PACKAGE LEAFLET: INFORMATION FOR THE USER

Xalatan® 0.005% w/v eye drops solution
(latanoprost)

Your medicine is available using the above name but will be referred to as Xalatan throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Even if you have already used Xalatan or a similar medicine before, we advise you to read this text carefully. The information may have been changed.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or the doctor treating your child or pharmacist.
- This medicine has been prescribed for you or for your child 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 the doctor treating your child or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Xalatan is and what it is used for
Xalatan belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from inside the eye into the bloodstream.

Xalatan is used to treat conditions known as **open angle glaucoma** and **ocular hypertension** in adults. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.

Xalatan is also used to treat increased eye pressure and glaucoma in all ages of children and babies.

2. What you need to know before you use Xalatan
Xalatan can be used in adult men and women (including the elderly) and in children from birth to 18 years of age. Xalatan has not been investigated in prematurely born infants (less than 36 weeks gestation).

Do not use Xalatan:
- If you are allergic (hypersensitive) to latanoprost or any of the other ingredients of this medicine (listed in section 6)
- If you are pregnant or trying to become pregnant
- If you are breast-feeding

Warnings and precautions
Talk to your doctor or the doctor treating your child or pharmacist before using Xalatan or before you give this to your child if you think any of the following apply to you or your child:
- If you or your child are about to have or have had eye surgery (including cataract surgery)
- If you or your child suffer from eye problems (such as eye pain, irritation or inflammation, blurred vision)
- If you or your child suffers from dry eyes
- If you or your child have severe asthma or the asthma is not well controlled
- If you or your child wear contact lenses. You can still use Xalatan, but follow the instruction for contact lens wearers in Section 3
- If you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Other medicines and Xalatan
Xalatan may interact with other medicines. Please tell your doctor, the doctor treating your child or pharmacist if you or your child are using or have used any other medicines including those medicines (or eye drops) obtained without a prescription.

Pregnancy and Breast-feeding
Do not use Xalatan when you are pregnant or breast-feeding.
Tell your doctor immediately if you are pregnant, think you are pregnant, or are planning to become pregnant.

Driving and using machines
When you use Xalatan you might have blurred vision for a short time. If this happens to you, **do not drive** or use any tools or machines until your vision becomes clear again.

Xalatan contains Benzalkonium chloride
Xalatan contains a preservative called benzalkonium chloride. This preservative may cause eye irritation or disruption to the surface of the eye. Benzalkonium chloride can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses.

If you or your child wear contact lenses, they should be removed before using Xalatan. After using Xalatan you should wait 15 minutes before putting the contact lenses back in. See the instructions for contact lens wearers in Section 3.

3. How to use Xalatan
Always use Xalatan exactly as your doctor or the doctor treating your child has told you. You should check with your doctor or the doctor treating your child or pharmacist if you are not sure.

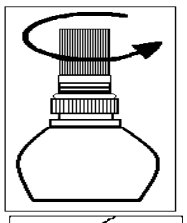
The usual dosage for adults (including the elderly) and children is one drop once a day in the affected eye(s). The best time to do this is in the evening.

Do not use Xalatan more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use Xalatan as instructed by your doctor or by the doctor treating your child until they tell you to stop.

Contact lens wearers
If you or your child wear contact lenses, they should be removed before using Xalatan. After using Xalatan you should wait 15 minutes before putting the contact lenses back into the eyes.

Instructions for use



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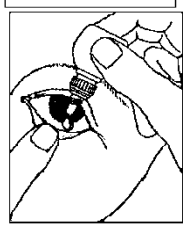
2. Unscrew the protective cap. The protective cap should be retained.



3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Place the tip of the bottle close to, but not touching your eye.
5. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
6. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.
7. Repeat in your other eye if your doctor has told you to do this.
8. Put the protective cap back on the bottle.

If you use Xalatan with other eye drops
Wait at least 5 minutes between using Xalatan and taking other eye drops.

If you use more Xalatan than you should
If you put too many drops into the eye, it may lead to some minor irritation in the eye and the eyes may water and turn red. This should pass, but if you are worried contact your doctor or the doctor treating your child for advice.

Contact your doctor as soon as possible if you or your child swallows Xalatan accidentally.

If you forget to use Xalatan
Carry on with the usual dosage at the usual time. Do not take a double dose to make up for the dose you have forgotten. If you are unsure about anything talk to your doctor or pharmacist.

If you stop using Xalatan
You should speak to your doctor or the doctor treating your child if you want to stop taking Xalatan.

