PATIENT INFORMATION LEAFLET (PIL)

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

TRIAMCINOLONE 0.1%w/w CREAM

Triamcinolone

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. WHAT TRIAMCINOLONE CREAM IS AND WHAT IT IS USED FOR

Triamcinolone belongs to a group of medicines called topical corticosteroids which are used for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

2. BEFORE YOU USE TRIAMCINOLONE CREAM

Do not use TRIAMCINOLONE CREAM
- if you are allergic (hypersensitive) to the active substance or any of the other ingredients of TRIAMCINOLONE CREAM.

PRECAUTIONS

General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug.

Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Pediatric patients may absorb proportionally larger amounts of topical corticosteroids and thus, be more susceptible to systemic toxicity (See PRECAUTIONS-Pediatric use).

If irritation develops, topical corticosteroids should be discontinued, and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient

Patients using topical corticosteroids should receive the following information and instructions:
- This medication is to be used as directed by the physician. It is for external use only. Avoid contact
- with the eyes.
- Patients should be advised not to 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 the physician.
- Patients should report any signs of local adverse reactions especially under occlusive dressing.
- Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Carcinogenesis, Mutagenesis, and Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.
Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy and breast-feeding
Ask your health care provider for advice before taking any medicine.

Pregnancy Category C
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

3. HOW TO USE TRIAMCINOLONE CREAM

Always use Triamcinolone Cream exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

The usual dose is to apply the cream to the affected area as a thin film from two or three times daily depending on the severity of the condition.
Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.
If an infection develops, the use of occlusive dressings should be discontinued, and appropriate antimicrobial therapy instituted.

If you use more TRIAMCINOLONE CREAM than you should
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. (See PRECAUTIONS)

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Triamcinolone Cream can cause side effects, although not everybody gets them.

The following local effects are reported infrequently with topical corticosteroids but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRIAMCINOLONE CREAM

Keep all medicines out of the reach of children.
Do not use this medicine after the expiry date which is stated on the carton after 'Exp. Date' used for expiry date. The expiry date refers to the last day of that month.
Store below 30°C, in a dry place.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What TRIAMCINOLONE CREAM contains:

- The active pharmaceutical ingredient is Triamcinolone.

What TRIAMCINOLONE CREAM looks like and contents of the pack:
25g cream in a tube, placed in a carton with insert.

Supplier and Manufacturer
Fidson Healthcare Plc,
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	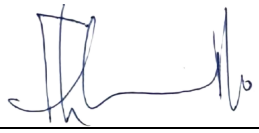	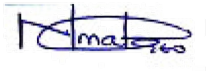
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Regulatory	**HoM**	**HQRA**