

## Naftin

Naftifine Hydrochloride 2%

### COMPOSITION:

**Naftin** Cream: Each gram cream contains Naftifine Hydrochloride USP 20 mg.

### PHARMACOLOGY:

The exact mechanism of action against fungi is not known, Naftifine Hydrochloride appears to interfere with sterol biosynthesis by inhibiting the enzyme squalene 2, 3-epoxidase. This inhibition of enzyme activity results in decreased amounts of sterols, especially ergosterol, and a corresponding accumulation of squalene in the cells.

### INDICATION:

**Naftin** cream is indicated for the topical treatment of tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Trichophyton tonsurans*, *Epidermophyton floccosum*.

### DOSAGE & ADMINISTRATION:

**Naftin** Cream: Apply BID to the affected areas a 0.5-inch margin of healthy surrounding skin for 4 weeks.

### CONTRAINDICATIONS:

It is contraindicated in individuals who have shown hypersensitivity to any of their components.

### WARNING & PRECAUTION:

#### General

**Naftin** cream is for external use only. If irritation or sensitivity develops with the use of **Naftin** cream treatment should be discontinued and appropriate therapy instituted. Diagnosis of the disease should be confirmed either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide or by culture on an appropriate medium.  
*Information for patients*

The patient should be told to:

1. Avoid the use of occlusive dressings or wrappings unless otherwise directed by the physician.

2. Keep **Naftin** cream, 1% away from the eyes, nose, mouth and other mucous membranes.

### SIDE EFFECTS:

Transient burning/stinging (5-6%), Skin tenderness (0.5-3%), Dryness, Erythema, Pruritus, Local irritation, Rash.

### USE IN PREGNANCY AND LACTATION:

Pregnancy Category B.

There are no adequate and well-controlled studies of Naftifine cream in pregnant women. Because animal reproduction studies are not always predictive of human response, Naftifine cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

*Nursing Mothers:* It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Naftifine cream is administered to a nursing woman.

### USE IN CHILDREN AND ADOLESCENTS:

*Children:* Safety and effectiveness in pediatric patients <12 years of age have not been established.

*Adolescents:* Safety and effectiveness were similar to those reported by younger patients.

### DRUG INTERACTIONS:

No data are available.

### OVERDOSAGE:

No data are available.

### STORAGE:

Store in a cool and dry place (below 30°C), protected from light and moisture. Keep out of reach of children.

### PACKING:

**Naftin** Cream: Each lami tube contains 10 g/15 g/ 20 g of **Naftin** cream.

### Manufactured By :

 **MEDICON Pharmaceuticals Ltd.**  
Mirpur, Dhaka, Bangladesh

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