Summary of Product Characteristics

1) Name of the medicinal product :

FLUCOMED – 150 (Fluconazole Capsules 150 mg)

2) Qualitative and Quantitative composition:

Composition:

Each capsule contains:
Fluconazole USP (150 mg)
Approved colour used in Empty Capsule
Shell (-) Excipients: (- QS)

3) Pharmaceutical Form: Capsules

Hard gelatin capsules having Red coloured cap and Red coloured body, Containing white coloured powder.

4) Clinical Particulars

4.1) Therapeutic indication

Fluconazole is indicated for the treatment of:
Vaginal candidiasis (vaginal yeast infections due to Candida).
Oropharyngeal and esophageal candidiasis. Cryptococcal meningitis.
Before prescribing
Prophylaxis. Fluconazole capsule is also indicated to decrease the incidence of candidiasis in patients undergoing bone marrow transplantation who receive cytotoxic chemotherapy and/or radiation therapy.
Systemic and invasive candida infections, including candida esophagitis.
Oral candidiasis in immunocompromised patients.
Cryptococcal meningitis.
Verified fungal **skin infection** caused by dermatophytes (tinea corporis/cruris) when local.

4.2) Posology and method of administration:

Adults

For oropharyngeal candidiasis, the usual dose is 50 to 100mg once daily for 7-14 days. In patients with severely compromised immune function, treatment can be continued for longer periods if necessary.
For Chronic mucocutaneous candidiasis, the dose is 50 mg to 100 mg daily Up to 28 days. Longer periods depending on both the severity of infection or underlying immune compromisation and infection.
For dermatomycosis, the dose is 50 mg once daily for 2 to 4 weeks.

Children

For the treatment of oropharyngeal candidiasis in children, the recommended fluconazole dosage is 6 mg/kg on the first day, followed by 3 mg/kg once daily. To lower the likelihood of relapse, treatment should be administered for at least 2 weeks.

4.3) Contraindications

Fluconazole should not be used in patients with known sensitivity to the drug or to related triazole compounds.
Multiple dose therapy is contra-indicated in patients with renal impairment.

4.4) Special warnings and precautions for use

Severe hepatic toxicity, including death, has been reported in rare cases

after treatment with fluconazole, mainly in patients suffering from severe underlying diseases. No obvious relationship to daily dose, duration of therapy, sex or age has been observed.
Hepatotoxicity has usually been reversible on discontinuation of fluconazole therapy. Patients who develop abnormal liver function values during fluconazole therapy should be monitored for the development of more serious hepatic injury. No obvious relationship between hepatotoxicity and daily dose, duration of therapy, sex or age has been observed.
Patients have rarely developed exfoliative cutaneous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, during treatment with fluconazole. AIDS patients are more prone to develop severe cutaneous reactions to many drugs. If a rash develops in a patient treated for a superficial fungal infection which is considered attributable to fluconazole, therapy should be discontinued. If patients with invasive/systemic fungal infections develop rashes, they should be monitored closely.
Therapy should be discontinued if bullous lesions or erythema multiforme develop.
Cases of Torsade de Points during treatment with fluconazole have been reported. Therefore fluconazole should be used with caution in patients with hereditary or acquired prolongation of the QTc interval, disturbances in the electrolyte balance, especially in hypokalaemia or hypomagnesemia, and in patients with clinically relevant bradycardia, cardiac arrhythmia, severe cardiac insufficiency or cardiomyopathy. If concomitant treatment with drugs known to cause QTc prolongation - e.g. antiarrhythmic drugs class IA and III - is necessary, the patient should be closely monitored, including ECG, as an additive effect cannot be excluded.
Fluconazole is a potent inhibitor of cytochrome P450 (CYP) isoenzyme 2C9 and a moderate inhibitor of CYP3A4. Patients who receive concomitant treatment with fluconazole and substances with a narrow therapeutic range (e.g. warfarin and fenytoin) and which are metabolised through CYP2C9 and CYP3A4, should be closely monitored. Fluconazole may prolong the prothrombin time after administration of warfarin.
Close monitoring of the prothrombin time is recommended.During concomitant treatment with terfenadine and fluconazole at daily doses of less than 400 mg, the patient should be monitored closely.Anaphylactic reactions have in rare cases been reported.Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5) Interactions with other medicinal products and other forms of interaction

-Anticoagulants: Fluconazole has been shown to prolong prothrombin times in subjects receiving warfarin. Benzodiazepines Concurrent oral administration of midazolam and fluconazole resulted in substantial increases in midazolam concentrations and its Psychomotor effects. This effect on midazolam appears to be more pronounced following oral administration of fluconazole than with fluconazole administered intravenously.

Oral hypoglycemics: Fluconazole has been shown to prolong the serum half-life of concomitantly administered oralsulphonylureas.
-Cyclosporin: A kinetic study in renal transplant patients found fluconazole

200 mg daily to slowly increase cyclosporin concentrations. However, in another multiple dose study with 100 mg daily, fluconazole did not affect cyclosprin levels in patients with bone marrow transplants. Cyclosporin plasma concentration monitoring in patients receiving fluconazole is recommended.
-Hydrochlorothiazide: Co-administration of multiple doses of hydrochlorothiazide may increase the plasma concentrations of fluconazole.
Phenytoin: Concomitant administration of fluconazole and phenytoin may increase the levels of phenytoin to a clinically significant degree.

