hovid-Ketoconazole 200mg Tablet ®

Ketoconazole (200 mg)

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What *hovid-Ketoconazole 200mg Tablet* is used for

Ketoconazole should be used only when other effective antifungal therapy is not available. It is used for the treatment of systemic fungal infections (e.g. blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis).
Ketoconazole should not be used for fungal meningitis because it does not penetrate well into the central nervous system (CNS).

How *hovid-Ketoconazole 200mg Tablet* works

Ketoconazole is an antifungal agent which will disrupt production of fungal cell membrane components, therefore damaging and changing its permeability. This results in loss of essential cell elements and buildup of toxicity in fungal cells and will lead to the death of fungal cells. Ketoconazole works effectively against Candida albicans.

Before you use *hovid-Ketoconazole 200mg Tablet*

-When you must not use it

In patients with acute porphyria, acute or chronic liver disease, or allergic to other azole antifungals (itraconazole, fluconazole, miconazole). Ketoconazole should not be taken together with terfenadine, astemizole and cisapride. Ketoconazole is not recommended during pregnancy. Nursing mothers should stop breast-feeding when beginning and throughout treatment with ketoconazole for 24 to 48 hour thereafter as it is excreted in breast milk and may increase the possibility of kernicterus in the nursing infant. Ketoconazole should not be used in children unless the potential benefit outweighs the risks.

-Before you start to use it

Liver function tests should be performed before starting the therapy to rule out acute or chronic liver disease, after two weeks of treatment and then on a monthly basis.

-Taking other medicines

Concurrent use with alcohol or other hepatotoxic medications may result in higher risk of hepatotoxicity, especially those on prolonged administration or those with a history of liver disease; with concurrent use of dantrolene, females over 35 years of age may be especially at risk. Concurrent use with antacids, anticholinergics, antispasmodics, histamine H2-receptor antagonists or omeprazole may reduce absorption of ketoconazole. Anticoagulant effects may be increased when these agents are used concurrently with ketoconazole. Ketoconazole has been reported to increase blood concentrations of cyclosporine, increasing the risk of kidney toxicity. Concurrent administration of ketoconazole with dideoxyinosine (ddI) may decrease the absorption of ketoconazole. Concurrent use of isoniazid or rifampin either separately or together with ketoconazole may result in decreased antifungal activity. Concurrent use with phenytoin may result in altered blood concentration of either or both medications. Ketoconazole inhibits the metabolism of terfenadine, thus causing increase in the risk of heart damage.

How to use *hovid-Ketoconazole 200mg Tablet*

-How much to use

Adults: 200 mg (one tablet) once daily. If the response is insufficient within the expected time, the dose may be increased to 400 mg (two tablets) once daily. **Children-**over 2 yrs: 3.3 to 6.6 mg/kg once daily. Under 2 years: Dosage has not been studied.

-When to use it

Take ketoconazole exactly as your doctor has told you**.**

-How long to use it

The usual duration of therapy for systemic infection is 6 months. Treatment should be continued until active fungal infection has subsided. Refer to your doctor or pharmacist.

-If you forget to use it

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

-If you use too much (overdose)

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Contact your doctor, an emergency department or a poisoning center immediately.

While you are using it

-Things you must do

Let the doctor know the medications you are taking or any disorders you are having.

-Things you must not do

Not to take alcoholic beverages. Do not change dosing regimen or take any new medicines without consulting your doctor.

-Things to be careful of

Caution if dizziness or drowsiness occurs. Caution use in children. Inform your doctor before treatment if you are pregnant or becoming pregnant or breast-feeding during treatment.

Side effects

Ketoconazole may cause gastrointestinal discomfort or disturbances such as nausea, vomiting, constipation, abdominal pain, and diarrhoea. Other advsere effects include hepatitis, hypersensitivity, skin rash, pruritus, dizziness, drowsiness and headache, breast enlargement in man, impotence, menstrual irregularities, abnormal sensitivity of eyes to light and low blood platelet count.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of *hovid-Ketoconazole 200mg Tablet*

- Storage

Store below 30˚C. Protect from moisture.

- Disposal

Ask your doctor or pharmacist for the right way to dispose the medications.

Product Description

- What it looks like

Round, white uncoated tablet, bevel-edged, shallow convex faces, “HD” and break-bar embossed on one face.

- Ingredients

Ketoconazole

- MAL number:

MAL NO: MAL19987375AZ

Manufacturer

HOVID Bhd.
Lot 56442, 7 ½ Miles, Jalan Ipoh/Chemor, 31200 Chemor, Malaysia.

Product Registration Holder

HOVID Bhd.
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