

LATISSE[®] topical solution

(bimatoprost 300 microgram per mL)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LATISSE[®] topical solution. 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 LATISSE[®] topical solution 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 LATISSE[®] topical solution is used for

LATISSE[®] topical solution is used as a treatment to improve the length, thickness and darkness of natural eyelashes.

Human hair growth is a cyclic process whereby the hair follicle undergoes periods of growth, transition and rest. In response to a stimulus new hair shafts are formed within the hair follicles resulting in the growth of eyelashes.

The active ingredient in LATISSE[®] stimulates hair growth and hair follicles by increasing the growth phase and reducing the resting phase of the growth cycle. This means that the lashes grow for a longer period and so become longer and thicker.

LATISSE[®] topical solution is only available with a doctor's prescription from pharmacies. Your doctor may have prescribed LATISSE[®] topical solution for another reason.

Ask your doctor if you have any questions about why

LATISSE[®] has been prescribed for you.

Before you use LATISSE[®] topical solution

When you must not use it

Do not use LATISSE[®] topical solution if:

- you have an allergy to bimatoprost or any of the ingredients listed at the end of this leaflet
- 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 has passed

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

The preservative in LATISSE[®] topical solution (benzalkonium chloride) may be absorbed by soft contact lenses. You should remove contact lenses prior to administration of LATISSE[®]. You can put your soft contact lenses back into your eyes 15 minutes after you have used LATISSE[®].

It is not known if LATISSE[®] is safe and useful for children and adolescents under 18 years.

This solution is for topical use only.

Before you start to use it

Tell your doctor if:

1. you have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes.
2. if you have liver or kidney

problems.

3. if you are pregnant or intend to become pregnant. Like most medicines, LATISSE[®] topical solution should not be used during pregnancy, unless clearly necessary.

4. if you are breast-feeding or intend to breast-feed.

5. if you are being treated for increased pressure in the eye.

6. If you are being treated for or have a history of eye inflammation problems or problems with the back of the eye.

LATISSE[®] topical solution is intended for use on the skin of the upper eyelid margins at the base of the eyelashes. Do not apply to the lower eye lid.

Before you start using LATISSE[®] topical solution your doctor should tell you that some changes to your eyes which may occur may be permanent.

LATISSE[®] may cause darkening of the eyelid skin which may be reversible. LATISSE[®] use may also cause the coloured part of the eye to become darker which can be permanent.

None of these changes affect vision. If you have any concerns, ask your doctor or pharmacist.

It is possible for hair growth to occur in other areas of your skin that LATISSE[®] frequently touches.

Any excess solution outside the upper eyelid margin should be blotted with a tissue or other absorbent material to reduce the chance of this from happening. It is also possible for a difference in eyelash length, thickness, fullness, pigmentation, number of eyelash hairs, and/or direction of eyelash growth to occur between eyes. These differences, should they

occur, will usually go away if you stop using LATISSE®.

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.

If you are being treated for eye pressure problems tell your doctor as there is a potential for LATISSE® to affect some eye pressure lowering medications.

It is not expected that LATISSE® will interact with other medicines, however you should always ask your doctor or pharmacist if you have any concerns about using LATISSE® topical solution as well as other medications.

How to use LATISSE® topical solution

How much to use

Use LATISSE® topical solution only as prescribed by your doctor.

The recommended dose of LATISSE® topical solution is one application nightly to the skin of the upper eyelid margin at the base of the eyelashes only.

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

How to use it

If you are wearing soft contact lenses, remove them before using LATISSE® solution.

To open a new bottle of LATISSE® topical solution 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. Ensure your face is clean and makeup and contact lenses are removed.