4. Possible side effects
Like all medicines, Xalatan can cause side effects, although not everybody gets them. The following are known side effects of using Xalatan:

Very common (may affect more than 1 in 10 people):
- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop although it is normally seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use Xalatan in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after Xalatan treatment is stopped.
- Redness of the eye.
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye). If you experience eye irritation severe enough to make your eyes water excessively, or make you consider stopping this medicine, talk to your doctor, pharmacist or nurse promptly (within a week). You may need your treatment to be reviewed to ensure you keep receiving appropriate treatment for your condition.
- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye, seen mostly in people of Japanese origin. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.

Common (may affect up to 1 in 10 people):
- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain, light sensitivity (photophobia), conjunctivitis.

Uncommon (may affect up to 1 in 100 people):
- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision, inflammation of the coloured part of the eye (uveitis), swelling of the retina (macular oedema).
- Skin rash.
- Chest pain (angina), awareness of heart rhythm (palpitations).
- Asthma, shortness of breath (dyspnoea).
- Chest pain.
- Headache, dizziness.
- Muscle pain, joint pain.

Rare (may affect up to 1 in 1000 people):
- Inflammation of the iris (iritis), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema), misdirected eyelashes or an extra row of eyelashes, scarring of the surface of the eye, fluid filled area within the coloured part of the eye (iris cyst).
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Worsening of asthma.
- Severe itching of the skin.
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Very rare (may affect up to 1 in 10,000 people):
- Worsening of angina in patients who also have heart disease, sunken eye appearance (eye sulcus deepening).

Side effects seen more often in children compared to adults are: runny itchy nose and fever.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

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 XALATAN
- Store unopened bottle in a refrigerator (2°C to 8°C). Once the bottle has been opened, it is not necessary to store it in a refrigerator but do not store above 25°C.
- Keep the bottle in the outer carton in order to protect from light.
- Use within four weeks of opening.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (exp) which is stated on the carton and bottle. The expiry date refers to the last day of that month.
- If you have any left-over/unused eye drops please return them to your pharmacist for safe disposal.
- If your eye drops appear to be discoloured, damaged or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Xalatan contains
Each bottle contains 2.5ml of solution, made up of the active ingredient latanoprost.
Each ml of eye drop solution contains latanoprost 50 micrograms (0.005% w/v).

The other ingredients are: sodium chloride, benzalkonium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous and water for injections.

What Xalatan looks like and contents of the pack
The solution is a clear colourless liquid. Each carton contains one bottle of Xalatan.

Manufacturer
Manufactured by: Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

PPA No: 1151/75/1

Leaflet revision & issue date ref: 27.06.17

Xalatan® is a registered trademark of Pfizer Health AB.

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

Xalatan: Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, Netherlands, Portugal, Spain, United Kingdom.

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:
Product name: Xalatan 0.005% w/v eye drops solution
Reference No: 1151/75/1

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Do not use Xalatan:
- If you are allergic (hypersensitive) to latanoprost or any of the other ingredients of this medicine (listed in section 6)
- If you are pregnant or trying to become pregnant
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Warnings and precautions
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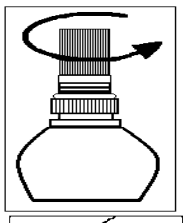

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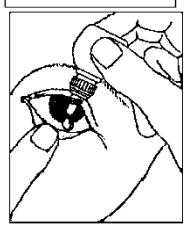

3. Use your finger to gently pull down the lower eyelid of your affected eye.
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- Redness of the eye.
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- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye, seen mostly in people of Japanese origin. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.

Common (may affect up to 1 in 10 people):
- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain, light sensitivity (photophobia), conjunctivitis.

Uncommon (may affect up to 1 in 100 people):
- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision, inflammation of the coloured part of the eye (uveitis), swelling of the retina (macular oedema).
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Rare (may affect up to 1 in 1000 people):
- Inflammation of the iris (iritis), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema), misdirected eyelashes or an extra row of eyelashes, scarring of the surface of the eye, fluid filled area within the coloured part of the eye (iris cyst).
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- Worsening of angina in patients who also have heart disease, sunken eye appearance (eye sulcus deepening).

Side effects seen more often in children compared to adults are: runny itchy nose and fever.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

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By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE XALATAN
- Store at room temperature (below 25°C).
- Keep the bottle in the outer carton in order to protect from light.
- Use within four weeks of opening.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (exp) which is stated on the carton and bottle. The expiry date refers to the last day of that month.
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The other ingredients are: sodium chloride, benzalkonium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous and water for injections.

