Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

FLUCONAZOLE GEL 0.5 %
Brand Name: FLUZOLE

2. Qualitative and quantitative composition

Composition:
Fluconazole BP 0.5 % w/w
Chlorocresol (As Preservative) 0.1 % w/w
Gel Base Q.S.

A white to off white coloured gel.

Excipient(s) with known effect:
Chlorocresol and polysorbate 80 (see section 4.4).
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Topical Gel

4. Clinical particulars

4.1 Therapeutic indications

Fluconazole is indicated in the treatment of dermatomycoses caused by dermatophytes, yeasts and molds: in particularly Tinea pedis, tinea corporis, tinea cruris, tinea versicolor and infections of Candida.

4.2 Posology and method of administration

Fluconazole should be applied once in a day, using a gentle massage on the affected skin and the immediate surrounding area. In internal areas should be applied in small quantities and spread well to avoid phenomena of maceration.
The duration of treatment required for healing varies with etiological agent responsible for the infection. Treatment of 1 - 3 weeks is usually sufficient for healing in most patients.
Particularly with resistant forms, the treatment period may be extended up to 6 weeks.

Method of administration
For topical use

4.3 Contraindications

Hypersensitivity to the components of the product or to other closely related substances from the chemical point of view. Generally contraindicated in pregnancy and lactating mothers.

4.4 Special warnings and precautions for use

Hypotension: Higher risk for patients with impaired sympathetic response, volume-depletion or salt restriction.
Renal Impairment: Patients with pre-existing kidney disease may be at higher risk.
Monitor serum electrolytes periodically.
Chlorocresol may cause allergic reactions.
Polysorbate 80 can cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Fluzole interacts with such medications as:

- a blood thinner such as warfarin (Coumadin) cyclosporine (Gengraf, Sandimmune, Neoral);
- an oral diabetes medicine such as glipizide (Glucotrol), glyburide (Diabeta, Micronase, Glynase), tolbutamide (Orinase), tolazamide (Tolinase), chlorpropamide (Diabinese), and others;
- rifabutin (Mycobutin) or rifampin (Rifadin, Rifater, Rifamate, Rimactane);
- a sedative such as diazepam (Valium), lorazepam (Ativan), alprazolam (Xanax), or midazolam (Versed);
- seizure medication such as phenytoin (Dilantin) or valproic acid (Depakene); tacrolimus ((Prograf);
- theophylline (Theo-Dur, Theolair, Theochron, Elixophyllin, Slo-Phyllin, others).

Also note that interaction between two medications does not always mean that you must stop taking one of them. Usually, it affects the the effect of drugs, so consult your doctor about the way these interactions are being managed or should be managed.

4.6 Pregnancy and Lactation

Pregnancy: Studies in animals have shown reproductive toxicity. So use of Fluconazole is not advised during pregnancy.
Breast-feeding: Fluconazole passes into breast milk. Use of Fluconazole during lactation is not advised.

4.7 Effects on ability to drive and use machines

Fluconazole Gel has no or negligible effects on the ability to drive and use machines.

4.8 Undesirable effects

The use of topical products, especially if prolonged, may give rise to phenomena of sensitization and produce side effects. In this case the patient must stop treatment and establish an appropriate therapy.
Side effects includes:

- Burning sensation of skin
- Redness of skin

- Skin irritation

4.9 Overdose

Symptoms of Fluzole overdose may include: confusion or unusual thoughts or behavior. If you experience one of them, call your doctor immediately.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Fluconazole is a Triazole antifungal. **ATC code:** J02AC01

Mechanism of action

- Fluconazole is antifungal belonging to a new class of triazole agents, which is a potent and specific inhibitor of fungal sterol synthesis.
- Fluconazole used topically is a broad-spectrum antifungal agent. It was effective against the microorganisms responsible for dermatomycoses, cutaneous candidiasis and versicolor pityriasis (i.e. Microsporum spp., Trichophyton spp., Epidermophyton spp., Candida spp. and Malassezia furfur or Pityrosporum orbiculata.)
- Its activities are performed against dermatophytes, yeasts and molds. Fluconazole is highly specific for fungal enzymes dependent on cytochrome P-450. It inhibits lanosterol C-14 demethylase enzyme that converts lanosterol in to the sterol present in the membrane of fungi i.e. the ergosterol.

5.2 Pharmacokinetic properties

A pharmacokinetic study conducted with the fluconazole Gel, showed that plasma levels achieved by fluconazole are so low as to exclude a systemic effect of the drug.

Fluconazole has also been widely studied systemically in pediatric patients and neonates and showed a good tolerability profile similar to that of the adult patient.

A study conducted to evaluate the dermal tolerance and phototoxicity of the drug showed that the fluconazole Gel is well tolerated by human skin and is not phototoxic, so it is suitable for use as a topical antifungal.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the human exposure indicating little relevance to clinical use.

Carcinogenesis

Fluconazole showed no evidence of carcinogenic potential in mice and rats treated orally for 24 months at doses of 2.5, 5, or 10 mg/kg/day (approximately 2-7 times the recommended human dose). Male rats treated with 5 and 10 mg/kg/day had an increased incidence of hepatocellular adenomas.

Mutagenesis

Fluconazole, with or without metabolic activation, was negative in tests for mutagenicity in 4 strains of Salmonella typhimurium, and in the mouse lymphoma L5178Y system. Cytogenetic studies in vivo (murine bone marrow cells, following oral administration of fluconazole) and in vitro (human lymphocytes exposed to fluconazole at 1000 μg/ml) showed no evidence of chromosomal mutations.

Reproductive toxicity

Fluconazole did not affect the fertility of male or female rats treated orally with daily doses of 5, 10, or 20 mg/kg or with parenteral doses of 5, 25, or 75 mg/kg.

There were no foetal effects at 5 or 10 mg/kg; increases in foetal anatomical variants (supernumerary ribs, renal pelvis dilation) and delays in ossification were observed at 25 and 50 mg/kg and higher doses. At doses ranging from 80 mg/kg to 320 mg/kg embryolethality in rats was increased and foetal abnormalities included wavy ribs, cleft palate, and abnormal cranio-facial ossification.

The onset of parturition was slightly delayed at 20 mg/kg orally and dystocia and prolongation of parturition were observed in a few dams at 20 mg/kg and 40 mg/kg intravenously. The disturbances in parturition were reflected by a slight increase in the number of still-born pups and decrease of neonatal survival at these dose levels. These effects on parturition are consistent with the species specific oestrogen-lowering property produced by high doses of fluconazole.

6. Pharmaceutical Particulars

6.1 List of Excipients

Chlorocresol Purified Water
Carbomer-940
Triethanolamine
Hypromellose (Methocel E 50 Premium LV)
Polysorbate 80
Glycerin

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

36 Months

6.4 Special Precautions for storage

Store below 30° C. Protect from light and moisture.

6.5 Nature and Content of container

20.0gm Lami Tubes packed in a mono Carton

6.6 Special precautions for disposal and other handling
Not Applicable

7. Marketing Authorization Holder
Bueno Salud Care (India) Pvt Ltd
Plot No. K-20 and K-21, Gallops Industrial Park,
Bavla-Rajkot N.H-No.8,
Village-Vasana-Chacharawadi, Tal-Sanand,
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8. Marketing Authorization Number
CTD9106

9. Date of first authorization/renewal of the authorization
27/07/2023

10. Date of revision of the text
11/05/2025