

Dermasim[®]

Clotrimazole

Description

Dermasim[®] is a preparation of Clotrimazole which is a synthetic imidazole derivate with broad-spectrum antifungal activity; it also exhibits activity against *Trichomonus*, *Staphylococci*, *Streptococci* and *Bacteroides*. It inhibits biosynthesis of sterols, particularly ergosterol, and an essential component of the fungal cell membrane, thereby damaging and affecting the permeability of the cell membrane. This results in leakage and loss of essential intracellular compounds and eventually causes cell lysis. It is used for the treatment of superficial infections caused by species of pathogenic dermatophytes, yeasts, and *Malassezia furfur*.

Indication

Dermasim[®] Cream, Ointment and Solution are indicated in:

1. All dermatomycosis due to dermatophytes (e.g. *Trichophyton species*)
2. All dermatomycosis due to yeasts (e.g. *Candida species*)
3. Dermatomycosis due to mould and other fungi
4. Skin diseases showing superinfections with these fungi

The dermatomycosis mentioned above (1) to (4) include among others. For example, interdigital mycoses (e.g. athlete's foot), paronychias (associated with nail mycoses), mycoses in skin folds, Candida vulvitis, Candida balanitis, Pityriasis versicolor, erythrasma.

Dosage and direction of application

Dermasim[®] Cream and Ointment: Wash the affected area with water and dry thoroughly before application. **Dermasim[®]** cream and ointment should be applied thinly to the affected area(s) 2 to 3 times daily and rubbed gently. The duration of treatment varies; it depends on other factors e.g. the extent and localization of the disease.

Recommended duration of treatment

Dermatomycoses due to dermatophytes and yeasts	: 3 to 4 weeks
Candida vulvitis and Candida balanitis	: 1 to 2 weeks
Erythrasma	: 2 to 4 weeks
Pityriasis versicolor	: 1 to 3 weeks

Treatment of fungal infection should be continued for approximately 2 weeks after the disappearance of all symptoms despite a rapid, subjective improvement, in order to prevent relapse. For Athlete's foot; pay special attention to the spaces between the toes.

Dermasim[®] Solution: Apply thinly to the affected area(s) 2 to 3 times daily. Because of its excellent efficacy a few drops of solution is usually sufficient for an area about the size of the palm. Successful treatment demands that Dermasim be applied correctly and over a sufficiently long period of time.

The duration of treatment varies. In general, it is 3 to 4 weeks in the case of dermatomycoses due to dermatophytes and yeasts; in Candida vulvitis and Candida balanitis, 1 to 2 weeks; and approximately 2 to 4 weeks in Erythrasma and 1 to 3 weeks in Pityriasis versicolor.

Use in Pregnancy & lactation

In the first trimester of pregnancy, clotrimazole should be used only when it is essential for the welfare of the patient. Administration of clotrimazole to a small number of women in the 2nd and 3rd trimesters of pregnancy has produced no obvious untoward effect on the course of the pregnancy or on the fetus. Although systemic absorption following topical or vaginal administration is low, caution should be exercised when clotrimazole is administered to nursing mothers as there is no information on whether or not clotrimazole is excreted in breast milk.

Side Effects

Clotrimazole is well tolerated when applied topically. Local irritation and burning sensation may occur in a very few cases but these symptoms are not considered harmful. Contact allergic dermatitis has been reported, if this occurs, treatment should be discontinued.

Precautions

Clotrimazole may damage latex (rubber) condoms and diaphragms (caps) and so make them ineffective at preventing pregnancy and STIs; use an alternative method of contraception for at least five days after using the cream, or preferably avoid having sex until after the infection has cleared up. If the sexual partner also has symptoms of thrush, it is important to treat the partner same time to prevent the re-infected.

Warnings

Cream & Ointment: Clotrimazole cream and ointment is for external use only. It is not intended for ophthalmic use. Use with caution around the eyes. Discontinue the product if skin rash or new irritation occurs.

Solution: Clotrimazole solution is very inflammable. Keep away from open flame. For external use only. Consult with physician if there is abdominal pain, fever or a foul-smelling vaginal discharge before or during the use of this medication. Consult with physician if symptoms recur within two months. Discontinue the product if skin rash or new irritation occurs

Contra-indication

Clotrimazole is contraindicated in patients with known hypersensitivity to clotrimazole or any other imidazole agent.

Pharmaceutical Precautions

Store in a cool, dry place. Keep out of reach of children.

Presentation

Derimasim[®] Cream : White cream containing containing Clotrimazole BP 1% w/w

Derimasim[®] Ointment: White Ointment containing Clotrimazole BP 1% w/w

Derimasim[®] Solution : 1% clotrimazole clear solution. Each ml contains clotrimazole BP
10mg.

Package quantities

Derimasim[®] Cream : Tube of 15 g

Derimasim[®] Ointment : Tube of 15 g

Derimasim[®] 1% Solution : 20ml in plastic dropper bottle

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