

FONGINOX®
100 mg capsules

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about FONGINOX

Each FONGINOX capsule for oral administration contains 100 mg itraconazole. Itraconazole is a synthetic triazole antifungal having a broad spectrum antifungal activity. Itraconazole inhibits the cytochrome P450-dependent synthesis of ergosterol, which is a vital component of fungal cell membranes.

FONGINOX capsules are indicated in the treatment of fungal infections of the skin, hair and nails:

- Onychomycosis of the toenail and fingernail due to dermatophytes (tinea unguium) (fungal infection of the nail)
- Dermatophytosis (fungal infections of the skin and hair caused by dermatophytes: tinea corporis, tinea cruris, interdigital and plantar tinea pedis, tinea manuum)
- Pityriasis versicolor
- Vulvovaginal candidiasis, oropharyngeal candidiasis, esophageal candidiasis, cutaneous candidiasis
- Systemic mycoses in immunocompromised and non-immunocompromised patients

The way to take FONGINOX

FONGINOX must be administered as directed by your doctor. Do not exceed the maximum recommended dosage. Capsules should be administered after a full meal. The usual recommended dosages are:

Fungal infection	Dosage	Number of capsules	Duration of treatment
Tinea corporis, tinea cruris	200 mg once daily	2 capsules once daily	7 days
Tinea corporis, tinea cruris (alternative dose)	100 mg once daily	1 capsule once daily	15 days
Tinea pedis (interdigital and plantar/mocassin type), tinea manuum	200 mg twice daily	2 capsules twice daily	7 days
Tinea pedis, tinea manuum (alternative dose)	100 mg once daily	1 capsule once daily	30 days
Pityriasis versicolor	200 mg once daily	2 capsules once daily	7 days
Toenail onychomycosis (pulse therapy)	200 mg twice daily	2 capsules twice daily	for 7 days repeated twice after drug-free intervals of 21 days
Toenail onychomycosis	200 mg once daily	2 capsules once daily	12 consecutive weeks
Fingernail onychomycosis (pulse therapy)	200 mg twice daily	2 capsules twice daily	for 7 days repeated once after drug-free interval of 21 days
Fingernail onychomycosis	200 mg once daily	2 capsules once daily	6 consecutive weeks

Vulvovaginal candidiasis	200 mg twice daily	2 capsules twice daily	1 day
Oral/ esophageal candidiasis	100 mg once daily	1 capsule once daily	15 days/ 28 days
Oropharyngeal candidiasis in patients with AIDS or neutropenia	200 mg once daily	2 capsules once daily	15 days
Systemic mycoses	200 mg once daily or 200 mg twice daily	2 capsules once daily or 2 capsules twice daily	Minimum 3 months
Fungal keratitis	200 mg once daily	2 capsules once daily	21 days

For fungal nail infections, improved nails may not be obvious for 6 to 9 months after the treatment period is finished because it usually takes about 6 months to grow a new fingernail and 12 months to grow a new toenail. Also FONGINOX is present in the nail for a long period of time after treatment has stopped.

For skin, vulvovaginal and oropharyngeal infections, optimal clinical and mycological effects are reached 2 to 4 weeks after cessation of treatment. This is because elimination of itraconazole from skin, nails and mucous membranes is slower than from plasma.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following cases:

- Known hypersensitivity to any of the components
- In patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF
- Coadministration of cisapride, oral midazolam, nisoldipine, pimozide, quinidine, dofetilide, triazolam, levacetylmethadol, lovastatin, simvastatin, atorvastatin, ergot alkaloids, bepridil, mizolastine

Precautions

- Caution should be taken in elderly patients and in patients with impaired hepatic or renal function, chronic obstructive pulmonary disease; and other edematous disorders
- Prior to initiating treatment, appropriate laboratory testing is sometimes recommended to confirm the diagnosis of fungal infection.
- It is recommended to monitor hepatic function in patients receiving long-term treatment with this drug.
- Inform your doctor before using this medication in case of pregnancy or lactation. It is recommended not to initiate treatment with this drug during pregnancy or lactation.

Associations with other medications

Contact your physician before taking any concomitant medications to ensure there are no potential drug interactions.

Drug interaction may occur with the following medications: digoxin, dofetilide, quinidine, disopyramide carbamazepine, rifabutin, busulfan, docetaxel, vinca alkaloids, pimozide, alprazolam, diazepam, midazolam, triazolam, dihydropyridines, verapamil, cisapride, atorvastatin, lovastatin, simvastatin, cyclosporine, tacrolimus, sirolimus, oral hypoglycemics, indinavir, ritonavir, saquinavir, ergot alkaloids, halofantrine, alfentanil, buspirone, methylprednisolone, budesonide, dexamethasone, fluticasone, trimetrexate,

warfarin, cilostazol, eletriptan, fentanyl, carbamazepine, phenobarbital, phenytoin, isoniazid, rifampin, clarithromycin, erythromycin, tolterodine, ebastine, sildenafil, vardenafil.

The absorption of itraconazole may be decreased with the concomitant administration of antacids, H₂-receptor antagonists, or proton pump inhibitors.

Adverse reactions

This drug is generally well tolerated when used as directed.

Most reported adverse reactions include: gastrointestinal disorders, headache, rash, dizziness.

Peripheral edema, congestive heart failure and elevated liver enzymes have been rarely reported.

Inform your doctor if any adverse effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

FONGINOX, itraconazole 100 mg, pack of 16 capsules

FONGINOX, itraconazole 100 mg, pack of 4 capsules

Revision date: 12/2009

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