National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

ZEENAT FLUCONAZOLE EYE DROPS (FLUCONAZOLE EYE DROPS)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Each ml contains

Fluconazole ---------- 0.3% w/v

Benzalkonium Chloride NF --------- 0.01% w/v

(As preservative)

Excipients with known effect:

Benzalkonium Chloride solution
Sodium dihydrogen ortho phosphate
Disodium hydrogen ortho phosphate
Hydroxy propyl beta cyclodextrin
Sodium chloride
Citric Acid
Water For Injection

3. PHARMACEUTICAL FORM

Ophthalmic solution A clear, light yellow solution

4. Clinical particulars

4.1 Therapeutic indications

Fluconazole is indicated for the treatment of fungal infection.

4.2 Contraindications

Allergy

Fluconazole 0.3% Eye Drops is not recommended for use if you have a known allergy to this medicine.

- QT Interval prolonging drugs

Fluconazole 0.3% Eye Drops is not recommended for co-administration with drugs that are known to cause specific changes in heart rhythm

4.3 Special warnings and precautions for use

Liver Injury

- Fluconazole 0.3% Eye Drops can cause moderate to severe side effects on liver and may result in liver failure in rare cases. Any known incidence of liver disease should be reported to the doctor.

Dosage adjustments and safety monitoring might be required in such cases.

- **Allergy**

- Fluconazole 0.3% Eye Drops and other medicines of the same group i.e Azoles could cause allergy in some patients. Any such known instance of allergy should be reported to the doctor.

- **Skin disorders**
- Fluconazole 0.3% Eye Drops may cause a condition where the skin starts to peel off in some patients. If you have had fungal infections in the past, then symptoms of infections should be monitored closely.

- **Heart condition**
- Caution is advised while using this medicine in patients with a history of cardiovascular disorder. Suitable dose adjustment and safety monitoring might be required in such cases.

- **Kidney disease**
- It is recommended to report any history of or active renal disorders to the doctor prior to the start of therapy with this medicine as necessary dosage adjustments may be made by the doctor for the safe use of this medicine.

- **Dizziness and seizures**
- This medicine may cause dizziness or even seizures in few patients. Hence caution is adviced while driving and operating heavy machinery after taking this medicine.

- **Other drugs and supplements**
- Fluconazole 0.3% Eye Drops is known to interact with a large number of other medicines and hence it becomes mandatory for you to report the use of all of them to the doctor.

- **Birth control**
- Fluconazole 0.3% Eye Drops may interact with the birth control pill you might be consuming and hence contraception might be ineffective. Alternate means of birth control are to be adopted while you are taking this medicine

Interaction with other medicinal products and other forms of interaction

All drugs interact differently for person to person. You should check all the possible interactions with your doctor before starting any medicine.

Interaction with Alcohol
- **Description**
- Interaction with alcohol is unknown. It is advisable to consult your doctor before consumption.
- **Instructions**
- Interaction with alcohol is unknown. It is advisable to consult your doctor before consumption

4.4 Pregnancy and Lactation
- **Pregnancy**
- This medicine is not recommended for use in pregnant women unless absolutely necessary. Discuss all the risks and benefits with your doctor before using this medicine.
- **Breast-feeding**
- This medicine is not recommended for use in breastfeeding women unless necessary. All the risks and benefits should be discussed with the doctor before taking this medicine. If you use the medicine, you are advised to monitor the baby closely for any adverse effects..

4.5 Effects on ability to drive and use machines

None.

4.6 Undesirable effects

Headache
Nausea and Vomiting
Abdominal pain
Diarrhea
Skin rash
QT Prolongation
Alopecia
Seizures
Swelling of face, lips, eyelids, tongue, hands and feet*s*

4.7 Overdose

Oral and Topical forms: Seek emergency medical attention or contact your doctor in case of an overdose with Zocon 0.3% Eye Drops. Injection: Since this medicine is administered in the hospital setting by a qualified healthcare professional, the likelihood of an overdose is very low. However, emergency medical treatment will be initiated by the doctor if an overdose is suspected.

PHARMACOLOGICAL PROPERTIES

4.8 Pharmacodynamics properties

ATC CODE:J02AC01
Fluconazole is an inhibitor of the human cytochrome P450 system, particularly the isozyme CYP2C19 (CYP3A4 and CYP2C9 to lesser extent) In theory, therefore, fluconazole decreases the metabolism and increases the concentration of any drug metabolised by these enzymes. In addition, its potential effect on QT interval increases the risk of cardiac arrhythmia if used concurrently with other drugs that prolong the QT interval. Berberine has been shown to exert synergistic effects with fluconazole even in drug-resistant Candida albicans infections. Fluconazole may decrease the metabolism of benzodiazepines. Fluconazole may increase the serum concentration of Citalopram(Risk X: avoid combination).
Fluconazole may increase the serum concentration of Erythromycin (Risk X: avoid combination)

4.9 Pharmacokinetic properties

The pharmacokinetic properties of fluconazole are similar following administration by the intravenous or oral routes. Following oral dosing, fluconazole is almost completely absorbed within two hours. Bioavailability is not significantly affected by the absence of stomach acid. Concentrations measured in the urine, tears, and skin are approximately 10 times the plasma. concentration, whereas saliva, sputum, and vaginal fluid concentrations are approximately equal to the plasma concentration, following a standard dose range of between 100 mg and 400 mg per day. The elimination half-life of fluconazole follows zero order kinetics, and only 10% of elimination is due to metabolism, the remainder being excreted in urine and sweat. Patients withimpaired renal function will be at risk of overdose.
In a bulk powder form, it appears as a white crystalline powder, and it is very slightly soluble in water and soluble in alcohol.

4.10 Preclinical safety data

There is no preclinical data available that is of relevance to the prescriber

5. PHARMACEUTICAL PARTICULARS

5.1 List of excipients

Benzalkonium Chloride solution NF
Sodium dihydrogen ortho phosphate BP
Disodium hydrogen ortho phosphate BP
Hydroxy propyl beta cyclodextrin IH
Sodium chloride BP
Citric Acid BP
Water For Injection BP

5.2 Incompatibilities

None known

5.3 Shelf life

36 Months

5.4 Special precautions for storage

Store below 30^{0}C Protect form light. Do not Freeze.

5.5 Nature and contents of container <and special equipment for use, administration or implantation>

5 ml LDPE white plastic bottle.

5.6 Special precautions for disposal <and other handling>

No special requirements

6. APPLICANT/MANUFACTURER:

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