

DIFLUVID CAPSULE

Fluconazole (150 mg)

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What Difluvid is used for

Difluvid is used to treat infections caused by fungi and prevent candida infection. The most common cause of fungal infections is a yeast called *Candida*.

Difluvid is used to treat the following type of fungal infections:

- *Mucosal thrush* (infection affecting the lining of the mouth, throat and denture of sore mouth)
- *Genital thrush* (infection of the vaginal or penis)
- *Dermatomycolosis* (infection of the skin)

Difluvid is also used to:

- Stop *mucosal thrush* from coming back
- Reduce recurrence of *vaginal thrush*
- Stop you from getting an infection caused by *Candida* (if your immune system is weak and not working properly)

How Difluvid works

This medicine belongs to a group of medicines called "antifungals". The active substance is fluconazole.

Fluconazole works by preventing the growth of the fungal and yeast organisms causing your infection.

Before you use Difluvid

When you must not take it

Do not take this medicine if:

- you are hypersensitive to fluconazole or any of the other ingredients of this product .
- you are hypersensitive to medicines related to fluconazole such as miconazole, ketoconazole or clotrimazole
- you are pregnant or planning to become pregnant
- you are taking fluconazole at doses lower than 400 mg per day with terfenadine
- you are pregnant or planning to become pregnant
- you are breast-feeding or wish to breast-feed

Difluvid may cause harm to your unborn baby. You should not take Difluvid while you are pregnant unless your doctor has told you to.

If you are a woman of child-bearing potential, avoid becoming pregnant during treatment. Use effective contraception during treatment and for 1 week after treatment.

- you are breastfeeding

Difluvid is excreted in human breast milk, hence its use in nursing mothers is not recommended. However, breast-feeding may be maintained if you took a single dose of Difluvid 150 mg. Breast-feeding is not recommended after a high dose (more than 150 mg) or repeated use of Difluvid.

Do not take this medicine if you are taking any of the following medicines:

- cisapride (a medicine used to treat stomach problems)
- astemizole, terfenadine (antihistamine medicines used to treat allergies)
- pimozone (a medicine used for treating mental illness)
- quinidine (a medicine used to treat an irregular heartbeat)
- if you received terfenadine and fluzonazole at multiple doses of 400 mg per day.

-Before you start to take it

Tell your doctor if:

- you have any liver or kidney problems
- you have any heart problems
- you develop severe skin reactions

-Taking other medicines

Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtained without a prescription.

Some medicines interfere with Difluvid.

They include:

- Anticoagulants (Blood thinning drugs) E.g. warfarin
- Drugs for anxiety (Short-acting benzodiazepine) E.g. midazolam
- Cisapride (used to treat stomach problems)
- Cyclosporin and tacrolimus (medications to prevent organ transplant rejection)
- Hydrochlorothiazide (used for treating fluid problems)
- Oral contraceptives (Birth control pill)
- Phenytoin (used to treat epilepsy)
- Pimozone (used to treat mental illness)
- Rifabutin and rifampicin (Antibiotic medicineto treat tuberculosis)
- Sulfonylureas (Used for diabetes) E.g. chlorpropamide, glipizide, tolbutamide or glibenclamide
- Terfenadine and astemizole (Used to treat allergies)
- Theophylline (used to treat asthma)
- Zidovudine (antiviral medication)
- Other drugs metabolized by the cytochrome P-450 system.

Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to take Difluvid

-How much to take

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Adults:

Prevention of relapse of oropharyngeal candidiasis in patients with AIDS:

After receiving a full course of primary therapy, fluconazole may be administered at a 150 mg once weekly dose.

For treatment of vaginal thrush, fluconazole 150 mg should be administered as a single oral dose.

To reduce the incidence of recurrent vaginal candidiasis:

A 150 mg once monthly dose may be used. The duration of therapy should be individualized, but ranges from 4-12 months. Some patients may require more frequent dosing.

For Candida Balanitis (inflammation of the head of the penis caused by Candida fungus):

A 150 mg should be taken as a single oral dose.

Prevention of candidiasis:

50 to 400 mg once daily, based on patient's risk of fungal.

For dermal infections (Athlete's foot, ringworm, jock itch and candida infections):

Recommended dosage is 150 mg once weekly. Duration of treatment is normally 2 to 4 weeks but athlete's foot may require treatment for up to 6 weeks.

