

YUCOMY[®] CREAM

Ketoconazole, the active ingredient of Yucomy Cream, is a broad spectrum imidazole antifungal agent. Chemically, ketoconazole is (±)-cis-1-acetyl-4{4-[2-(2,4-dichlorophenyl)-2-imidazole-1-ylmethyl-1,3-dioxolan-4-ylmethoxy]phenyl}piperazine.

Ingredient:

Each gram contains:

Ketoconazole 20mg

Pharmacodynamics:

1. Ketoconazole is a broad spectrum antifungal agent which acts by inhibiting the biosynthesis of ergosterol, damaging the fungal cell wall membrane and altering its permeability. As a result, loss of essential intracellular elements may occur.
2. Ketoconazole also inhibits the fungal biosynthesis of triglycerides and phospholipids, and inhibits oxidative and peroxidative enzymes activity which may contribute to the deterioration of subcellular organelles and cellular necrosis.
3. Topically, ketoconazole inhibits the growth of the common dermatophytes such as *Trichophyton rubrum*, *T. mentagrophytes*, *T. tonsurans*, *Microsporum canis*, *M. audouini*, *M. gypseum*, and *Epidermophyton floccosum*; and yeast, such as *Candida albicans* and *C. tropicalis*. It is also active against *Malassezia furfur*, the organism that causes tinea versicolor.

Pharmacokinetics:

No systemic absorption was detected at a sensitivity level of 5 ng/ml in the blood over a 72- hour period following a single topical application to the chest, back, and arms of normal volunteers.

Indication:

Yucomy cream is effective for the treatment of fungal infection caused by dermatophytes and yeasts as below:

Clinical Manifestation	Causative Microorganism
1. Tinea corporis (ringworm of the body)	<i>Trichophyton rubrum</i> , <i>T. mentagrophytes</i> , <i>Microsporum canis</i> , <i>Epidermophyton floccosum</i>
2. Tinea cruris (Jock itch)	
3. Tinea pedis (athlete's foot)	
4. Tinea manus (tinea involving the interdigital spaces of hands)	
5. Tinea versicolor (white Spots)	<i>Malassezia furfur</i>
6. Seborrhoeic dermatitis	<i>Pityrosporum ovale</i>
7. Cutaneous candidiasis	<i>Candida albicans</i> , <i>C. tropicalis</i> .

Dosage and Administration:

Apply once daily to the affected area. The treatment should be carried out without interruption until one week after the lesion has completely disappeared.

Contraindications:

Hypersensitivity to ketoconazole, propylene glycol or to any other component of this preparation.

Precaution (s) / Warning(s):

1. Ketoconazole should never be employed for the treatment of infection of the eye.
2. If a reaction suggesting sensitivity or chemical irritation occurs, use of ketoconazole cream should be promptly discontinued.
3. Limited short-term studies in animals and in human volunteers on whom limited quantities of the cream were tested have failed to demonstrate the absorption of ketoconazole in detectable amounts. Due to the teratogenic nature of the active ingredient, ketoconazole, caution should be exercised when ketoconazole cream is administered to pregnant or nursing women.

Drug Interaction(s):

No interaction have been reported with topical use of Ketoconazole.

Side Effect(s) / Adverse Reaction(s):

Short-term studies indicate that ketoconazole cream is well tolerated by the skin. Side effects of ketoconazole cream consist mainly of irritation, pruritus and stinging.

Symptoms And Treatment For Overdosage, And Antidote(s):

Exaggerated use can bring on local irritation and erythema. Discontinuation of treatment remedies this effect.

Shelf-life:

3 years from the date of manufacture.

Storage Condition:

Keep in an airtight container. Store at temperature below 30°C. Protect from light and moisture.

Product Description and Packing:

A white to off-white color cream.
Aluminium tube of 20gm x 40.



Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor, Malaysia.
Ordering Line: 1 800 88 3027
Product Info: 1 800 88 3679