HYDROCORTISONE ACETATE

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
HYDROCORTISONE ACETATE cream is a topical preparation containing hydrocortisone acetate 1% in a hydrophilic base. 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:
- Temporary relief of itching associated with minor skin irritations
- Inflammation and rashes due to eczema
- Insect bites
- Skin irritations associated with poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics or jewelry.
- Seborrhoeic dermatitis
- Psoriasis
- External genital and anal itching
- Contact dermatitis and atopic dermatitis
- Lichen planus and lichen simplex chronicus
- Discoid lupus erythematosus
- First- and second-degree localized burns and sunburns
- Severe diaper rash
- Dyshidrosis

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

The way to use HYDROCORTISONE
Use as directed by your physician. Do not discontinue the treatment without consulting your doctor. HYDROCORTISONE ACETATE cream is generally applied to the affected area as a thin film 2 to 3 times daily depending on the severity of the condition. With continuous use, your doctor may recommend to reduce the number of applications.

Application
Apply the cream sparingly in a light film; rub in gently. Washing or soaking the area before application may increase drug penetration.

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 hydrocortisone topical 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 drug should not be used in case of hypersensitivity to any of the components.

Precautions
- This medication is for external use only. Avoid contact with the eyes.
- Don't use this medication for any disorder other than for which it was prescribed.
- 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. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

- Do not discontinue treatment abruptly after a long-term use.
- Notify your doctor if the condition being treated gets worse, or if burning, swelling or redness develops. Report any signs of local adverse reactions.
- Do not increase the dose 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. Use only as recommended by your doctor.
- Do not use tight-fitting diapers on a child being treated in the diaper area, as it may constitute an occlusive dressing.

**Association 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.

**Side effects**

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, secondary infection or skin atrophy.

The risk of adverse reactions may be minimized by reducing the dosage or using intermittent therapy.

The use over large surface areas, prolonged use and the addition of occlusive dressings increase systemic absorption of topical corticosteroids and the risk of systemic side effects.

**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

**Issue date: 5/2004**