NOVARTIS

PATANOL®

(olopatadine hydrochloride)

1 mg/ml, Eye Drops, Solution

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S2**

PATANOL® 1 mg/ml Eye Drops (solution)

Olopatadine

Read all of this leaflet carefully because it contains important information for you

PATANOL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use PATANOL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PATANOL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

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

1. What PATANOL is and what it is used for

What PATANOL is:

PATANOL 0,1 % eye drops, solution contains the active substance olopatadine hydrochloride, and is used to reduce the intensity of the allergic reaction.

What it is used for:

PATANOL is used for the treatment of itching, redness and swelling of the surface of your eye caused by allergy to house dust, pollen, animal fur, or other allergens (allergic conjunctivitis).

2. What you need to know before you use PATANOL

Do not use PATANOL:

- if you are hypersensitive (allergic) to olopatadine or any of the other ingredients of PATANOL (listed in section 6).

Warnings and precautions

Take special care with PATANOL:

- if you wear contact lenses;
- PATANOL contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses (*see section PATANOL contains benzalkonium chloride*).

Children/ and adolescents

Patanol can be used in children or adolescents between the ages of 3 years and 18 years at the same dose as for adults.

Other medicines and PATANOL

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

In case of concomitant therapy with other topical eye medicines, an interval of 5 minutes should be allowed between each application.

Pregnancy and breastfeeding and fertility

You should not use PATANOL if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding your baby or think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using PATANOL.

Driving and using machines

It is not always possible to predict to what extent PATANOL may interfere with the daily activities of a patient. PATANOL may cause temporary blurred vision or other visual disturbances Patients should ensure that they do not engage in mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision until they are aware of the measure to which PATANOL affects them.

PATANOL contains benzalkonium chloride

- PATANOL 0,1 % eye drops contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. In case you are allowed to wear contact lenses, you must remove the contact

lenses prior to application of PATANOL 0,1 % eye drops and wait at least 15 minutes before reinsertion.

- As the possibility of adverse effects on the cornea of the eye and the danger of disruption of the surface of the cornea with prolonged or repeated usage of benzalkonium chloride preserved eye preparations such as PATANOL 0,1 % eye drops cannot be excluded, regular eye examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medication such as PATANOL 0,1 % eye drops over an extended period in patients with extensive eye surface disease.

3. How to use PATANOL

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

Always use PATANOL exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

- Instill one drop of PATANOL in the conjunctival sac of the affected eye(s) twice daily.
- To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas, or other surfaces with the dropper tip of the bottle.
- Keep the bottle tightly closed when not in use.
- After the bottle cap is removed, if the tamper evident snap collar is loose, snap collar should be removed before using the product.

- If more than one topical ophthalmic medicine is used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.
- Do not wear contact lenses in case of eye redness.

If you have the impression that the effect of PATANOL is too strong or too weak, tell your doctor or pharmacist.

If you use more PATANOL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use PATANOL

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

PATANOL can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;

- rash or itching;
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Eye surface inflammation with or without surface damage (signs of punctate keratitis); This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Eye discomfort

The following side effects have been reported less frequently:

- Eye pain;
- dry eye;
- eyelid swelling;
- itchy eye;
- eye discharge;
- eye redness, eyelid redness;
- increased sensitivity of the eyes to light (photophobia);
- headache;

- disturbed sense of taste (dysgeusia);
- nasal dryness;
- tiredness (fatigue);
- itchy rash (contact dermatitis);
- dizziness.

The following side effects have been reported but the frequency is unknown:

- Blurred vision;
- watering eye (increased lacrimation);
- rhinitis (stuffy nose);
- nausea;
- dry mouth;
- erythema (skin redness);
- allergy.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PATANOL.

5. How to store PATANOL

- Store at or below 25 °C.
- DO NOT USE MORE THAN 30 DAYS AFTER OPENING
- Store all medicines out of reach of children.
- Store in the original package / container.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PATANOL contains:

- The active substance is:

Olopatadine hydrochloride 1,11 mg/ml equivalent to 1 mg/ml olopatadine

- The other ingredients are:

Benzalkonium chloride

Sodium chloride

Disodium phosphate dodecahydrate

Purified water

Hydrochloric acid and/or sodium hydroxide (pH adjuster)

What PATANOL looks like and contents of the pack

5 ml opaque low–density polyethylene bottles with dispensing plugs and polypropylene screw caps.

Holder of Certificate of Registration and Manufacturer

Novartis South Africa (Pty) Ltd.

Magwa Crescent West

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Namibia: NS1 Reg. No.: 06/15.4/0068

Zimbabwe: PIM Reg. No.: 2002/19.9/4020

Manufacturer

Novartis Manufacturing NV Rijksweg 14,

Puurs-Sint-Amands, 2870, Belgium

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website