1. Name of the medicinal product
Itrafungex 100 mg Capsules.
2. Qualitative and quantitative composition
Each capsule contains itraconazole 100 mg.
For excipients, see 6.1.
3. Pharmaceutical form
Hard gelatin capsule
4. Clinical particulars
4.1 Therapeutic indications
1. Vulvovaginalcandidosis.
2. Pityriasisversicolor.
3. Dermatophytoses caused by organisms susceptible to itraconazole *(Trichophyton spp., Microsporumspp.,Epidermophytonfloccosum*) e.g. tineapedis, tineacruris, tineacorporis, tineamanuum.
4. Oropharyngealcandidosis.
5. Onychomycosis caused by dermatophytes and/or yeasts.
6. The treatment of histoplasmosis.
7. Itrafungex is indicated in the following systemic fungal conditions when first-line systemic anti-fungal therapy is inappropriate or has proved ineffective. This may be due to underlying pathology, insensitivity of the pathogen or drug toxicity.
- Treatment of aspergillosis and candidosis
- Treatment of cryptococcosis (including cryptococcal meningitis): in immunocompromised patients with cryptococcosis and in all patients with cryptococcosis of the central nervous system.
- Maintenance therapy in AIDS patients to prevent relapse of underlying fungal infection.
Itrafungex is also indicated in the prevention of fungal infection during prolonged neutropenia when standard therapy is considered inappropriate.
4.2 Posology and method of administration
Itrafungex is for oral administration and must be taken immediately after a meal for maximal absorption. The

capsules must be swallowed whole.
Treatment schedules in adults for each indication are as follows:

Indication	***Dose***	***Remarks***
Vulvovaginalcandidosis Pityriasisversicolor	200 mg twice daily for 1 day 200 mg once daily for 7 days	

Tineacorporis, tineacruris 100 mg once daily for 15 days or 200
mg once daily for 7 days
Tineapedis, tineamanuum 100 mg once daily for 30 days
Oropharyngealcandidosis 100 mg once daily for 15 days Increase dose to 200 mg once daily
for 15 days in AIDS or neutropenic
patients because of impaired
absorption in these groups.
Onychomycosis (toenails with or
without fingernail involvement)
200 mg once daily for 3 months
For skin, vulvovaginal and oropharyngeal infections, optimal clinical and mycological effects are reached 1 - 4 weeks after cessation of treatment and for nail infections, 6 - 9 months after the cessation of treatment. This is because elimination of itraconazole from skin, nails and mucous membranes is slower than from plasma.
The length of treatment for systemic fungal infections should be dictated by the mycological and clinical response to therapy:

Indication	***Dose[1]*** 200 mg once daily	***Remarks***
Aspergillosis	Increase dose to 200 mg twice daily in case of invasive or disseminated disease Increase dose to 200 mg twice daily in case of invasive or disseminated disease	
Candidosis	100-200 mg once daily	
Non-meningeal Cryptococcosis Cryptococcal meningitis	200 mg once daily 200 mg twice daily	
See 4.4. Special warnings and special precautions for use.		
Histoplasmosis Maintenance in AIDS	200 mg once daily - 200 mg twice daily 200 mg once daily	on
See	note	
absorption below		
Prophylaxis in neutropenia	200 mg once daily	See

impaired			
note	on	impaired	

absorption below
1 The duration of treatment should be adjusted depending on the clinical response.
Impaired absorption in AIDS and neutropenic patients may lead to low itraconazole blood levels and lack of efficacy. In such cases, blood level monitoring and if necessary, an increase in itraconazole dose to 200 mg twice daily, is indicated.

Special populations

Paediatrics

Clinical data on the use of itraconazolecapsules in paediatric patients are limited. The use of Itrafungexcapsules in paediatric patients is not recommended unless it is determined that the potential benefit outweighs the potential risks. See section 4.4 *Special warnings and precautions for use*.

Elderly

Clinical data on the use of itraconazole Capsules in elderly patients are limited. It is advised to use Itrafungex Capsules in these patients only if it is determined that the potential benefit outweighs the potential risks. In general, it is recommended that the dose selection for an elderly patient should be taken into consideration, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. See section 4.4 *Special warnings and precautions for use.*

Renal impairment

Limited data are available on the use of oral itraconazole in patients with renal impairment. The exposure of itraconazole may be lower in some patients with renal insufficiency. Caution should be exercised when this drug is administered in this patient population and adjusting the dose may be considered.

Hepatic impairment

Limited data are available on the use of oral itraconazole in patients with hepatic impairment. Caution should be exercised when this drug is administered in this patient population. (See section 5.2 *Pharmacokinetic properties - Special Populations, Hepatic impairment*)

4.3 Contraindications

• Itrafungex Capsules are contra-indicated in patients with known hypersensitivity to itraconazole or to any of the excipients.

• Coadministration of a number of CYP3A4 substrates is contraindicated with Itrafungex Capsules. Increased plasma concentrations of these drugs, caused by coadministration with itraconazole, may increase or prolong both therapeutic and adverse effects to such an extent that a potentially serious situation may occur. For example, increased plasma concentrations of some of these drugs can lead to QT prolongation and ventricular tachyarrhythmias including occurrences of torsade de pointes, a potentially fatal arrhythmia. Specific examples are listed in section 4.5 *Interaction with other medicinal products and other forms of interaction.*

• Itrafungex Capsules should not be administered to patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF except for the treatment of life-threatening or other serious infections. See section 4.4 *Special warnings and precautions for use*.

• Itrafungex Capsules must not be used during pregnancy except for life-threatening cases (see section 4.6 *Fertility, pregnancy and lactation*)

• Women of childbearing potential taking Itrafungex Capsules should use contraceptive precautions. Effective contraception should be continued until the menstrual period following the end of Itrafungex Capsules therapy.

5 Special precautions for storage

Keep out of reach OF children.

Store at a temperature not exceeding 30°c in a dry place.

5.1 Nature and contents of container

- Carton box contains 1 Transparent Pvdc / aluminum blister of 4 hard gelatin capsules with insert leaflet.
- Carton box contains 3 Transparent Pvdc / aluminum blisters, each blister 5 hard gelatin capsules with insert leaflet