LATISSE® (bimatoprost 300 microgram/mL) topical solution -CMI Version 1.0

3. Remove the lid/cap from the bottle.
4. Remove an applicator from its tray. Then holding the sterile applicator horizontally, carefully place one drop of LATISSE® on the area of the applicator close to the tip but not on the tip.
5. Then immediately apply evenly and lightly along the skin of the upper eyelid margin at the base of the eyelashes (where the eyelashes meet the skin). The eyelid margin is the area from the inner part of your lash line to the outer part of your lash line.
6. Blot any excess solution beyond the eyelid margin (area the solution is applied to) with a tissue or absorbent cloth.
7. Dispose of the applicator after one use.
8. Repeat for the opposite upper eyelid margin using a new sterile applicator. Do not reuse applicators. This helps minimize any potential for contamination from one eyelid to another.
9. Replace the lid/cap on the bottle, sealing it tightly.
10. 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 any other surface to avoid contaminating the topical solution.

DO NOT APPLY in your eye or to the lower lid. Only use the sterile applicators supplied with LATISSE® to apply the product.

How long to use it

Continue using LATISSE® topical solution for as long as your doctor prescribes.

If you stop using LATISSE®, your eyelashes are expected to return to their previous appearance over several weeks to months.

Any eyelid skin darkening has been reported to be reversible in most patients.

Any darkening of the coloured part of the eye known as the iris is NOT expected to reverse and is likely permanent.

If you forget to use it

If you miss a dose and it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Then go back to using the solution 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. Use of LATISSE® more than once a day will not increase the growth of eyelashes.

If you use too much (overdose)

If any LATISSE® solution accidentally gets into the eye, it is not expected to cause any harm. The eye should not be rinsed.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of LATISSE® solution, immediately telephone your doctor or **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 LATISSE® topical solution

Things you must do

LATISSE® solution is intended for use on the skin of the upper eyelid margins at the base of the eyelashes.

Do not apply to the lower eyelid.

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 LATISSE[®] topical solution because of possible contamination of the old one.

If you become pregnant while using LATISSE[®] topical solution tell your doctor immediately.

If you wear soft contact lenses, remove them before using LATISSE[®] topical solution. Leave your lenses out for at least 15 minutes after applying the topical solution.

Tell your doctor if your condition gets worse or does not get better while using LATISSE[®] topical solution.

If you are about to start any new medicine tell your doctor and pharmacist that you are using LATISSE[®]. Tell your doctor or pharmacist you are using LUMIGAN[®] eye drops or other products in the same class for elevated intraocular pressure (IOP), or if you have a history of abnormal IOP as you should only use LATISSE[®] under the close supervision of your physician in these circumstances.

You should tell anyone conducting an eye pressure screening that you are using LATISSE[®] topical solution.

Things you must not do

Do not give LATISSE[®] topical solution to anyone else, it may not be appropriate for them to use.

Things to be careful of

LATISSE[®] topical solution is not expected to cause any problems with your ability to drive a car or operate machinery. However, as a general precaution be careful driving or operating machinery until you know how LATISSE[®] topical solution affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using LATISSE[®] topical solution.

Check with your doctor as soon as possible if you have any problems while you are using LATISSE[®] topical solution, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Ask your doctor or pharmacist any questions you may have.

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

- red, congested eyes
- itching or irritation of eye/s
- other eye-related effects such as allergic effects on the eye and surrounding eyelid
- an increase in colouring or pigment of the iris and/or area around the eye.
- Changes to eyelashes (including temporary or permanent loss of eyelashes and/or breakage of eyelashes)
- Rash to eyelids and surrounding area

After using LATISSE[®] topical solution

Storage

Keep your LATISSE[®] topical solution and applicators in a cool place where the temperature stays below 25°C.

Keep the bottle and applicators where children cannot reach them.

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

Disposal

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

The topical solution contains a preservative which helps prevent germs from 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 topical solution or it has passed the expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What does LATISSE[®] topical solution look like:

Clear, colourless, sterile solution in a plastic dropper bottle accompanied by 60 sterile, disposable applicators.

Solution ingredients

Active ingredient:
Bimatoprost 300 microgram /mL

Preservative:
Benzalkonium chloride

Inactive ingredients:
Sodium phosphate dibasic
Sodium chloride
Citric acid monohydrate
Sodium hydroxide and/or
Hydrochloric acid may be added to adjust pH
Purified water

Manufacturer/Supplier

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