SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERAL PHARMACEUTICALS LTD.

ONAPAT EYE DROPS 5 ML (Summary of Products Characteristics)

Date: 02.08.2023

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Executive, International Regulatory Affairs

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1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

a) Product Name : Onapat Eye Drops 5 ml

b) Strength : Olopatadine 0.2% w/v

c) Pharmaceutica : Eye Drops (Sterile) l Dosage Form

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The qualitative and quantitative composition of each component in the drug product is listed.

Unit Composition

Material Name	Compendial Reference	Unit	Quantity /5 ml	Justification
Active Ingredients				
Olopatadine Hydrochloride	USP	mg	11.100	Active
Excipients				
Sodium Perborate	BP	mg	0.500	Preservative
Sodium Chloride (For Sterile)	BP	mg	40.000	Osmotic agent
Disodium Hydrogen Phosphate Dodecahydrate (For sterile)	BP	mg	20.000	Buffering agent
Sodium Hydroxide	BP	mg	0.400	pH adjusting agent
Water for Injection	BP	mg	q.s to 5.000 ml	Solvent

3. PHARMACEUTICAL FORM

Eye Drops (Sterile)

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Onapat Eye Drops is indicated for the treatment of signs and symptoms (itchy, watery, red and swollen eyes and/or eyelids) of allergic conjunctivitis including vernal keratoconjunctivitis, vernal blepharoconjunctivitis and giant papillary conjunctivitis

4.2. Posology and method of administration

The recommended dose of Onapat eye drop is 1 drop in the affected eye(s) once daily.

4.3. Contraindications

It is contraindicated in persons with a known hypersensitivity to any component of this product.

4.4. Special warnings and special precautions for use

Patients should be advised not to wear a contact lens if their eye is red. Onapat eye drop should not be used to treat contact lens related irritation. Benzalkonium Chloride, preservative of this eye solution, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and whose eyes are not red should be instructed to wait at least 10 minutes after instillation of Onapat eye drop before they insert their contact lenses. The treatment should be discontinued in the presence of an allergic reaction.

4.5 Interaction with other FPPs and other forms of interaction

No interaction studies with other medicinal products have been performed.

4.6. Pregnancy and lactation

Onapat eye drop was found not to be teratogenic in rats and rabbits. There are, however, no adequate and well controlled studies in pregnant women. This drug should be used in pregnant women only if the potential benefit justifies the potential risk to the fetus. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk.

Nevertheless, caution should be exercised when Onapat eye drop is administered to a nursing mother.

4.7. Effects on ability to drive and use machines

Onapat eye drop Eye Drops has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Rarely headaches have been reported. Other adverse effects: asthenia, blurred vision, burning or stinging, cold syndrome, dry eye, foreign body sensation,

hyperemia, hypersensitivity, keratitis, lid edema, nausea, pharyngitis, pruritus, sinusitis, and taste perversion.

Reporting of suspected adverse reactions

Health care professionals are asked to report any suspected adverse reactions via the https://pv.pharmacyboardkenya.org

4.9. Overdose

There is no information on Onapat eye drop overdose. However, excessive use of any medication can have serious consequences. If you suspect an overdose, seek medical attention without delay.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Onapat eye drop inhibits the release of histamine from the mast cell and is relatively selective histamine H1 -antagonist that inhibits the in vivo and in vitro type 1 immediate hypersensitivity reaction including inhibition of histamine induced effects on human conjunctival epithelial cells. Onapat eye drop has no effects on alphaadrenergic, dopamine and muscarinic type 1 and 2 receptors.

5.2. Pharmacokinetic properties

Absorption

Olopatadine is absorbed systemically, as are other topically administered medicinal products. However, systemic absorption of topically applied olopatadine is minimal with plasma concentrations ranging from below the assay quantitation limit (<0.5 ng/ml) up to 1.3 ng/ml. These concentrations are 50-to 200-fold lower than those following well tolerated oral doses.

Elimination

From oral pharmacokinetic studies, the half-life of olopatadine in plasma was approximately eight to 12 hours, and elimination was predominantly through renal excretion. Approximately 60-70% of the dose was recovered in the urine as active substance. Two metabolites, the mono-desmethyl and the N-oxide, were detected at low concentrations in the urine.

Since olopatadine is excreted in urine primarily as unchanged active substance, impairment of renal function alters the pharmacokinetics of olopatadine with peak plasma concentrations 2.3-fold greater in patients with severe renal impairment (mean creatinine clearance of 13.0 ml/min) compared to healthy adults. Following a 10 mg oral dose in patients undergoing haemodialysis (with no urinary output), plasma olopatadine concentrations were significantly lower on the haemodialysis day than on the non-haemodialysis day suggesting olopatadine can be removed by haemodialysis.

Studies comparing the pharmacokinetics of 10 mg oral doses of olopatadine in young (mean age 21 years) and elderly (mean age 74 years) showed no

significant differences in the plasma concentrations (AUC), protein binding or urinary excretion of unchanged parent drug and metabolites.

A renal impairment study after oral dosing of olopatadine has been performed in patients with severe renal impairment. The results indicate that a somewhat higher plasma concentration can be expected with Opatanol in this population. Since plasma concentrations following topical ocular dosing of olopatadine are 50-to 200-fold lower than after well-tolerated oral doses, dose adjustment is not expected to be necessary in the elderly or in the renally impaired population. Liver metabolism is a minor route of elimination. Dose adjustment is not expected to be necessary with hepatic impairment.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium Perborate

Sodium Chloride (For Sterile)

Disodium Hydrogen Phosphate Dodecahydrate (For sterile)

Sodium Hydroxide

Water for Injection

6.2. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products

6.3. Shelf life

2 years

6.4. Special precautions for storage

This medicinal product does not require any special storage conditions.

Store below 30°C.

6.5. Nature and contents of container

5 ml round white opaque plastic dropper bottle with plug and cap.

Pack Size: 5ml/dropper

6.6 Instructions for use and handling <and disposal>

No special requirements.

7.1 NAME AND ADDRESS OF MANUFACTURER

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7.2 NAME OF MARKET AUTHORIZATION HOLDER

DAWA LIMITED

Plot No 7879/8, Baba Dogo Road-Ruaraka.

P.O BOX 16633-00620 NAIROBI

8. REGISTRATION NUMBER

N/A

9. CATEGORY FOR DISTRIBUTION

Prescription only Medicine

10. DATE OF PUBLICATION OF THIS PACKAGE INSERT N/A

7. MARKETING AUTHORISATION HOLDER

DAWA LTD

PLOT NO 7879/8, BABA DOGO RD-RUARAKA,

P.O BOX 16633-00620 NAIROBI

8. MARKETING AUTHORISATION NUMBER(S)

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