HYDROCORTISONE ACETATE 1% Cream

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about HYDROCORTISONE ACETATE

HYDROCORTISONE ACETATE cream for topical administration contains 1% hydrocortisone acetate in a hydrophilic base with the following excipients: vaseline, emulsifying wax, paraffin oil, propylene glycol, methyl paraben, and propyl paraben.

Hydrocortisone is a topical corticosteroid sharing anti-inflammatory, anti-pruritic and vasoconstrictive actions. It is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Some of the conditions in which HYDROCORTISONE ACETATE cream is effective include:

- -Irritant contact dermatitis
- -Allergic contact dermatitis
- -Insect bite reactions
- -Mild to moderate eczema

HYDROCORTISONE ACETATE cream may be useful in the treatment of other dermatoses as well.

The way to use HYDROCORTISONE ACETATE

Use as directed by your physician. Do not discontinue the treatment without consulting your doctor. Apply the cream sparingly to a small area, once or twice a day, for a maximum of 7 days.

In case of overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. If you suspect an overdose, irritation develops, or if the cream has been ingested, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Apply the missed dose as soon as you remember unless the next application is near. Go on applying the next scheduled dose as directed. Do not apply a double dose at once.

Contraindications

This cream should not be used on the eyes or face, the ano-genital area or on broken or infected skin including impetigo, cold sores, acne or athlete's foot.

Precautions

- -Don't use this medication for any disorder other than for which it was prescribed or for longer than the prescribed time period.
- -The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by your doctor.
- -Ask your doctor about the use of this medicine in case of pregnancy or lactation.
- -Notify your doctor if the condition being treated gets worse. Report any signs of local adverse reactions.
- -Do not increase number of applications without consulting your doctor. More frequent applications may increase the risk of side effects without ameliorating the therapeutic effects.
- -Children may be more susceptible to topical corticosteroid-induced systemic toxicity than adults. Do not use for children under 10 years of age without medical advice.
- -Do not discontinue treatment abruptly after a long-term use.

Associations with other medications

Please inform your doctor if you are using any other medication. Do not put cosmetics or other skin products over the treated area unless directed by your physician. You should avoid preparations that may dry or irritate your skin. Other corticosteroid containing products should not be used with this cream without first talking to your doctor.

Adverse reactions

The following local adverse reactions have been reported with the use of topical corticosteroids: dryness, itching, burning, local irritation, striae, skin atrophy, atrophy of subcutaneous tissues,

telangiectasia, hypertrichosis, change in pigmentation, pustules, miliaria, folliculitis, pyoderma, contact sensitivity and secondary infection.

It should be noted that infection can be masked by the anti-inflammatory action of topical corticosteroids.

If applied to the face, acne rosacea or perioral dermatitis can occur. Adrenal suppression has also been reported following topical corticosteroid therapy.

Conditions that may increase systemic absorption include use over a prolonged period of time, use over a large surface area and use with an occlusive dressing.

Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack presentation

Hydrocortisone acetate 1% cream, tube of 15 grams

Revision date: 07/2015

HYDR1/002

Manufactured by Mediphar Laboratories -Lebanon