids, eye swelling, halo vision, decreased eye sensation, inflammation of the glands of the eyelids, pigmentation inside the eye, increase in pupil size, change in the texture of the eyelashes.

General side effects: eye viral infection, bad taste, irregular or decreased heart rate, increased or decreased blood pressure, cough, voice changes, gastrointestinal discomfort or ulcer, constipation, dry mouth, redness or itching of the skin, rash, hair colour change, loss of eyelashes, musculoskeletal pain, generalised weakness, breathing problems, sore throat.

Not known: frequency cannot be estimated from the available data

Effects in the eye: inflammation of the back of the eye, eyes appear more inset.

General side effects: depression, anxiety, sensation of false movement, ringing in ears, chest pain, worsening of asthma, diarrhea, abdominal pain, nausea, itching, abnormal hair growth, joint pain, painful or involuntary urination, increase in prostate cancer marker, increase in heart rate.

In children and adolescents, the most common side effects seen with Bondulc are eye redness and growth of eyelashes. Both side effects were observed with a higher incidence in children and adolescents compared to adults.

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bondulc

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 bottle and the box after 'Exp'. The expiry date refers to the last day of the month.

Do not use this medicine if you notice that the tamper evident seal has been broken or damaged before you first open it.

Before opening, keep bottle in overwrap pouch in order to protect from moisture.

After first opening, this medicine does not require any special storage conditions.

You must throw away the bottle 4 weeks after you first opened it, to prevent infections, and use a new bottle. Write down the date you opened the bottle in the space on each bottle label and box.

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 Bondulc contains

- The active substance is travoprost. Each ml of solution contains 40 micrograms of travoprost.
- The other ingredients are benzalkonium chloride solution, macrogol glycerol hydroxy stearate 40, trometamol, disodium edetate, boric acid (E284), mannitol (E421), sodium hydroxide for pH adjustment and water for injection.

What Bondulc looks like and the contents of the pack

Bondulc eye drop solution is a clear, colourless solution supplied in packs containing translucent polypropylene 5ml bottle(s) with transparent low density polyethylene (LDPE) dropper and white high density polyethylene (HPDE) tamper-proof screw cap packaged in overwrap pouch. Each bottle contains 2.5 ml solution.

The product is available in the following pack sizes:
Cartons containing 1 or 3 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

Pharmathen S.A.
Dervenakion 6
Pallini 15351
Attiki
Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria	Bondulc
Croatia	Bondulc 40 mikrograma/ml kapi za oko, otopina
Czech Republic	Bondulc 40 mikrogramů/ml
Denmark	Bondulc
Estonia	Bondulc
Finland	Bondulc
Ireland	Bondulc 40 micrograms/ml Eye drops, Solution
Latvia	Bondulc 40 mikrogrami/ml acu pilieni, šķīdums
Lithuania	Bondulc 40 mikrogramų/ml akių lašai (tirpalas)
Malta	Bondulc
Romania	Bondulc 40 micrograme/ml, Picături oftalmice, soluție
Slovakia	Bondulc 40 mikrogramov/ml
Slovenia	Bondulc 40 mikrogramov/ml kapljice za oko, raztopina
Sweden	Bondulc
United Kingdom	Bondulc 40 micrograms/ml Eye drops, Solution

This leaflet was last revised in July 2015