140.00 mm

Medroxin Cream
(Methylprednisolone aceponate)

میڈروکسن کریم
(میتھائیل پریڈنیسلون ایسپونیٹ)

COMPOSITION:
Each gram contains:
Methylprednisolone aceponate 1mg
(Innovator's specifications)

DESCRIPTION:
Methylprednisolone is a corticosteroid used to treat inflammation or immune reactions across a variety of organ systems, endocrine conditions, and neoplastic diseases.
Chemically, methylprednisolone is a synthetic pregnane steroid hormone derived form hydrocortisone and prednisolone. It belongs to a class of synthetic glucocorticoids and more generally, corticosteroids. It acts as a mineralocorticoid and glucocorticoid receptor agonist. In comparison to other exogenous glucocorticoids, methylprednisolone has a higher affinity to glucocorticoid receptors than to mineralocorticoid receptors.

MECHANISM OF ACTION:
After topical application, methylprednisolone aceponate suppresses inflammatory and allergic skin reactions as well as reactions associated with hyperproliferation, leading to regression of the objective symptoms (erythema, edema, infiltration, and lichenification) and the subjective complaints (itching, burning, pain). It is known that methylprednisolone aceponate itself binds to the intracellular glucocorticoid receptor and this is especially true of the principal metabolite 6 alpha-methylprednisolone-17-propionate, which is formed after cleavage in the skin. The steroid receptor complex binds to certain regions of DNA, thereby triggering a series of biological effects. Binding of the steroid receptor complex results in induction of macrocortin synthesis. Macrocortin inhibits the release of arachidonic acid and thus the formation of inflammation mediators such as prostaglandins and leukotrienes. The immunosuppressive action of glucocorticoids can be explained by inhibition of cytokine synthesis and an antimitotic effect, which so far is not well understood. Inhibition of the synthesis of vasodilating prostaglandins or potentiation of the vasoconstrictive effect of adrenaline finally result in the vasoconstrictive activity of glucocorticoids.

INDICATIONS:
Atopic dermatitis (endogenous eczema, neurodermatitis), contact eczema, degenerative, dyshidrotic, vulgar eczema, eczema in children.

DOSAGE & ADMINISTRATION:
Medroxin cream is for EXTERNAL TOPICAL USE ONLY and NOT FOR OPTHALMIC USE. In general, the Medroxin cream is applied thinly once per day to the diseased areas of skin. In general, the duration of use should not exceed 12 weeks in adults and 4 weeks in children.
As a low-fat formulation with a high water content, Medroxin cream is particularly suitable for acute and subacute weeping stages of eczema, for very greasy skin and for use on exposed or hairy parts of the body.

PHARMACOKINETICS:
Methylprednisolone aceponate (MPA) becomes available in the skin from all formulations (cream, ointment). The concentration in the stratum corneum and living skin decreases from outside to inside. Methylprednisolone aceponate is hydrolysed in the epidermis and dermis to the main metabolite 6α-methylprednisolone-17-propionate, which binds more firmly to the corticoid receptor – an indication of "bioactivation" in the skin. The degree of percutaneous absorption depends on the state of the skin, the formulation and the conditions of application (open/occlusion). Studies in juvenile and adult patients with neurodermatitis and psoriasis have shown that the percutaneous absorption on open application was only slightly (≤ 2.5%) greater than the percutaneous absorption in volunteers with normal skin (0.5–1.5%). When the horny layer is removed before the application, the corticoid levels in the skin are about three times higher than after application to intact skin. After reaching the systemic circulation, the primary hydrolysis product of MPA, 6αmethylprednisolone-17-propionate, is quickly conjugated with glucuronic acid and inactivated as a result. The metabolites of MPA (main metabolite: 6α - methylprednisolone-17-propionate-21-glucuronide) are eliminated primarily via the kidneys with a half-life of about 16 hours. Following intravenous administration, excretion of the ^{14}C-labeled substances with the urine and faeces was complete within 7 days. No accumulation of substance or metabolites takes place in the body.

