

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sporizole[®]
100mg capsules
Itraconazole

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Sporizole[®]

1.2. Composition

Active substance: Itraconazole.

Excipients: Sucrose, Hypromellose, Sodium methylparaben E219, Sodium propylparaben E217, Sugar spheres, Titanium dioxide E171 CI 77891, Brilliant blue FCF E133 CI 42090, Gelatine.

1.3. Pharmaceutical form

Capsules.

1.4. Quantitative composition

Each capsule contains 100mg itraconazole.

1.5. Description – Packaging

Carton box containing 4, 6, 15 or 28 capsules in blisters and a leaflet.

1.6. Pharmacotherapeutic group

Anti-fungal.

1.7. Marketing Authorization Holder

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1.8. Manufacturer

RAFARM AEBE, Athens, Greece

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1. General information

Itraconazole is a broad spectrum anti-fungal agent that is indicated for the treatment of fungal infections of vagina, skin, mouth, eyes nails and internal organs.

2.2. Indication

Gynecological indications:

- a) acute vulvovaginal candidiasis, as alternative of topical treatment.
- b) relapsing vulvovaginal candidiasis, as alternative of topical treatment, providing confirmation via culture (to exclude allergic reaction or hypersensitivity and prove infectious etiology).

Dermatological/Ophthalmological indications:

Alternative treatment in dermatomycosis caused by dermatophytes and yeasts, in pityriasis versicolor and in fungal keratitis.

Note: Systemic treatment for the above indications is recommended when the infection affects an extended skin area, scalp and nails or patients with impaired defense system, poor response in local treatment or persistent fungal infection despite treatment.

Nail mycosis caused by dermatophytes and yeasts (*Trichophyton* sp., *Candida* sp. etc.) that have been confirmed through laboratory testing.

Systemic mycosis:

- Pulmonary and extrapulmonary aspergillosis.
- Alternative treatment in systemic candidiasis
- Alternative treatment in cryptococcal infections (including cryptococcal meningitis) in immunosuppressed patients.
- Oropharyngeal candidosis in HIV (+) patients
- Endemic mycosis: histoplasmosis, blastomycosis, paracoccidoidomycosis
- Extradermal sporotrichosis.

NOTE: Specimens for fungal culture and other relevant laboratory tests (including biopsy, microscopy, and histopathology) should be obtained prior to treatment to isolate and identify causative factor.

Prophylaxis: For primary and secondary prophylaxis of histoplasmosis in patients with AIDS. Alternative treatment for the prophylaxis of cryptococcal meningitis in patients with AIDS.

Caution is needed in long term treatment with azoles; although to a lesser extent with itraconazole, as there is increased likelihood of developing strains of *C. krusei*, *Aspergillus*, *Mucorales*, *Fusarium*, *T. glabrata*, usually resistant to azoles.

2.3. Contraindications

Do not use itraconazole:

- In pregnancy and breast-feeding (see section 2.6).
- If you are hypersensitive to the active substance or any of the excipients.

Do not take itraconazole when you are treated with:

- some allergy medications such as terfenadine, astemizole and mizolastine.
- cisapride, a medicine used to treat digestive disorders.
- some medications that lower blood cholesterol such as simvastatin or lovastatin.
- some tranquilizer medicines such as triazolam or oral midazolam.
- pimozide, a medicine for psychotic disorders.
- some medicines used for the treatment of abnormal cardiac rate such as quinidine and dofetilide.

2.4. Special warnings and precautions for use

2.4.1. General

- You should always tell to your doctor or pharmacist if you are taking other medications because combining certain medicines may be harmful for your health.
- You should tell to your doctor if you have any issues with your liver, as the dosage may need adjustment for you.
- Consult your doctor immediately if you experience any of the following symptoms while taking this medicine: anorexia, nausea, vomiting, fatigue, abdominal pain or dark-colored urine.
- If you need to take this medicine continuously for more than one month, your doctor might ask you to do regular blood tests. This is to exclude the possibility of liver impairment which is a rare event.
- You should tell to your doctor if you experience any heart problem. If your doctor decides to prescribe this medicine to you, will also give you instructions for the symptoms you need to track. Consult your doctor immediately if you experience decrease in the breathing capacity, unexpected weight gain, swelling of the legs or abdomen, unusual fatigue or sudden waking up at nights.
- You should tell to your doctor if you have any kidney impairment, as the dosage may need adjustment.
- You should also tell your doctor immediately if you have an unusual feeling of tingling, numbness or weakness in the hands or feet while you take the capsules.
- You should tell to your doctor if you previously presented an allergic reaction to any other anti-fungal medication.

