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Candione Clotrimazole Anti-Fungal Cream 1%w/w

Treat skin fungal infections, ringworm, athlete's foot, jock itch and white spot

CANDIONE CLOTRIMAZOLE ANTI-FUNGAL CREAM 1%w/w

COMPOSITION:
Clotrimazole 1% w/w, Chlorocresol 0.2%w/w

DESCRIPTION:
White colour, smooth application, sticky and phenolic odor cream.

PHARMACODYNAMIC:
Clotrimazole is an imidazole derivative with a broad spectrum antimycotic activity.

MECHANISM OF ACTION:
Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

PHARMACODYNAMIC EFFECTS:

Clotrimazole has a broad antimycotic spectrum of action in-vitro and in-vivo, which includes dermatophytes, yeasts, moulds, etc.

Under appropriate test conditions, the minimum inhibitory concentration (MIC) values for these types of fungi are In the region of less than 0.062-4(-8) mg/ml substrate. The mode of action of Clotrimazole is primarily fungistatic. In-vitro activity is limited to proliferating fungal elements; fungal spores are slightly sensitive.

In addition to its antimycotic action,Clotrimazoie also acts on Trichomonas vaginalis, gram-positive microorganisms (Streptococci/Staphylococci) and gram-negative microorganisms (Bacteroides /Gardnerella vaginalis).

In-vitro Clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci-with the exception of Enterococci in concentrations of 0.5-10 mg/ml substrate and exerts a trichomonacidal action at 100 mg/ml.

Primary resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

PHARMACOKINETIC:
Absorption of Clotrimazole is less than 0.5% after topical application.

INDICATION:

- All dermatomycoses due to dermatophytes (Trichophyton species) e.g. athlete's foot (Tinea pedis), jock itch (Tinea cruris) and body ringworm (tinea corporis)
- All dermatomycoses due to yeast - Candidiasis, Pityriasis versicolor
- Dermatomycoses due to moulds and other fungi
- Skin diseases showing secondary infection with these fungi

RECOMMENDED DOSE:
General: The affected area should be washed and thoroughly dried. Thin layer of Candione Clotrimazole Anti-fungal Cream is evenly rubbed into the affected area twice daily. Treatment should continue for 2-4 weeks after the disappearance of all signs of infection to ensure mycological cure and prevent relapse.

Adult & Paediatric dosing based on type of infection:

- Candidiasis (topical): twice daily for up to 4 weeks
- Pityriasis versicolor (Tinea versicolor): twice daily for up to 4 weeks
- Tinea corporis: twice daily for up to 4 weeks
- Tinea cruris: twice daily for up to 4 weeks
- Tinea pedis: twice daily for up to 4 weeks

ROUTE OF ADMINISTRATION:
Topical

CONTRAINDICATION:
Hypersensitivity to Clotrimazole

WARNING & PRECAUTIONS:
For irritation or sensitivity caused with the use of Clotrimazole; treatment should be discontinued and appropriate therapy instituted. The patient should be advised to use the medication for the full treatment time even though the symptoms may have improved.

This medicine should be used in the first trimester of pregnancy after consideration of the benefit/ risk relation and by physician decision. It is not known whether Clotrimazole is excreted in human being milk. As many drugs are excreted In human being milk, caution should be exercised with Clotrimazole used by nursing mothers.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
It is unlikely to impair a patient's ability to drive or use machinery.

INTERACTIONS WITH OTHER MEDICAMENTS:
Not known

PREGNANCY & LACTATION:
Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during pregnancy and breastfeeding.

SIDE EFFECTS:
Local reactions include irritation, burning sensation, contact dermatitis, blister, edema, erythema, peeling of skin, pruritus, urticaria and stinging of skin.

SYMPTOMS & TREATMENT OF OVERDOSE:
Acute overdosage with topical application of Clotrimazole is unlikely and would not be expected to lead to a life-threatening situation.

STORAGE CONDITION:
Store below 30ºC. Keep out of reach of children.

SHELF LIFE:
Please refer to the packaging. Do not use beyond the expiry date.

PACKING:
10g, 15g and 30g in aluminium tube

The information contained in this leaflet is limited. For further information, please consult your doctor or pharmacist

Ubat Kurap Clotrimazole 1%w/w Candione

Merawat kurap, kulat air pada kaki, gatal pangkal paha dan panau

UBAT KURAP CLOTRIMAZOLE 1%w/w CANDIONE

KOMPOSISI:
Clotrimazole 1% w/w, Chlorocresol 0.2%w/w

DESKRIPSI:
Krim berwarna putih, mudah disapu, melekit dan berbau fenolik.

FARMAKODINAMIK:
Clotrimazole adalah derivatif imidazole dengan aktiviti antimikotik spektrum yang luas.

TINDAKAN MEKANISME:
Clotrimazole bertindak terhadap fungus dengan merencatkan sintesis ergosterol. Perencatan sintesis ergosterol membawa kepada kemerosotan struktur dan fungsi membrane sitoplasmik.

KESAN FARMAKODINAMIK:
Clotrimazole memiliki tindakan antimikotik berspektrum luas in-vitro dan in-vivo yang berkesan terhadap dermatofit, yis, kulat dan sebagainya.