For tinea versicolor (fungal infection of the skin):

Recommended dose is 300 mg once weekly for 2 weeks; a third weekly dose of 300 mg may be needed in some patients, whereas in some patients, a single dose of 300 to 400 mg may be sufficient.

Use in Renal impairment:

- No adjustments in single-dose therapy are necessary.
- In multiple-dose therapy, normal doses should be given on day 1 and day 2 of treatment, and thereafter the dosage intervals of daily dose should

be modified accordance with creatinine clearance below:

| Creatinine Clearance (ml/min) | Dosage intervals/ Daily dose |
|--------------------------------|---------------------------------------|
| > 50 | Normal dosage regime |
| 11 - 50 | 50% of normal daily dose |
| Patients with regular dialysis | One dose after every dialysis session |

These are suggested dose adjustments based on pharmacokinetics following administration of single doses. Further adjustment may be needed depending on clinical condition.

Children:

There are limited data available on the use of fluconazole for genital candidiasis in children below 16 years old. Use at present is not recommended unless antifungal treatment is imperative and no suitable alternative agent exists.

Swallow the capsule (s) with a full glass of water.

-When to take it

To be taken with or without a meal

-How long to take it

You are advised to take it as long as your doctor tells you to.

-If you forget to take it

Do not take double dose to make up for a forgotten dose.

If you forget to take your dose, take it as soon as you remember. Skip the missed dose if it is almost time for your next dose.

-If you take too much (overdose)

Contact your doctor immediately as

soon as you realise you have taken too much.

Overdose symptoms may include:

- hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour).

Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

While you are using Difluvid

-Things you must do

- Tell your doctor immediately if you become pregnant.
- Tell your doctor if you decide to breast-feed your baby.
- If you are about to have any blood tests, tell your doctor you are taking Fluconazole.
- Before starting any new medicine, tell your doctor or pharmacist that you are taking Difluvid.

-Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other complaints unless you are told by your doctor or pharmacist.
- Stop taking the medicine or change the dosage on your own before asking your doctor.

-Things to be careful of

- Drinking will make it worse. Watch your intake.
- Be careful while driving or operating machinery as Fluconazole may cause dizziness and affect your eyesight.
- Be sure to follow your doctor's advice if regular checks on your liver are recommended.
- If you suffer from HIV or have a weakened immune system and develop a rash while taking

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Fluconazole, tell your doctor immediately.

Side effects

All medicines can cause unwanted side effects. These effects can be serious but most of the time, they are mild and temporary.

Tell your doctor if you notice any of the following and they worry you:

The more common side effects of Fluconazole are:

- Stomach pain, diarrhea, flatulence, nausea or feeling sick, vomiting
- Headache
- Rash
- Altered taste
- Increase in blood tests of liver function

Other undesirable effects include:

- Dizziness
- Serious skin disorders including Stevens–Johnson syndrome and toxic epidermal necrolysis (more common in patients with AIDS)
- Leucopenia (reduction in white blood cells)
- Thrombocytopenia (reduction in platelets)
- Hyperlipidaemias (abnormally elevated lipid levels)
- Anaphylaxis (severe allergic reaction) and angioedema (swelling under the skin)
- Hepatotoxicity (in patients with severe underlying disease such as AIDS or malignancy)

Other unwanted side effects not listed may occur. Tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public-> Reporting Medicinal Problems / Side effects / AEFI / Vaccine Safety).

Storage and Disposal of Difluvid

-Storage

Keep out of reach of children. Protect from moisture.

Store Difluvid below 30°C.

-Disposal

No specific instructions. Please ask your pharmacist how to dispose unused medicines properly.

Product description

-What it looks like

Light turquoise opaque/light turquoise opaque capsule with “HOVID” printed on one end and “FL150” printed on the other end of the capsule. The capsule is filled with white to off-white powder. Each size 1 capsule contains Fluconazole 150 mg.

-Ingredients

-Active ingredients

Each Difluvid capsules contains Fluconazole 150 mg.

-Inactive ingredients

Lactose monohydrate
Pregelatinised starch
Magnesium stearate
Colloidal silicon dioxide
Sodium starch glycolate
Microcrystalline cellulose
Sodium lauryl sulphate

-MAL Number:

MAL09072798AZ

Manufacturer

HOVID Bhd.
Lot 56442, 7¹/₂ Miles,
Jalan Ipoh / Chemor,
31200 Chemor, Perak, Malaysia.

Product Registration Holder

HOVID Bhd.
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(Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.