What Xalatan looks like and contents of the pack
The solution is a clear colourless liquid.
Each carton contains one bottle of Xalatan with a screw cap and tamper evident overcap.
Each bottle contains 2.5ml of solution.

Manufacturer
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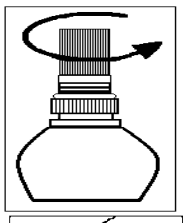

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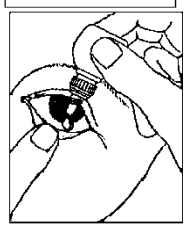

3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Place the tip of the bottle close to, but not touching your eye.
5. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
6. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.
7. Repeat in your other eye if your doctor has told you to do this.
8. Put the protective cap back on the bottle.

If you use Xalatan with other eye drops
Wait at least 5 minutes between using Xalatan and taking other eye drops.

If you use more Xalatan than you should
If you put too many drops into the eye, it may lead to some minor irritation in the eye and the eyes may water and turn red. This should pass, but if you are worried contact your doctor or the doctor treating your child for advice.

Contact your doctor as soon as possible if you or your child swallows Xalatan accidentally.

If you forget to use Xalatan
Carry on with the usual dosage at the usual time. Do not take a double dose to make up for the dose you have forgotten. If you are unsure about anything talk to your doctor or pharmacist.

If you stop using Xalatan
You should speak to your doctor or the doctor treating your child if you want to stop taking Xalatan.

4. Possible side effects
Like all medicines, Xalatan can cause side effects, although not everybody gets them. The following are known side effects of using Xalatan:

Very common (may affect more than 1 in 10 people):
- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop although it is normally seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use Xalatan in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after Xalatan treatment is stopped.
- Redness of the eye.
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye). If you experience eye irritation severe enough to make your eyes water excessively, or make you consider stopping this medicine, talk to your doctor, pharmacist or nurse promptly (within a week). You may need your treatment to be reviewed to ensure you keep receiving appropriate treatment for your condition.
- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye, seen mostly in people of Japanese origin. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.

Common (may affect up to 1 in 10 people):
- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain, light sensitivity (photophobia), conjunctivitis.

Uncommon (may affect up to 1 in 100 people):
- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision, inflammation of the coloured part of the eye (uveitis), swelling of the retina (macular oedema).
- Skin rash.
- Chest pain (angina), awareness of heart rhythm (palpitations).
- Asthma, shortness of breath (dyspnoea).
- Chest pain.
- Headache, dizziness.
- Muscle pain, joint pain.

Rare (may affect up to 1 in 1000 people):
- Inflammation of the iris (iritis), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema), misdirected eyelashes or an extra row of eyelashes, scarring of the surface of the eye, fluid filled area within the coloured part of the eye (iris cyst).
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Worsening of asthma.
- Severe itching of the skin.
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Very rare (may affect up to 1 in 10,000 people):
- Worsening of angina in patients who also have heart disease, sunken eye appearance (eye sulcus deepening).

Side effects seen more often in children compared to adults are: runny itchy nose and fever.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

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 XALATAN
- Before Xalatan is first opened keep it in a refrigerator (+2° to 8°). Once the bottle has been opened, it is not necessary to store it in a fridge, Xalatan can be stored at normal room temperature (below 25°C). Each bottle should be thrown away four weeks after first opening.
- Keep the bottle in the outer carton in order to protect from light.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (exp) which is stated on the carton and bottle. The expiry date refers to the last day of that month.
- If you have any left-over/unused eye drops please return them to your pharmacist for safe disposal.
- If your eye drops appear to be discoloured, damaged or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Xalatan contains
Each bottle contains 2.5ml of solution, made up of the active ingredient latanoprost.
Each ml of eye drop solution contains latanoprost 50 micrograms (0.005% w/v).

The other ingredients are: benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous and water for injections.

What Xalatan looks like and contents of the pack
The solution is a clear colourless liquid. Each carton contains one bottle of Xalatan.

Manufacturer
Manufactured by: Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

PPA No: 1151/75/1

Leaflet revision & issue date ref: 27.06.17

Xalatan® is a registered trademark of Pfizer Health AB.

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

Xalatan: Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, Netherlands, Portugal, Spain, United Kingdom.

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:
Product name: Xalatan 0.005% w/v eye drops solution
Reference No: 1151/75/1