4.6 Pregnancy and lactation Pregnancy:
An observational study has suggested an increased risk of spontaneous abortion in women treated with fluconazole during the first trimester.
There have been reports of multiple congenital abnormalities (including brachycephalia, ears dysplasia, giant anterior fontanelle, femoral bowing and radio-humeral synostosis) in infants whose mothers were treated for at least three or more months with high doses (400- 800 mg daily) of fluconazole for coccidioidomycosis. The relationship between fluconazole use and these events is unclear.
Breast-feeding:
Fluconazole passes into breast milk to reach concentrations similar to those in plasma. Breast-feeding may be maintained after a single dose of 150mg fluconazole. Breast- feeding is not recommended after repeated use or after high dose fluconazole. The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for Fluconazole capsules and any potential adverse effects on the breast-fed child from Fluconazole capsules or from the underlying maternal condition.

4.6) Effects on ability to drive and use machines
Undesirable effects such as dizziness, vertigo, drowsiness, fatigue, visual disturbances or other central nervous system disorders are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.7) Undesirable Effects:
Adverse events were reported more frequently in HIV infected patients (21%) than in non HIV infected patients (13%). However, the pattern of adverse events was similar in patients with and without HIV infection.
The following additional adverse events have been observed under circumstances where a causal association to the treatment is uncertain (e.g. open trials during post-marketing experience):
Allergic reaction: angiooedema, facial oedema Skin: alopecia, toxic epidermal necrolysis
Haematopoietic and lymphatic system: leucopenia, including neutropenia and agranulocytosis, trombocytopenia
Hepatobiliary disorders: hepatic failure, hepatitis
Metabolism and nutrition disorders: hypercholesterolaemia, hypertriglyceridaemia, Hypokalaemia.

Section 4.8 Reporting of adverse effects
Reporting of suspected adverse reactions: Healthcare professionals are

requested to report any suspected adverse reactions via pharmacy and poisons board,Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.8) Overdose

Experience of overdosage with fluconazole is limited. Expected symptoms are enhanced side effects: headache, gastrointestinal problems and possibly hallucinations. CNS symptoms (including convulsions) are described in animal studies. The treatment is symptomatic. Gastric lavage should be considered if necessary.

Fluconazole is mainly excreted in the urine, and forced volume diuresis will probably increase the elimination rate. Haemodialysis for 3 hours decreases plasma levels by approximately 50%.

5) Pharmacological Properties

5.1) Pharmacodynamics properties

Pharmacotherapeutic group: Antimycotics for systemic use – triazole derivatives, ATC code: J02AC01

Fluconazole is a triazole derivative with fungistatic effect, which specifically inhibits the ergosterol synthesis of the fungus and causes defects in the cell membrane. Fluconazole is highly specific for fungal cytochrome P-450 enzymes. Doses of fluconazole 50 mg daily for 28 days have not been shown to affect testosterone plasma concentrations in men or steroid concentrations in fertile women. The spectrum of application includes a number of pathogenic fungi including Candida albicans and non-C. albicans, Cryptococcus spp., and dermatophytes. Candida krusei is resistant to fluconazole. Candida glabrata has an intrinsic decreased susceptibility to fluconazole, approx. 40 % of isolates are resistant. PK/PD data indicate that a dose of 800 mg per day might be an alternative in the treatment of C. glabrata infections in stable patients. Infections caused by Aspergillus spp. should not be treated with fluconazole.

Mechanisam of action

Fluconazole inhibits ergosterol synthesis in the cell wall of yeast and other fungi.

In Candida albicans, fluconazole may also inhibit the transformation of blastospores into the invasive mycelial form. Fluconazole is absorbed quickly after oral administration and is widely distributed.

5.2) Pharmacokinetics

properties Absorption

Orally administered fluconazole has a bioavailability of more than 90%. Absorption is not affected to any appreciable extent by concomitant food intake. Maximum plasma concentrations are generally reached 1/2 - 1 1/2 hours after dose intake. Following once daily doses, 90% of the steady state level is reached within 4-5 days. If the normal daily

dose is doubled on the first day of treatment, approximately 90% of the steady state level is obtained on day 2. Serum concentrations are proportional to the dose.

Distribution

Binding to plasma proteins is approximately 12 %. The apparent volume of distribution corresponds to that of total body water; 0.7 l/kg. Fluconazole has shown good penetration in different body fluids. The concentration of

fluconazole in saliva and sputum is the same as in plasma. In patients with fungal meningitis, fluconazole levels in the cerebrospinal fluid are approximately 80% of the corresponding plasma levels. High skin concentrations of fluconazole, above serum concentrations, have been found in the stratum corneum, epidermis-dermis and eccrine sweat. Fluconazole is accumulated in the stratum corneum. Following administration of 150 mg once weekly, the concentration of fluconazole in the stratum corneum was after two doses 23.4 µg/g, and a week later 7.1 µg/g.

Excretion

Clearance is 0.253 ml/min/kg. The biological half-life is about 30 hours. Fluconazole is mainly renally excreted. 80% of the dose is excreted in the urine in nonmetabolised form. In addition, approximately 10% of the dose is excreted in the urine as metabolites.

Fluconazole clearance is proportional to the creatinine clearance. Children eliminate fluconazole faster than adults. The biological half-life in children 5-15 years is between 15.2-17.6 hours.

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 27 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.

6) PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch, Sodium benzoate, Purified talc, E.H.G. Capsule size '2' Red/Red

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3years

6.4 Special precautions for storage

Store in a cool and dry place below 30°C

6.5 Nature and contents of container

Alu-Pvc Blisters of Capsules (1X1's)

6.6 Special precautions for disposal

No special requirements.

7. Marketing Authorisation Holder

Medico Remedies. Ltd**.** Plot Nos. 7, 8 & 9, Dewan & Sons Udyog Nagar, Lokmanya Nagar, Palghar Zone 2, Tal- Palghar, Dist. Palghar – 401 404, Maharashtra, India

8. Marketing Authorisation Number

21381

9. Date of First Authorisation/Renewal of the Authorisation

01/03/2026

10. Date of Revision of the Text

01/03/2026