

140.00 mm

## Monozole Lotion (Clotrimazole)

## Monozole-H Cream (Hydrocortisone + Clotrimazole)

### COMPOSITION:

#### MONOZOLE Lotion

Each ml contains:

Clotrimazole ..... 10mg

#### (USP Specifications)

#### MONOZOLE-H Cream

Each gram contains:

Hydrocortisone ..... 10mg

Clotrimazole ..... 10mg

#### (Innovator's Specifications)

### DESCRIPTION:

Clotrimazole is a broad spectrum antimycotic or antifungal agent, used for the treatment of a wide variety of dermatophyte infections and candidiasis. Clotrimazole falls under the imidazole category ofazole antifungals, possessing broad-spectrum antimycotic activity. The minimal side effect profile of this drug and its uncomplicated metabolic profile have led it to gain widespread acceptance for the treatment of mycotic outbreaks such as vaginal yeast infections as well as athlete's foot. Hydrocortisone is a corticosteroid used to treat inflammatory and pruritic corticosteroid-responsive dermatoses, ulcerative colitis, endocrine disorders, immune conditions, and allergic disorders.

### MECHANISM OF ACTION:

#### Clotrimazole:

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane. Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc. Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive. In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides). In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate. 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.

#### Hydrocortisone:

Hydrocortisone is a weak corticosteroid with both glucocorticoid and to a lesser extent mineralocorticoid activity. As the active ingredient in a topical cream it exerts anti-phlogistic, anti-pruriginous, anti-exudative and anti-allergic effects. Hydrocortisone, like other topically applied glucocorticoids, exerts an anti-inflammatory, antiallergenic, immunosuppressive, antimitotic (antiproliferative), antipruriginous and vasoconstrictive effect on skin. Thus, in addition to the elimination of inflammation and pruritus, a normalization of keratinisation, inhibition of excess fibroblast activity and epidermopoiesis, degradation of pathological metabolic products and inhibition of acantholysis are achieved. However, this is not a curative therapy but rather a symptomatic treatment.

### INDICATIONS:

**MONOZOLE-H Cream** is indicated for the treatment of the following

مونوزول لوشن  
(کلوٹرایمازول)

مونوزول-ایچ کریم  
(ہائیڈروکورتیسون + کلوٹرایمازول)

skin infections where co-existing symptoms of inflammation, e.g. itching, require rapid relief:

(i) Athlete's foot.

(ii) Candidal intertrigo.

**MONOZOLE Lotion** should be used to treat all fungal skin infections due to dermatophytes, yeasts, molds and other fungi. Fungal infections due to Candida and other sensitive pathogens, skin diseases showing secondary infection with these fungi, candidal nappy rash, vulvitis and balanitis, pityriasis versicolor, erythrasma. It is particularly suitable for use on hairy skin and in fungal infections of the outer ear (otitis externa) and middle ear (otomycoses).

### DOSAGE & ADMINISTRATION:

#### MONOZOLE-H Cream

#### Adults, elderly and children aged 10 years and over:

It should be thinly and evenly applied to the affected area twice daily and rubbed in gently. The maximum period of treatment is seven days.

A total daily dose of 10 mg cream per kg body weight should not be exceeded. For an adult weighing 50 kg the maximum daily dose is 500 mg cream which equals approximately 2 cm of cream to be divided into 2 applications per day.

#### Treatment duration:

If the acute symptoms have subsided after about 7 days but treatment is still required, this may be carried out with the corticoid-free preparation intended for this purpose.

#### MONOZOLE Lotion

It should be thinly and evenly applied to the affected area 2 or 3 times a day and gently rubbed in. A few drops are enough to treat an area of about the size of the hand. To prevent relapse, treatment should be continued for at least two weeks after the disappearance of all signs of infection. There is no separate dosage schedule for the elderly or the young.