PRECAUTIONS:
Care must be taken when using MEDROXIN to avoid contact with the eyes, deep open wounds and mucosae. Additional specific therapy is required in bacterially infected skin diseases and/or in fungal infections. Any spread of infection may require withdrawal of topical corticosteroid therapy. If the skin dries out excessively under protracted use of MEDROXIN cream, a switch should be made to ointment, a formulation which has a higher fat content. If signs of hypersensitivity develop, MEDROXIN should be discontinued and appropriate treatment instituted.
Any of the side effects that have been reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children. MEDROXIN is a potent steroid formulation, as with other corticosteroids of this type the possibility of hypothalamic-pituitary-adrenal (HPA) axis suppression resulting from percutaneous absorption of methylprednisolone must be considered when initiating or reviewing therapy. However, to date, no impairment of adrenocortical function has been observed when used on large areas (40–60% of the skin surface) or even occlusive treatment with MEDROXIN for up to 12 weeks in adults or 4 weeks in children. Nevertheless, for the treatment of large areas duration of use should be kept as brief as possible. Extensive application of topical corticosteroids to large areas of the body or for prolonged periods of time, in particular under occlusion, significantly increases the risk of systemic effects.
Note that nappies can be occlusive. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than adults because of a larger skin-surface-area to bodyweight ratio. Use of topical corticosteriods in children should be limited to the least amount required for therapeutic effect.
Chronic corticosteroid therapy may interfere with the growth and development of children. Local atrophy, telangiectasia and striae may occur after prolonged treatment or excessive application. Treatment should be discontinued if symptoms such as cutaneous atrophy occur. Prolonged use on flexures and in intertriginous areas is undesirable. MEDROXIN Cream should not be used around the eyes. The use of topical corticosteroids on the face can exacerbate rosacea and lead to peri-orofacial dermatitis. Patients should be warned against using MEDROXIN on the face except on medical advice and any use on the face should be restricted to short periods. As known from systemic corticoids, glaucoma may also develop from using local corticoids (e.g. after large doses or extensive application over a prolonged period, occlusive dressing techniques, or application to the skin around the eyes).

Pregnancy
There is no adequate data from the use of methylprednisolone aceponate in pregnant women. Animal experimental studies with methylprednisolone aceponate have shown embryonic and/or teratogenic effects (refer to the Preclinical safety data section). In general, the use of topical preparations containing corticoids should be avoided during the first trimester of pregnancy. In particular, treating large areas, prolonged use of occlusive dressing should be avoided during pregnancy.

Breastfeeding
It is not known if methylprednisolone aceponate is secreted in human milk; systemically administered corticosteroids have been reported to appear in human milk. It is not known whether topical administration of methylprednisolone could result in sufficient systemic absorption of methylprednisolone aceponate to produce detectable quantities in human milk. Therefore caution should be exercised when methylprednisolone is administered to a woman who is breastfeeding. Nursing mothers should not be treated on the breasts. Treating large areas, prolonged use or occlusive dressings should be avoided during lactation

SIDE EFFECTS:
General disorders and administration site reaction:
Application site burning, application site pruritus, application site dryness, application site erythema, application site vesicles, application site folliculitis, application site rash, application site paraesthesia, application site cellulitis, application site edema, application site irritation.
Immune system disorders: Drug hypersensitivity.
Skin and subcutaneous tissue disorders: Pyoderma, skin fissures, telangiectasia, skin atrophy, fungal skin infection, acne
As with other corticoids for topical application, the following local side effects may occur: skin atrophy, skin striae, application site folliculitis, hypertrichosis, telangiectasia, perioral dermatitis, skin discolorations, and allergic skin reactions to any of the ingredients of the formulations. Systemic effects due to absorption may occur when topical preparations containing corticoids are applied.

CONTRAINDICATIONS:
MEDROXIN is contraindicated in most viral diseases (e.g. vaccinia, varicella/herpes zoster) and when tuberculous or syphilitic processes and post-vaccination skin reactions are present in the area to be treated. If rosacea, acne vulgaris, atrophic skin diseases, or perioral dermatitis are present.
MEDROXIN must not be applied to the face.
Hypersensitivity to the active substance or to any of the excipients

STORAGE & INSTRUCTIONS:
Store between 15-25°C.
Protect from heat, sunlight and moisture. Do not freeze or refrigerate.
Keep away from the reach of the children.
To be sold on the prescription of a registered medical practitioner only.
FOR EXTERNAL USE ONLY.

HOW SUPPLIED:
Medroxin Cream: 5g, 10g

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:
دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ دھوپ، گرمی، نمی اور منجمد 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