

### Summary of Product Characteristics for Fluconazole

<b>Trade Name of the Medicinal Product:</b>	Gynofloran 50mg, 150mg.
<b>Qualitative and Quantitative Composition:</b>	Fluconazole 50mg, 150mg.
<b>Pharmaceutical Form:</b>	Capsules.
<b>Therapeutic indications:</b>	Treatment of: Genital candidiasis including vaginal candidiasis, acute or recurrent; Candidal balanitis. Consider the treatment of partners who present symptomatic genital candidiasis; Mucosal candidiasis including oropharyngeal, oesophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth); Systemic candidiasis such as candidaemia, disseminated candidiasis and other forms of invasive candidal infection of the peritoneum, endocardium and pulmonary and urinary tracts; Candidal infections in patients with malignancy, in intensive care units or those receiving cytotoxic or immunosuppressive therapy; Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g. pulmonary, cutaneous); Maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS; Tinea pedis, tinea corporis, tinea cruris, tinea versicolor and dermal candida infections. Fluconazole is not indicated for nail infections. Prevention of: Fungal infections in immunocompromised patients considered at risk as a consequence of neutropenia following cytotoxic chemotherapy or radiotherapy, including bone marrow transplant patients. Use in children: Fluconazole should not be used for tinea capitis.
<b>Contraindications:</b>	Hypersensitivity to fluconazole or to related azole compounds or to any other ingredient within the formulation. Concomitant use with terfenadine or cisapride.
<b>Special warnings and precautions for use:</b>	Abnormalities in the results of haematological, hepatic, renal and other biochemical function; Hepatotoxicity; Renal impairment; In rare cases, as with other azoles, anaphylaxis has been reported.
<b>Interactions with other medicinal products and other forms of interaction:</b>	Anticoagulants; Benzodiazepines; Sulphonylureas; Phenytoin; Hydrochlorothiazide; Theophylline; Rifampicin; Cyclosporin; Terfenadine; Zidovudine; Rifabutin; Cisapride; Tacrolimus; Astemizole, or other drugs metabolised by the cytochrome P450.
<b>Pregnancy and lactation:</b>	Fluconazole should not be used in pregnancy, or in women of childbearing potential, unless adequate contraception is employed. Use in nursing mothers is not recommended.
<b>Undesirable effects:</b>	Headache, rash, abdominal pain, diarrhoea, flatulence and nausea, hepatic toxicity changes in renal and haematological function test results, dizziness, seizures, alopecia, exfoliative skin disorders including Stevens-Johnson syndrome and toxic epidermal necrolysis, vomiting, leukopenia including neutropenia and agranulocytosis, thrombocytopenia, anaphylaxis (including angioedema, face oedema, pruritus), hepatic failure, hepatitis, hepatocellular necrosis, jaundice, hypercholesterolaemia, hypertriglyceridaemia, hypokalaemia, taste perversion, QT prolongation, torsade de pointes.

MAH: Codal-Synto Ltd.



 CODAL-SYNTO

Αποστειρωμένη θεραπεία κατά μυκητιακών λοιμώξεων



**Gynofloran®**  
Fluconazole

GYNOFLOLAN® 50mg capsules GYNOFLOLAN® 150mg capsules

## Drug Classes and Mechanisms of Action

Class	Mechanism of action	Drugs
Allylamine	Inhibits squalene epoxidase	Terbinafine
Azole	Impairs ergosterol synthesis	Ketoconazole
		<b>Fluconazole</b>
		Itraconazole
		Voriconazole
Echinocandin	Impairs $\beta$ 1,3 glucan synthesis	Caspofungin
Nucleoside analog	Impairs pyrimidine metabolism	Flucytosine
Polyene	Binds to ergosterol	Amphotericin B deoxycholate
		Amphotericin B colloidal dispersion
		Amphotericin B lipid complex
		Liposomal amphotericin B

Αποτελεσματική θεραπεία κατά μυκητιακών λοιμώξεων

Effective treatment for fungal infections

## General Patterns of Susceptibility of Candida Species

Candida Species	Fluconazole	Itraconazole	Flucytosine	Amphotericin B
C. Albicans	S	S	S	S
C. Tropicalis	S	S	S	S
C. Parapsilosis	S	S	S	S
C. Glabrata	S-DD to R	S-DD to R	S	S-I
C. Krusei	R	S-DD to R	I-R	S-I
C. Lusitaniae	S	S	S	S to R
C. Kefyr	S	S	S	S
C. Guilliermondii	S	S	S	S-R
C. Dubliniensis	S	S	S	S

I - intermediate; R - resistant; S - susceptible; S-DD - susceptible dose dependent.