### PHARMACOKINETICS:

#### Clotrimazole:

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 µg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

#### Hydrocortisone:

Dermal absorption of hydrocortisone depends on the thickness and condition of the skin. In healthy skin no systemic effects of corticoids have been observed after local application. However, in the case of inflamed or damaged skin, cutaneous absorption may be increased depending on the site of application, use of occlusive dressings, the degree of skin damage, and size of the treated area. Systemic effects can not be ruled out under such conditions. An increase in the skin temperature or moisture content, e.g. in skin folds or under an occlusive dressing, also promotes absorption. In infants and small children the epidermal "barrier" is still poorly developed, which facilitates transcutaneous uptake of drugs. The occurrence of systemic effects depends partly on the dose and, to a much greater extent, on the duration of treatment. More than 90% of the hydrocortisone absorbed is bound to plasma proteins. Hydrocortisone is metabolised in the liver and tissues, and the metabolites are excreted with urine. The biological half-life is approximately 100 minutes.

No relevant absorption of hydrocortisone acetate is expected after its

use for a short period on limited skin inflamed areas.

### PRECAUTIONS:

Because of its corticosteroid content, Clotrimazole/ Hydrocortisone should not be applied:

- To large areas (more than 5 - 10% of the body surface).
- In long term continuous therapy.
- Under occlusive dressings (such as nappies and bandages).

These restrictions apply particularly in children, where increased systemic absorption may occur resulting in adrenocortical suppression. This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

### Visual disturbance:

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

### Pregnancy

There is a limited amount of data from the use of clotrimazole or hydrocortisone in pregnant women. Animal studies with clotrimazole and corticosteroids have shown reproductive toxicity. At the low systemic exposures of clotrimazole and hydrocortisone following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole or hydrocortisone can be used during pregnancy, but only under the supervision of a physician or midwife. As a precautionary measure it is preferable to refrain from applying the cream for long periods during pregnancy.

### Lactation

No data on hydrocortisone is available, but topically applied hydrocortisone is unlikely to cause systematic effects due to the low percutaneous penetration. However, cutaneous absorption may be increased under certain circumstances, such as with use of occlusive dressing, the degree of skin damage, and the size of the treated area.

A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue Canesten Hydrocortisone therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

### SIDE EFFECTS:

**Immune system disorders:** allergic reaction (syncope, hypotension, dyspnea, urticaria)

**Skin and subcutaneous tissue disorders:** blisters, discomfort / pain, edema, erythema, irritation, peeling / exfoliation, pruritus, rash, stinging/burning.

**Eye disorders:** Blurred vision

After use on large areas (more than 10% of the body surface) and / or after long-term use (longer than 2-4 weeks) or use under occlusive dressings, local skin alterations such as skin atrophy, teleangiectasias, hypertrichosis, striations, hypopigmentation, secondary infection and acneiform symptoms may occur.

### CONTRAINDICATIONS:

Hypersensitivity to the active substances or to any of the excipients.

- Use on broken skin.
- Use on large areas of skin.
- Use for periods of longer than seven days.
- To treat cold sores or acne.
- Use on the face, eyes, mouth or mucous membranes.
- Children under 10 years of age, unless prescribed by a doctor.
- Pregnancy and lactation, unless prescribed by a doctor.
- Use on the ano-genital area, unless prescribed by a doctor.
- To treat ringworm, unless prescribed by a doctor.
- To treat secondarily infected skin conditions, unless prescribed by a doctor.
- Diseases affecting the skin (e.g. acne, rosacea, perioral dermatitis, lues, tuberculosis, etc.)
- Any untreated bacterial skin diseases

- Viral skin diseases (e.g. herpes simplex, chicken pox, shingles etc.)
- Dermal vaccination reactions.

### STORAGE & INSTRUCTIONS:

Storage temperature for Monozole-H Cream & Monozle Lotion is 15-25°C. Protect from heat, sunlight and moisture. Do not freeze or refrigerate. Keep away from the reach of children.

**To be sold on the prescription of a registered medical practitioner only.**

### FOR EXTERNAL USE ONLY.

### HOW SUPPLIED:

**MONOZOLE-H Cream:** 10g

**MONOZOLE Lotion:** 30ml

خوراک و طریقہ استعمال:

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:

مونوزول-ایچ کریم اور مونوزول لوشن کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت

کے درمیان رکھیں۔ دھوپ گرمی، نمی اور نمند ہونے سے بچائیں۔ ریفریجریٹر

میں نہ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت

کریں۔ صرف بیرونی استعمال کے لئے ہے۔

Manufactured by:

**PHARMASOL**  
**PRIVATE LIMITED**

Plot # 549, Sundar Industrial Estate,  
Lahore, Pakistan.

210.00 mm

210.00 mm