

Essential drugs / Oral drugs

FLUCONAZOLE oral

Prescription under medical supervision

Therapeutic action

- Antifungal

Indications

- Oesophageal candidiasis
- Moderate to severe oropharyngeal candidiasis
- Secondary prophylaxis of recurrent candidiasis in immunocompromised patients
- Cryptococcal meningitis, after treatment with amphotericin B + flucytosine or in combination with amphotericin B or flucytosine
- Secondary prophylaxis of cryptococcal infections

Forms and strengths

- 50 mg, 100 mg and 200 mg capsules or tablets
- 50 mg/5 ml oral solution

Dosage and duration

- *Oesophageal candidiasis, oropharyngeal candidiasis, secondary prophylaxis of candidiasis*

Child over 1 week: 3 to 6 mg/kg once daily

Adult: 50 to 200 mg once daily

These doses may be increased up to 400 mg daily if necessary. The treatment lasts 14 to 21 days for oesophageal candidiasis; 7 to 14 days for oropharyngeal candidiasis; as long as required for secondary prophylaxis.

- *Cryptococcal meningitis*

After treatment with amphotericin B + flucytosine	Child > 1 week	12 mg/kg once daily (max. 800 mg daily) for 1 week then 6 to 12 mg/kg once daily for 8 weeks (max. 800 mg daily)
	Adult	1200 mg once daily for 1 week then 800 mg once daily for 8 weeks

or		
In combination with amphotericin B or flucytosine	Child > 1 week	12 mg/kg on amphotericin B or flucytosine) then 6 to 12 mg/kg once daily for 8 weeks (max. 800 mg daily)
	Adult	1200 mg once daily for 2 weeks (with amphotericin B or flucytosine) then 800 mg once daily for 8 weeks

– *Secondary prophylaxis of cryptococcal infections*

Child: 6 mg/kg once daily (max. 200 mg daily), as long as required

Adult: 200 mg once daily, as long as required

Contra-indications, adverse effects, precautions

- Administer with caution to patients with hepatic or renal impairment, cardiac disorders (bradycardia, heart rhythm disorders, etc.). Reduce the dose by half in patients with renal impairment.
- May cause: gastrointestinal disturbances, headache, skin reactions sometimes severe, anaphylactic reactions; severe hepatic disorders, haematologic (leukopenia, thrombocytopenia) and cardiac disorders (QT-prolongation). Stop treatment in the event of anaphylactic reaction, hepatic disorders or severe skin reaction.
- In the event of prolonged treatment, monitor hepatic function.
- Do not administer simultaneously with rifampicin, administer 12 hours apart (rifampicin in the morning, fluconazole in the evening).
- Avoid or monitor combination with:
 - drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, haloperidol, mefloquine, pentamidine, quinine);
 - warfarin, carbamazepine, phenytoin, rifabutin, benzodiazepines, calcium-channel blockers, certain antiretrovirals (e.g. nevirapine, saquinavir, zidovudine): increased blood concentration of these drugs.
- Pregnancy and breast-feeding: to be used only in severe or life-threatening infections, particularly during the first trimester of pregnancy (risk of foetal malformations).

Remarks

- For the treatment of histoplasmosis, fluconazole is less effective than itraconazole. It should be used (child: 10 to 12 mg/kg once daily, max. 400 mg daily ; adult: 400 mg on D1 then 200 to 400 mg once daily, for 6 to 12 weeks) only in patients unable to tolerate itraconazole.
- For the treatment of dermatophytosis of the scalp, fluconazole may be used as a secondary option (child: 6 mg/kg once daily, max. 200 mg daily; adult: 200 mg once daily, for 2 to 4 weeks) but itraconazole is preferred for this indication.
- For the treatment of genital candidiasis (vulvovaginitis, balanitis), fluconazole is only used if local treatment fails: 150 mg single dose in adults.
- Storage: below 25 °C - ✎
Once reconstituted, oral solution keeps for 2 weeks.