

Oramax

Antifungal Agent Capsule

What is the composition of Oramax capsule?

Each capsule contains:

Active ingredient: Fluconazole 150mg.

Other ingredients: Lactose, starch, sodium lauryl sulphate, colloidal silicone dioxide, magnesium stearate and hard gelatin.

What is the available pack?

Oramax is available as a pack containing 1 capsule.

What should you know about Oramax?

The active ingredient of Oramax is fluconazole; this is related to a group of medicines called triazole antifungal agents. Fluconazole prevents in the sensitive fungi the production of ergosterol, one of the major component of the fungal cell membrane, damaging thereby the fungal cell membrane and results in leakage of the essential intracellular constituents.

What are the uses of Oramax?

Oramax is used for the treatment of the following fungal infections:

- In women - vaginal candidiasis (vaginal thrush), acute or recurrent.
- In men - candidal balanitis (inflammation of the end of the penis).

The treatment of partners who present with symptomatic genital candidiasis should be considered.

What is the dosage of Oramax and how to take?

Oramax capsule should only be taken by mouth.

The whole course of treatment for vaginal candidiasis or candidal balanitis is one capsule.

Take the capsule with a glass of water, at any time of the day without regard to meals.

How quickly will the treatment start to work?

Vaginal Thrush: Your condition should start to clear up within a few days - some women notice an improvement in one day.

If your condition does not clear up within a few days, you should go back to your doctor.

Candidal Balanitis: Your condition should start to clear up within a few days but it may take up to a week.

If your condition has not cleared up after one week, you should go back to your doctor.

When should you avoid the use of Oramax?

Do not take Oramax, if you have ever had an allergy to any of its components or to other drugs related to the same group (triazole antifungal agents).

What should you be aware of?

If the answer is YES to any of the following questions - tell your doctor before you take Oramax:

- Are you pregnant or trying to become pregnant? (see below).
- Are you breast-feeding? (see below).
- Is your age under 16 years? (see below).
- Do you have any disease or illness affecting your liver or have you had unexplained jaundice?
- Do you have any disease or illness affecting your kidneys? (However, no adjustment in single dose therapy is required).
- Do you suffer from heart disease, including heart rhythm problems?
- Do you suffer from serious diseases such as AIDS or cancer?

Use during pregnancy: Since there are no adequate and well controlled studies on the use of fluconazole in pregnant women, it should not be used for women who are pregnant or trying to become pregnant unless adequate contraception is employed. Ask your doctor or pharmacist for advice before taking any medicine.

Use during breast-feeding: Since fluconazole can end up in breast milk, it should not be used for women who are breast-feeding their babies. Ask your doctor or pharmacist for advice before taking any medicine.

Use in adolescents and children below 16 years: Despite extensive data supporting the use of fluconazole in adolescents and children below 16 years, there are limited data available on its use for genital candidiasis in this age group. Therefore, its use at present is not recommended unless antifungal treatment is considered essential and no suitable alternative agent exists.

Use in elderly: The normal adult dose should be used.

Effects on your ability to drive or use machines: Experience with fluconazole indicates that it is unlikely to impair your ability to drive or use machinery.

Does your medicine cause undesirable effects?

Most people taking this medicine find it causes no problems. However, some undesired effects are reported with the use of multiple-dose fluconazole in the treatment of other fungal infections not related to the genital tract.

The commonest undesirable effects, which are usually mild, are nausea, stomach discomfort, diarrhoea, wind, rash and headache.

Rarely, some undesirable effects may occur such as itching, vomiting, indigestion, seizure, abnormalities in blood/liver function/urine and other biochemical tests, liver toxicity (in patients with serious diseases such as AIDS or cancer), severe skin reactions (more commonly in patients with AIDS), hair loss, dizziness, swelling of the face, altered sense of taste and change in heart rate or rhythm.

A few people may develop allergic reactions to medicines. Tell your doctor immediately, if you develop any of the following undesirable effects: sudden wheeziness, difficulty in breathing or tightness in the chest; swelling of eyelids, face or lips; skin lumps or red itchy spots; itch all over the body.

What if you take too many capsules?

You need to take only one capsule. Taking more than this is unlikely to be dangerous unless many capsules are taken at once. In that case, do not delay, contact your doctor or your nearest hospital casualty department.

Is there any drug interaction?

No evidence of clinically important interactions with other commonly used drugs has so far been observed with single-dose fluconazole 150mg. However, drug interactions have been reported when certain medicines are concurrently used with multiple-dose fluconazole in the treatment of other fungal infections not related to the genital tract.

Inform your doctor if you are taking any of the following medicines:

- Celecoxib, parecoxib or alfentanil (pain relievers)
- Warfarin or coumarin drugs (to prevent blood clots)
- Oral sulphonylureas (such as chlorpropamide, glibenclamide, glipizide or tolbutamide) and nateglinide (to control diabetes)
- Diuretics, such as hydrochlorothiazide (used to treat fluid retention and high blood pressure)
- Eplerenone or bosentan (used to control high blood pressure)
- Atorvastatin or simvastatin (used to regulate lipid in the blood)
- Rifampicin or rifabutin (antibiotics)
- Nevirapine, ritonavir or saquinavir (antiviral)
- Amphotericin (antifungal)
- Artemether/lumefantrine (antimalarial)
- Zidovudine, also known as AZT (used in HIV-infected patients)
- Cyclosporin or tacrolimus (used to affect the immune response)
- Theophylline (used to control asthma)
- Oestrogens (oral contraceptive). However, there is only unreliable reports of contraceptive failure when fluconazole given with oestrogens.
- Ergotamine or methysergide (used for migraine)
- Phenytoin (used to control epilepsy)
- Pimozide, sertindole or quetiapine (used for the control of psychotic problems)
- Reboxetine (used to control depression)

How to store Oramax?

Keep out of the reach of children.

Store at a temperature of 15 - 25°C.

THIS IS A MEDICATION

- Medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medications out of the reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

Any information? Call Our Toll Free No. (971) 800-4994



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