2.4.2. Pregnancy

Do not use this medicine if you are pregnant.

If you are in reproductive age and there is a possibility to get pregnant, you should take adequate birth control measures, in order to avoid pregnancy while you are taking this medicine. As the drug remains in the body for some time although you stop the treatment, you should continue to use birth control measures until your next period, after treatment termination.

Itraconazole may be administered to a pregnant woman only if doctor decides and only if the systemic fungal infection is life-threatening and the potential benefit for the mother outweighs the potential risk to the fetus.

2.4.3. Lactation

You should not breast-feed when you are taking itraconazole. Small amounts of itraconazole may excrete to your milk.

2.4.4. Children

This medicine should not be given to children. Your doctor may recommend it only in exceptional cases.

2.4.5. Effect on the ability to drive and use of machines

There is no issue to drive or use machines when you take this medicine, unless you feel any dizziness.

2.4.6. Special warnings about excipients

None.

2.5. Interactions with other medicines or substances

Do not forget to tell to your doctor or pharmacist about all medication that you take.

Medicines that should not be taken with itraconazole (see section 2.3) are:

- some allergy medications such as terfenadine, astemizole and mizolastine.
- cisapride, a medicine used to treat digestive disorders.
- some medications that lowers blood cholesterol such as simvastatine or lovastatine.
- some tranquilizer medicines such as triazolam or oral midazolam.
- pimostide, a medicine for phychotic disorders.
- some medicines used for the treatment of abnormal cardiac rate such as quinidinea and dofetilide..

Some medicines may significantly reduce itraconazole's efficacy. Specifically this is referred to some medications used for the treatment of epilepsy (such as carbamazepine, phenytoin and phenobarbital) and tuberculosis (such as rifampicin, rifabutin and isoniazid).

You should consult your doctor if you use any of these medicines, so as appropriate actions may be taken.

Combination of itraconazole with some medications may require dosage adjustments for itraconazole or of the other drug. Such medications are:

- some antibiotics such as clarithromycin and erythromycin.
- some medication for the treatment of tuberculosis or epilepsy (rifampicin, isoniazid, carbamazepine).
- some medication for the heart and blood vessels (digoxin, and some calcium channel blockers like disopyramide, verapamil).
- medications used to reduce blood clotting (anti-coagulants).
- oral anti-diabetic drugs.
- methylprednisolone, oral or injectable anti-inflammatory medication.
- cyclosporine A, tacrolimus and rapamycin (also known as sirolimus) typically used after organ transplantation.
- some HIV-protease inhibitors like ritonavir, indinavir, saquinavir.
- some medication to treat cancer such as Vinca alkaloids, busulphan, docetaxel and trimetrexate.
- some sedatives or hypnotics like buspiron, alprazolam and bromizolam.
- some medications used as topical anesthetics, such as midazolam IV, alfentanil.
- ebasitne, an anti-allergy medication.
- reboxetine, medicine to treat depression.

If you receive any of the above medication you should talk with your doctor.

Itraconazole absorption is inadequate when the gastric acidity is low. Patients who also receive acid neutralizing medication (e.g. aluminium hydroxide), should take it at least 2 hours after the intake of itraconazole. Patients suffering achlorhydria, such as certain AIDS patients or patients on acid secretion suppressors (e.g. H₂-antagonists, proton pump inhibitors), it is recommended to take itraconazole with a carbonated beverage (soda or cola type).

If you have any doubts consult your doctor or pharmacist.

2.6. Posology

Itraconazole capsules should be received immediately after a full meal, because this is the only way for optimal absorption. Capsules should be taken with a small amount of water. The recommended dosage and duration of treatment depends on the type of fungus and the body part or area affected.

Your doctor will inform you in details on what to do and how to do it. In the tables below some indicative dosage schemes are presented:

TYPE OF MYCOSIS	CAPSULES PER DAY	DURATION OF TREATMENT
Vulvovaginal candidiasis acute or relapsing	2 capsules, twice daily or 2 capsules, once daily	1 day 3 days
Pityriasis Versicolor	2 capsules, once daily	7 days
Dermatomycosis	2 capsules, once daily or 1 capsule, once daily	7 days 2 weeks
Dermatophytosis / areas with hyperkeratosis (soles, palms)	2 capsules, twice daily or 1 capsule, once daily	7 days 1 month
Oropharyngeal candidosis in patients HIV (+)	1 capsule, once daily	2 weeks
Fungal keratitis	2 capsules, once daily	3 weeks

SYSTEMIC MYCOSIS	
Aspergillosis Candidiasis Non-meningeal cryptococcosis Cryptococcal meningitis Histoplasmosis Sporotrichosis Paracoccidiomycosis Chromomycosis Blastomycosis	Determination of higher dosages Determination of longer treatment periods

Onychomycosis: Dosage and duration of the treatment depend on each patient condition and needs and the doctor will determine whether continuous scheme of a cycle treatment will be followed.		
Continuous treatment scheme	2 caps, once daily	3 months
Cycle treatment scheme	2 caps, twice a day	1 week per month for 3 months (finger nails) and 3-4 months (toe nails)
Details on the cycle treatment scheme:	Following one week of treatment, you stop receiving the medicine for 3 weeks. This cycle will be repeated twice for the onychomycosis of finger nails and 2 to 3 times for the onychomycosis of the toe nails (with or without co-current finger nails onychomycosis), (see tables below).	

Week	1 st	2 nd -3 rd -4 th	5 th	6 th -7 th -8 th	9 th	10 th -11 th -12 th
Finger nails	2 caps, twice daily	None	2 caps, twice daily	None	2 caps, twice daily	None

Week	1 st	2 nd -3 rd -4 th	5 th	6 th -7 th -8 th	9 th	10 th -11 th -12 th	13 th	14 th -15 th -16 th
Toes nails (with or without co-current finger nails onychomycosis)	2 caps, twice daily	None	2 caps, twice daily	None	2 caps, twice daily	None	2 caps, twice daily	None

2.7. Overdose – Management

If you take more itraconazole than you should, consult your doctor who will take all needed measures.
Poison Center Athens, Tel.: +30 210 77 93 777

Information for the doctor in case of overdose:

In case of accidental overdose, general supportive measures should be taken. Gastric lavage can be implemented within one hour after administration. If needed, activated charcoal can be used. Itraconazole cannot be eliminated by haemodialysis. There is no specific antidote.

2.8. Possible side effects

The following symptoms may occur: indigestion, nausea, abdominal pain and constipation. Other symptoms to occur are: headache, reversible elevation of liver function enzymes, disorders of period or dizziness.

Hypersensitivity to itraconazole is rare. You may experience for example skin rash, itching, slow breathing and/or facial sweating. In such case, you should stop taking itraconazole and consult with your doctor.

Very rarely, it may occur a numbness feeling in the lips or severe skin disorder. In such case, stop taking itraconazole and ask for medical assistance.

Talk or consult your doctor if you experience decrease in the breathing capacity, unexpected weight gain, swelling of the legs or abdomen, unusual fatigue or sudden waking up at nights.

Especially in cases of long-term treatment, one or more of the following symptoms may occur, which are considered rare: muscle weakness, jaundice, dark urine and pale stools, body fluid accumulation, hair loss. In such cases, you should stop taking the medication and consult your doctor immediately.

In case you experience a side effect caused by this medicine, you should report it to your doctor or pharmacist or any other health care professional or directly to the National Drug Organization (284 Mesogeion Av. 15562, Cholargos, Athens Greece, www.eof.gr).

2.9. What you should know in case you forget to take one dose

If you should receive this medicine regularly and you forgot to take a dose, you should take it as soon as you remember. However, if it is near the time to receive your next dose then do not get the missed dose, simply continue the treatment as planned.

2.10. What should the patient know about the expiration date

It is mentioned in inner and outer packaging.
Do not use if this date has expired.

2.11. Special warnings about the storage of the product.

Store at temperature below 25°C.

2.12. Date of last revision of this leaflet

14-12-2012.

3. INFORMATION FOR THE RATIONAL USE OF MEDICINE

- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment with this medicine you experience any problem or issue, contact immediately your doctor or pharmacist.
- If you have any questions regarding the information for this product, its use or about the medical condition that you suffer, you should ask your doctor or pharmacist.
- This product will be safe and effective if it is used exactly according to instructions provided.
- For your own safety it is highly recommended that you read carefully all information provided for the prescribed medicine.
- Do not store medicines in bathroom lockers, as the high temperature and the humidity may degrade the product which may be harmful to your health.
- Store the product in the original packaging.
- If your doctor instructed you to stop the use of this product, dispose the remaining product and do not use it.
- Do not keep the medicine you do not need any more or those that are expired.
- Keep all medicines in safe place out of reach and sight of children.

4. PRESCRIBING INFORMATION

This medicine is subjected to medicinal prescription.