Fluticasone Propionate (Topical)

Proposed Core Safety Profile (CSP)

For the PSUR Worksharing Scheme
4.3. Contraindications

Rosacea.
Acne vulgaris.
Perioral dermatitis.
Primary cutaneous viral infections (e.g., herpes simplex, chickenpox).
Hypersensitivity to any of the ingredients.
Perianal and genital pruritus.

The use of fluticasone propionate cream, ointment and emulsion is not indicated in the treatment of primary infected skin lesions caused by infection with fungi or bacteria.

Dermatoses in infants under three months of age, including dermatitis and napkin eruptions.

4.4. Special warnings and precautions for use

Prolonged application of high doses to large areas of body surface, especially in infants and small children, might lead to adrenal suppression. Children and infants have a greater surface area to body weight ratio compared with adults. Therefore, in comparison with adults, children and infants may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. Care should be taken when using fluticasone propionate cream, ointment and emulsion to ensure the amount applied is the minimum that provides therapeutic benefit.

The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye so as to avoid the risk of local irritation or glaucoma.

Topical steroids may be hazardous in psoriasis for a number of reasons, including rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents.

Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressing, and so the skin should be cleansed before a fresh dressing is applied.
Cream and Ointment:

Overt suppression of the HPA-axis (morning plasma cortisol less than 5 micrograms/dL) is very unlikely to result from therapeutic use of fluticasone propionate Cream or Ointment unless treating more than 50% of an adult's body surface and applying more than 20 g per day for up to 3 weeks.

Cream and Emulsion:

Fluticasone propionate cream and emulsion may contain the excipient imidurea which releases traces of formaldehyde as a breakdown product.

Formaldehyde may cause allergic sensitization or irritation upon contact with the skin.

4.5. Interactions with other medicinal products and other forms of interaction

None reported

4.6. Pregnancy and Lactation

Pregnancy

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established; however, administration of fluticasone propionate during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Lactation

The excretion of fluticasone propionate into human breast milk has not been investigated. When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration there was evidence of fluticasone propionate in the milk. However plasma levels in patients following dermal application of fluticasone propionate at recommended doses are likely to be low.

4.7. Ability to perform tasks that require judgement, motor or cognitive skills

None reported.

4.8. Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. The background rates in placebo and comparator groups were not taken into account when assigning frequency categories to adverse events derived from clinical trial data, since these rates were generally comparable to those in the active treatment group. Rare and very rare events were generally derived from spontaneous data.
Infections and infestations

Very rare: Secondary infection.

Secondary infection, particularly when occlusive dressings are used or when skin folds are involved have been reported with corticosteroid use.

Immune system disorders

Very rare: Hypersensitivity.
If signs of hypersensitivity appear, application should stop immediately.

Endocrine disorders

Very rare: Features of hypercortisolism.

Prolonged use of large amounts of corticosteroids, or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercortisolism. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the napkin may act as an occlusive dressing (see Warnings and Precautions).

Vascular disorders

Very rare: Dilation of superficial blood vessels.

Prolonged and intensive treatment with potent corticosteroid preparations may cause dilation of the superficial blood vessels.

Skin and subcutaneous tissue disorders

Cream and Ointment:

Common: Pruritus.

Uncommon: Local burning.

Emulsion:

Common: Local burning

Uncommon: Pruritus.

Cream, Ointment and Emulsion:

Very rare: Thinning, striae, hypertrichosis, hypopigmentation, allergic contact dermatitis, exacerbation of dermatoses, pustular psoriasis.

Local burning and pruritus have been reported, however in clinical trials the incidence of these adverse reactions was generally comparable to placebo and comparator groups.

Prolonged and intensive treatment with potent corticosteroid preparations may cause local atrophic
changes in the skin such as thinning, striae, hypertrichosis and hypopigmentation.

Exacerbation of the signs and symptoms of the dermatoses and allergic contact dermatitis have been reported with corticosteroid use.

Treatment of psoriasis with a corticosteroid (or its withdrawal) may provoke the pustular form of the disease.

4.9. Overdose Symptoms and Signs

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may appear.

Treatment

In this situation topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency.