PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

ATANA® 50,0 µg/ml Ophthalmic Solution

Latanoprost

Read all of this leaflet carefully before you start using ATANA

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

What is in this leaflet

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

1. WHAT ATANA IS AND WHAT IT IS USED FOR

ATANA is an eye drop that is used to treat high fluid pressure in the eye due to glaucoma (open angle type) or other eye diseases (e.g. ocular hypertension). The pressure within the eyeball is naturally maintained by a continuous flow of liquid called aqueous humor. Liquid is always emptying out of the eye and more liquid is always being produced. If the eye fills up faster than it empties, the pressure inside the eye builds up. ATANA belongs to a group of medicines known as prostaglandin analogues and works by helping fluid flow out of the eye chamber which in turn lowers the pressure in the eye. Lowering high fluid pressure in the eye reduces the risk of vision loss, nerve damage and/or blindness.

ATANA can be used either alone or with another eye drop which lowers pressure in the eye for the treatment of high pressure in the eye in glaucoma or ocular hypertension.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ATANA

Do not use ATANA:

- If you are hypersensitive (allergic) to latanoprost, benzalkonium chloride or any other ingredients in ATANA.
- If you are pregnant or are attempting to become pregnant.
- While using contact lenses. The preservative benzalkonium chloride may be absorbed by your contact lenses. You should remove your lenses just before you instil ATANA and wait at least 15 minutes before you reinsert them.

Warnings and precautions:

Take special care with ATANA:

- If you do not have a lens in your eye or you have an artificial one and you have a torn posterior capsule (the membrane that surrounds the lens).
- If you have risk factors for developing cystoid macular oedema (fluid filled cysts).
- If you have any kidney or liver impairment.
- If you have extensive eye surface disease and you use ATANA for a long period of time. Regular eye

examinations are recommended.

- If you suffer from asthma because ATANA may bring on an attack.
- If the drainage canals in your eye are blocked causing high pressure within your eye (closed angle glaucoma).
- When used for a prolonged period of time. It is recommended that you go for regular eye examinations due to the risk of developing corneal side effects due to the preservative benzalkonium chloride.
- ATANA may change your eye colour by increasing the amount of brown pigment in your iris (the coloured part of your eye). If you have mixed-colour eyes (grey-brown, blue-brown and in particular green-brown and yellow-brown) you are more likely to see this change than if you have eyes of one colour (grey, blue, green or brown). Any changes in your eye colour may take years to develop although it is normally seen within 8 months of treatment. There is no further increase in brown pigmentation in your iris once you stop treatment but any change that did occur during treatment is permanent, and occurs only in the eye being treated. Therefore, if ATANA is used in one eye only, it could result in a cosmetic difference in eye colour between the treated and non-treated eye.
- You may also notice changes in your eyelashes.
- Ensure that you handle the dropper tip correctly. Avoid contact with your eye, surrounding structures or any other surface. Improper handling of the dropper tip may contaminate it and lead to serious eye infections which may damage your eye and affect your vision. It is important to report any eye infection or other eye trauma that may develop while using ATANA, to your doctor.
- You should consult a doctor if you develop any eye reactions to ATANA, particularly eyelid reactions and eye inflammation (red eyes or swelling).
- ATANA can be used either alone or with another eye drop which lowers pressure in the eye for the treatment of high pressure in the eye in glaucoma or ocular hypertension. However when eye drops containing thiomersal are used together with ATANA solid substances may be formed in the eye. Therefore if you are using eye drops that contain thiomersal or any other eye drops with ATANA you should instil them at least 5 minutes apart.

Other medicines and ATANA:

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

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Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

ATANA should not be used by pregnant women due to the risk of harm it may cause to the baby.
The safety of ATANA during breastfeeding has not been established.

Driving and using machines:

You may find that your vision is temporarily blurred just after you instil ATANA. Do not drive, use any machinery or perform any activity that requires clear vision until you are sure that you can perform such activities safely.

ATANA contains benzalkonium chloride:

The preservative used in ATANA (benzalkonium chloride) may be absorbed by contact lenses. Remove your lenses just before you use ATANA and wait at least 15 minutes before you reinsert your lenses.

3. HOW TO USE ATANA

Do not share medicines prescribed for you with any other person.

Always use ATANA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

The usual dose for reducing eye pressure is one drop into the affected eye(s) once daily in the evening.

Do not use more frequently than once a day as this may decrease the eye pressure lowering effect of the medicine.

Use this eye drop regularly in order to get the most benefit from it. Remember to use it at the same time each day.

If you are using other eye medications (e.g. drops or ointments) in addition to ATANA, you should wait at least 5 minutes before applying the other medication. Use eye drops before eye ointments in order to allow the eye drops to enter the eye.

Your doctor will tell you how long your treatment with ATANA will last. Do not stop using ATANA even if you feel well unless instructed to do so by your doctor.

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

ATANA is intended to be instilled into the eye only. Do not swallow.

Helpful hints:

You must not use the eye drops if the tamper-proof seal on the bottle neck is broken before you first use it.

Remove your contact lenses and wait at least 15 minutes after you instil ATANA to reinsert them. Apply your eye drops in the following way:

Wash your hands. Shake the bottle gently to make sure that the medicine is well mixed. Tilt your head back and look upward. Gently pull the lower eyelid down. Bring the eye drops near the eye, turn the bottle upside down and squeeze it to release a drop into the eye. Avoid touching the eye, eyelids or eye lashes with the dropper. Let go of the lower lid, and close your eye for 30 seconds. While your eyes are closed, gently press your fingers on the inner corner(s) of your eye(s). This will prevent the eye drops from draining out of the eye.

