Approved Patient Information Leaflet for Medicines for Human Use: OFTAPAT

SCHEDULING STATUS: S2

OFTAPAT, 1 mg/mL eye drops, solution

Olopatadine

Contains preservative benzalkonium chloride 0,01 % *m/v*

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

OFTAPAT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use OFTAPAT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share OFTAPAT 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 5 days.

What is in this leaflet

1. What OFTAPAT is and what it is used for

OFTAPAT contains olopatadine and is used for the treatment of signs and symptoms of seasonal allergic conjunctivitis.

Allergic conjunctivitis. Some materials (allergens) like pollens, house dust or animal fur may cause allergic reactions resulting in itching, redness as well as swelling of the surface of your eye.

OFTAPAT is a medicine for treatment of allergic conditions of the eye. It works by reducing the intensity of the allergic reaction.

2. What you need to know before you use OFTAPAT

Do not use OFTAPAT

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

Warnings and precautions

Take special care with OFTAPAT**:**

- if signs of serious reactions or hypersensitivity occur, discontinue the use of OFTAPAT, tell your doctor immediately or go to the casualty department of the nearest hospital (see section 4. Possible side effects).
- if you are using multiple dose containers of topical ophthalmic products there is a possibility of an eye infection known as bacterial keratitis. Do not let the tip of the dispensing container contact the eye or surrounding structures, this could cause the tip to become contaminated (see section 3 How to use OFTAPAT).
- if you wear contact lenses, OFTAPAT must not be instilled into the eye while wearing contact lenses. Remove the contact lenses before application of OFTAPAT and wait 10 minutes after instillation of the dose before reinsertion.
- if you are using OFTAPAT, which contains the preservative benzalkonium chloride, over an extended period and you have diseases of the cornea (the outer layer covering the surface of the eye), you need to have regular eye examinations by your doctor to check the condition of your eye as benzalkonium chloride can damage the cornea.

Children

- Do not use OFTAPAT in children under the age of 3 years.

Other medicines and OFTAPAT

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

If you are using other eye drops or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

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 health care provider for advice before taking this medicine.

You should not use OFTAPAT if you are breastfeeding, ask your doctor for advice before using OFTAPAT.

Driving and using machines

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

OFTAPAT contains Benzalkonium chloride

OFTAPAT.contains 0,1 mg benzalkonium chloride (a preservative) in each millilitre eye drop solution which is equivalent to 0,01 % *m/v*.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 10 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using OFTAPAT, talk to your doctor.

3. How to use OFTAPAT

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

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

The usual dose is one drop in the affected eye or eyes, twice a day, morning and evening.

Use this much unless your doctor tells you to do differently. Only use OFTAPAT in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

Duration of administration

Unless prescribed otherwise, OFTAPAT should be taken for a period of 5 - 7 days. Talk to your doctor if the symptoms persist longer than 5 - 7 days, worsen or recur periodically.

Method of administration

OFTAPAT should only be used as an eye drop.

Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, wash your hands before using OFTAPAT and keep the tip of the container away from contact with any surface. If you think your medicine may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

Instructions for use

1. Before using OFTAPAT for the first time, be sure the tamper evident snap collar on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.

2. First wash your hands, then tear off the tamper evident snap collar to break the seal.

3. To open the bottle, unscrew the cap by turning it the left. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.

4. Tilt your head back and pull your lower eyelid down slightly to form a pouch between your eye and eyelid.

5. Invert the bottle and press lightly with the thumb or index finger until a single drop is dispensed into the eye as directed by your doctor. **DO NOT LET YOUR EYE OR EYELID TOUCH THE DROPPER TIP.**

6. After using OFTAPAT press a finger into the corner of your eye, by the nose, or close your eyelids for 2 minutes. This helps to stop the medicine from getting into the rest of the body.

7. Repeat steps 4 and 5 in the other eye if instructed to do so by your doctor.

8. Replace the cap by turning until it is firmly touching the bottle. Do not overtighten or you may damage the bottle and cap.

9. The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.

If you wear soft contact lenses

Do not use the drops with your soft contact lenses in. After using the drops wait at least 10 minutes before putting your lenses back in (see section 2, OFTAPAT contains Benzalkonium chloride).

If you are using other eye drops or eye ointments

If you are using OFTAPAT with another eye drop, the drops should be instilled at least 5 minutes apart. Eye ointments should be administered last. (See section 2, Other medicines and OFTAPAT).

If you use more OFTAPAT than you should

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

Immediately following overdosage into your eye(s), rinse it all out with warm water. Do not put in any more drops until it's time for your next regular dose.

If you put too many drops in your eye or swallow any of the contents of the container, among other effects, you may experience eye pain and eye discomfort, have a headache, dry nose, bad taste in your mouth or feel very tired.

If you forget to use OFTAPAT

Use a single drop as soon as you remember, and then go back to your regular dosing routine. However, if it is almost time for your next dose, skip the missed dose before going back to your regular dosing routine. Do not use a double dose to make up for the one missed.

If you stop using OFTAPAT

Do not stop using OFTAPAT without first speaking to your doctor.

If you have any further questions on the use of OFTAPAT, ask your doctor or pharmacist.

4. Possible side effects

OFTAPAT can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to OFTAPAT. 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:

Frequent:

- eye pain
- dry eye

Less frequent:

- corneal disorder
- eye surface inflammation with or without surface damage
- inflammation or infection of the conjunctiva
- eye discharge

Frequency unknown:

- eye swelling
- corneal swelling
- change in pupil size
- increased allergic symptoms
- cloudy patches on the cornea due to calcium build-up during treatment have developed in some patients with severe damage to the clear layer at the front of the eye (the cornea)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- eye irritation
- abnormal eye sensation
- eye discomfort
- headache
- fatigue
- dry nose
- bad taste

Less frequent side effects:

- blurred, reduced, or abnormal vision
- sensitivity to light
- increased tear production
- itchy eye
- redness of the eye
- eyelid abnormality
- itching, redness, swelling, or crusting of the eyelid
- abnormal or decreased sensation
- dizziness
- runny nose
- dry skin
- skin inflammation

Side effects with frequency unknown:

- drowsiness
- generalized weakness
- nausea
- vomiting
- sinus infection
- skin redness and itching.

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. 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 OFTAPAT.

5. How to store OFTAPAT

Store all medicines out of reach of children

- Store unopened container at or below 30 °C in the original packaging until required for use.
- Opened container must be stored at or below 25 °C.
- Do not use more than 28 days after opening.
- 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 OFTAPAT contains

- The active substance is olopatadine
- The other ingredients are:

  benzalkonium chloride

  sodium chloride

  anhydrous disodium phosphate

  hydrochloric acid (to adjust pH)

  sodium hydroxide (to adjust pH)

  purified water for injection.

What OFTAPAT looks like and contents of the pack

OFTAPAT eye drops, is a clear colourless liquid (a solution), free from visible particulate matter and is supplied in a 5 mL (fill volume 5 mL in a 5 mL bottle) ethylene oxide sterilized white LDPE bottle with natural LDPE nozzle and white HDPE cap.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: +27860287835

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