

PRODUCT NAME

Mecort C (Clotrimazole and Hydrocortisone Acetate Cream)

NAME AND STRENGTH OF ACTIVE INGREDIENT

Clotrimazole Ph. Eur. 1% w/w
Hydrocortisone Acetate Ph. Eur. 1% w/w

PRODUCT DESCRIPTION

White thick homogenous consistent cream and no particles appear under microscope.

PHARMACODYNAMICS

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives, combinations.

ATC code: D01AC20

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. 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.

Hydrocortisone acetate:

Hydrocortisone acetate 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 antiallergic effects.

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 acetate

Dermal absorption of hydrocortisone acetate 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 cannot 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 acetate absorbed is bound to plasma proteins. Hydrocortisone acetate is metabolised in the liver and tissues, and the metabolites are excreted with urine. The biological half-life is approximately 100 minutes.

INDICATION

Mecort C (Clotrimazole and Hydrocortisone Cream) is indicated for the Treatment of skin infections with co-existing symptoms of inflammation, e.g. itching, requiring rapid relief:

- Dermatomycoses caused by dermatophytes (e.g. athlete's foot),yeasts (e.g. candidalintertrigo), moulds, and other fungi.
- Infections of the labia and adjacent areas caused by yeast fungi(candida vulvitis); inflammation of the glans and prepuce of thesexual partner caused by yeast fungi (candidal balanitis).
- Skin diseases superinfected with organisms sensitive to clotrimazole.

RECOMMENDED DOSAGE

Mecort C (Clotrimazole and Hydrocortisone Cream) should be apply thinly to the affected skin area once or twice a day (in the morning or in the morning and evening) and rubbed in.

Treatment should be for a maximum of 7 days.

A total daily dose of 10 mg cream per kg body w eight 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.

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.

ROUTE OF ADMINISTRATION

Topical.

CONTRAINDICATIONS

- Hypersensitivity to the active substances or to any of theexcipients of this formulation
- Use on broken skin
- 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.

WARNING AND PRECAUTIONS

Because of its corticosteroid content, Mecort C (Clotrimazole and Hydrocortisone Cream) should not be applied: to large areas (more than 5 - 10% of the body surface).

back

140x140mm

in long term continuous therapy.
under occlusive dressings (such as nappies and bandages).

These restrictions apply particularly in:
Infants, where the nappy can act as an occlusive dressing and increase systemic absorption.
Infants and 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 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.

INTERACTIONS WITH OTHER MEDICAMENTS

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently, the effectiveness of such contraceptives may be reduced. To date this has not been reflected in clinical practice.

PREGNANCY AND LACTATION

Pregnancy

There is a limited amount of data from the use of clotrimazole or hydrocortisone in pregnant women. At the low systemic exposures of clotrimazole and hydrocortisone following topical treatment, harmful effects with respect to reproductive toxicity are not predicted.
Mecort C (Clotrimazole and Hydrocortisone Cream) 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 Clotrimazole and Hydrocortisone therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

SIDE EFFECTS

As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible
Immune system disorders: allergic reaction (syncope, hypotension, dyspnea, urticaria)

Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, erythema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning
Eye disorders: vision, blurred
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.

OVERDOSAGE AND TREATMENT

No reports are available on cases of intoxication with Mecort C (Clotrimazole or Hydrocortisone Cream). No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote. However, in the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

EFFECTS ON ABILITY TO DRIVE AND OPERATE MACHINERY

Clotrimazole and hydrocortisone has no influence on the ability to drive and use machines.

STORAGE

Store at a temperature below 30°C. Keep out of reach of children.

DOSAGE FORM

Topical Cream.

PACKAGING AVAILABLE

15g and 30g aluminium tubes with white HDPE screwcap.

PRODUCT OWNER/ MANUFACTURER

Mepro Pharmaceuticals Pvt. Ltd.
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PRODUCT REGISTRATION HOLDER

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LEAFLET REVISION DATE

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