Dalam keadaan ujian yang sesuai, nilai kepekatan perencatan minimum (MIC) untuk jenis-jenis fungus ini adalah dalam lingkungan kurang daripada 0.064-4(-8) mg/ml substrat. Cara tindakan utama Clotrimazole ialah fungistatik. Aktiviti in-vitro adalah terhad kepada pembiakan fungus manakala spora fungus adalah kurang sensitif.

Tambahan kepada tindakan antimikotik, Clotrimazole juga bertindak terhadap Trichomonas vaginalis, mikroorganisma gram-positif (Streptococci/Staphylococci), mikroorganisma gram-negatif (Bacteroides/Gardnerell avaginalis).

Clotrimazole merencatkan pembiakan Corynebacteria dan koki gram-positif kecuali Enterococci dalam kepekatan 0.5-1.0 mg/ml substrat dan member tindakan Tirichomonasida pada 100 mg/ml.

Jarang sekali berlaku variasi resistan primer spesis fungus yang sensitif; kemunculan resistan sekunder oleh spesis fungus yang sensitif hanya diperhatikan dalam kes asing dalam keadaan terapeutik.

FARMAKOKINETIK:
Penyerapan Clotrimazole adalah kurang daripada 0.5% selepas aplikasi topikal.

INDIKASI:

- Semua dermatomikosis yang disebabkan oleh dermatofit (spesis Trichophyton) seperti kaki atlet (Tinea pedis, gatal pangkal paha (Tinea cruris) dan kurap pada badan (Tinea corporis)
- Semua dermatomikosis disebabkan oleh yis (spesis Candida) seperti - Candida vulvitis, Candida balanitis
- Dermatomikosis yang disebabkan oleh kulapuk dan kulat yang lain
- Penyakit kulit yang menpunyai jangkitan sekunder oleh fungus

DOS SARANAN:
Umum: Basuh dan keringkan bahagian yang dljangkiti. Sapukan lapisan nipis krim Ubat Kurap Clotrimazole Candione dengan sekata di bahagian yang dijangkiti dua kali sehari. Rawatan perlu diteruskan 2-4 minggu selepas kehilangan semua tanda-tanda jangkitan untuk memastikan penyembuhan yang sempuma dan mengelakkan jangkitan berulangan.

Dos dewasa dan pediatrik bergantung kepada jenis jangkitan:

- Kandidiasis (topikal): dua kali sehari untuk jangkamasa sehingga 4 minggu
- Pityriasis versicolor (Tinea versicolor): dua kali sehari untuk jangkamasa sehingga 4 minggu
- Tinea corporis: dua kali sehari untuk jangkamasa sehingga 4 minggu
- Tinea cruris: dua kali sehari untuk jangkamasa sehingga 4 minggu
- Tinea pedls:dua kali sehari untuk jangkamasa sehingga 4 minggu

CARA PEMBERIAN:
Topikal

KONTRAINDIKASI:
Hipersensitiviti kepada Clotrimazole

AMARAN & PERHATIAN:
Untuk iritasi atau sensitiviti yang diakibatkan oleh penggunaan Clotrimazole; rawatan perlu dihentikan dan terapi yang sesuai perlu dimulakan. Pesakit adalah dinasihati supaya menghabiskan ubat untuk seluruh jangkamasa rawatan walaupun simptom mungkin telah bertambah baik.

Ubat ini boleh digunakan pada trimester pertama kehamilan setelah mempertimbangkan manfaat/ risiko atas nasihat doktor. Ia tidak diketahui sama ada Clotrimazole digolongkan dalam susu ibu. Oleh sebab banyak ubat masuk dalam susu ibu, perhatian perlu diberikan oleh ibu yang menyusukan anak ketika menggunakan Clotrimazole.

KESAN TERHADAP KEBOLEHAN MEMANDU DAN MENGENDALIKAN MESIN:
Ia tidak mungkin menjejaskan keupayaan pesakit untuk memandu atau mengendalikan mesin.

INTERAKSI DENGAN UBAT LAIN:
Tidak ada interaksi ubat yang diketahui.

KEHAMILAN & LAKTASI:
Timbangkan potensi manfaat rawatan ubat terhadap potensi risiko sebelum menetapkan preskripsi ubat ini semasa kehamilan dan laktasi.

KESAN SAMPINGAN:
Tindak balas setempat termasuk iritasi, sensasi panas, dermatitis kontak, lepuh, edema, eritema, pengelupasan kulit, gatal-gatal, urtikaria dan sengatan kulit.

SIMPTOM DAN RAWATAN OVERDOS:
Aplikasi topikal Clotrimazole yang berlebihan jarang berlaku dan tidak akan menyebabkan keadaan yang mengancam nyawa.

KEADAAN PENYIMPANAN:
Simpan di bawah 30°C. Jauhkan daripada capaian kanak-kanak.

TEMPOH HAYAT:
Sila rujuk kepada bungkusan. Jangan guna selepas tamat tarikh luput.

SAIZ BUNGKUSAN:
10g,15g dan 30g dalam tiub aluminium

Maklumat dalam risalah ini adalah terhad. Untuk informasi selanjut, sila jumpa doktor atau ahli farmasi.

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Manufactured by:
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