If a drop misses your eye, try again. Wipe away any excess with a clean tissue. Replace and tighten the cap straight after use to avoid contamination. Store upright.

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

Keep to the dosage as instructed by your doctor. You should always check with your doctor or pharmacist if you are unsure.

If you use more ATANA than you should:

If you use more ATANA than you should you may experience pink eyes or eye irritation.

In the event of overdosage or if ATANA is accidentally swallowed, stop using ATANA and consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre. If you have placed too many drops in your eye(s), wash the eye(s) with clean water.

If you forget to use ATANA:

Ignore the dose you missed and continue with the next dose as planned.

Do not take a double dose to make up for a missed dose.

If you have missed several doses, consult your doctor.

If you seem to always have trouble remembering when to use/take your medicines, ask your pharmacist for some helpful hints.

4. POSSIBLE SIDE EFFECTS

ATANA can have side effects. Not all side effects reported for ATANA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ATANA, please consult your healthcare provider for advice.

The following side effects may occur when using ATANA:

If any of the following should happen, stop using ATANA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Skin rash / allergic skin reactions;
- Chest pain / discomfort / tight feeling in your chest (angina);
- Shortness of breath, asthma or worsening of asthma symptoms.

These are very serious but less frequent side effects. You may need urgent medical attention.

Contact your doctor as soon as possible if you notice that you are experiencing infections such as upper respiratory tract infections, colds and flu.

Tell your doctor if you experience any of the following frequent but mild side effects:

- Mild to moderate pink eyes and eye irritation;
- Change in eye colour due to an increase in brown pigmentation in your iris (the coloured part of your eye);
- Slight foreign body sensation (the sensation of having a foreign particle in your eye);
- Changes in your eyelashes.

The following frequent side effect may also occur. Inform your doctor should you experience:

- Irritation or disruption on the surface of the cornea (white part of the eye), this may occur with, but mostly without symptoms. Symptoms to watch for are red eyes, tearing, burning, sensitivity to light and foreign body sensation (the sensation of having a foreign particle in your eye).

Also tell your doctor if you experience any of the following less frequent side effects:

- Build up of fluid or fluid filled cysts around the eyes, the white part of the eye (cornea) or any other part of the eye. This may occur mainly in people who have no lens or have an artificial lens and have a torn posterior lens capsule (the membrane that surrounds the lens). Symptoms to watch for are pain, watery eyes, blurred vision and sensitivity to light;
- Inflammation in the iris (the coloured part of the eye);
- Darkening of the eyelid skin;
- Muscle pain;
- Joint pain;
- Back pain.

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

Reporting of side effects:

If you experience side effects, talk to your doctor or pharmacist.

You can report side effects to Gen-Eye (Pty) Ltd via email: pharmacovigilance@gen-eye.co.za or telephonically on 011 312 3812.

You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

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

5. HOW TO STORE ATANA

Store at 2 °C – 8 °C in a refrigerator. Avoid freezing. Protect from light.

Keep the bottle in the carton until required for use.

Keep well closed after initial opening.

Once the container is opened store at or below 25 °C. The contents must be used within 30 days.

Throw out any unused drops 30 days after first opening.

Store in the original container. Keep the container in the outer carton and store upright.

Keep all medicines out of the reach and sight of children.

Do not use this medicine after the expiry date stated on the bottle and carton.

To protect the solution from contamination, keep the container tightly closed and do not touch the dropper tip to any surface.

Do not use ATANA if you notice visible signs of deterioration.

Do not use ATANA if you notice the tamper-proof seal on the bottle is broken. Contents are sterile if seal is intact.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ATANA contains:

The active substance is latanoprost.

1 ml of ATANA® Ophthalmic Solution contains 50,0 µg latanoprost.

The other ingredients are: Benzalkonium chloride 0,02 % *m/v* (preservative), disodium phosphate anhydrous, sodium chloride, sodium dihydrogen phosphate monohydrate, sodium hydroxide / hydrochloric acid and water for injection.

What ATANA looks like and contents of the pack:

ATANA ophthalmic solution is a clear, colourless aqueous solution.

ATANA ophthalmic solution is supplied in a low density polyethylene 5 ml sterile white bottle containing 2,5 ml solution, with a sterile white high density polyethylene screw cap and a sterile white low density polyethylene under-cap dropper. The dropper bottle is contained in an outer cardboard carton.

HOLDER OF CERTIFICATE OF REGISTRATION

Gen-Eye (Pty) Ltd[1]

Unit 7, Royal Palm Business Estate

646 Washington Street, Halfway House, Midrand, 1685

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THIS LEAFLET WAS LAST REVISED IN

1 June 2022

REGISTRATION NUMBER

47/15.4/0116

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

The corresponding Professional Information is available electronically on www.gen-eye.co.za.

Alternatively, to obtain this Professional Information please contact Gen-Eye (Pty) Ltd on 011 312 3812 or email info@gen-eye.co.za.

[1] Company Registration number: 2009/009360/07

Namibia:

Scheduling Status: NS2

Registration number: 15/15.4/0138