SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fluticasone propionate 0.05% cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g of cream contains:

Fluticasone propionate 0.05g.

Excipients with known effect:
Cetostearyl alcohol 5.25 g
Imidurea 0.20 g
Propylene glycol (E-1520) 10.00 g
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream.

White, viscous and homogeneous cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For adults and children aged 1 year and over:

Fluticasone propionate is indicated for symptomatic treatment of inflammatory dermatoses not caused by micro-organisms and responsive to corticosteroids such as:

- Eczema including atopic and discoid eczemas
- Psoriasis (excluding widespread plaque psoriasis)
- Lichen planus
- Lichen

- Contact sensitivity reactions
- Discoid lupus erythematosus
- As adjunct to systemic steroid therapy in generalised erythroderma

Children
For children aged 1 year and over who are unresponsive to lower potency corticosteroids, this medicine is indicated for the relief of the inflammatory and pruritic manifestations of atopic dermatitis under the supervision of a specialist. Expert opinion should be sought prior to the use of this medicine in other corticosteroid responsive dermatoses in children.

Children
For children aged 1 year and over who are unresponsive to lower potency corticosteroids, this medicine is indicated for the relief of the inflammatory and pruritic manifestations of atopic dermatitis under the supervision of a specialist.

4.2 Posology and method of administration

For topical administration.
For adults and children aged 1 year and over, apply a thin film of fluticasone cream to the affected skin areas one to twice daily (see 4.4).

Duration of use:
Daily treatment should be continued until adequate control of the condition is achieved.

Frequency of application should thereafter be reduced to the lowest effective dose.

When fluticasone cream is used in the treatment of children, if there is no improvement within 7 – 14 days, treatment should be withdrawn and the child re-evaluated. Once the condition has been controlled (usually within 7-14 days) frequency of application should be reduced to the lowest effective dose for the shortest possible time. Continuous daily treatment for longer than 4 weeks is not recommended.

An increase in the number of daily applications might aggravate side effects without improving the therapeutic effects.

Method of administration:
In adults and children, use the method of finger-tip unit to specify the quantity of cream applied to a given surface. The finger-tip unit corresponds to the amount of cream applied from the distal skin-crease to the tip of the index finger. This quantity permits to treat a skin surface corresponding to 2 hands

of an adult (approximately 250 to 300 cm^2). A finger-tip unit corresponds to approx. 0.5g of product. A tube of 30 grams contains 60 finger-tip unities.

4.3 Contraindications

- Rosacea.
- Acne vulgaris.
- Perioral dermatitis.
- Primary cutaneous viral infections (e.g.: herpes simplex, chickenpox).
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Perianal and genital pruritus.
- Ulceration of the skin
- Atrophy of the skin
- Fragile skin vessels
- Ichthyosis
- Juvenile dermatosis
- Dermatoses in infants under 1 year of age, including dermatitis and napkin eruptions
- Injuries ulcerated
- The use of fluticasone cream is not indicated in the treatment of primary infected skin lesions caused by infection with fungi or bacteria.

4.4 Special warnings and precautions for use

The label will state strong steroid.

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. This effect is more likely to occur in infants and children if occlusive dressings are used. In infants, the napkin may act as an occlusive dressing. Care should be taken when using fluticasone cream 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.

The prolonged use of corticosteroids on the face may cause steroid-induced dermatitis.

These incidents disappear at withdrawal of treatment, but a sudden withdrawal may be followed by an acute adrenal insufficiency.

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 unless treating more than 50% of an adult's body surface and applying more than 20g per day.

Long-term continuous use should be avoided in children. The safety and efficacy of fluticasone propionate when used continuously for more than 4 weeks has not been established.

If signs of hypersensitivity appear, application should stop immediately.

The safety and efficacy in paediatric patients below 1 year of age have not been established.

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.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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 and referral to a dermatologist is required before using Fluticasone to treat psoriasis in children.

Topical steroid withdrawal syndrome

Long term use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and

specialist advise is recommended in these cases or other treatment options should be considered.

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.

Contains cetostearyl alcohol, which may cause local skin reactions (e.g.: contact dermatitis).

Contains imidurea which releases traces of formaldehyde as a breakdown product. Formaldehyde may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 100 mg propylene glycol in 1 gram of cream.

Fire hazard

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, 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 Effects on ability to drive and use machines

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 (≥ 1/1,000 and < 1/100), rare (≥ 1/10,000 and < 1/1,000) very rare (< 1/10,000, including isolated reports) and not known (cannot be estimated from the available data). 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 infections (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 Special Warnings and precautions for use).

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.

Eye disorders

Not known: Vision, blurred (see section 4.4)

Skin and subcutaneous tissue disorders

Common: pruritus

Uncommon: local burning

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

Not known: Vascular purpura, skin fragility, peri-oral dermatitis, rosacea, scab, leg ulcer, acne, impaired healing.

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.

Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D07AC17

Fluticasone propionate as a glucocorticoid has anti-inflammatory and vasoconstrictive features. Applied topically on the skin it suppresses inflammatory reactions and symptoms although without curing the underlying disorder. Systemic absorption through the subcutaneous tissues is low.

Fluticasone Propionate is classed as a potent corticosteroid.

5.2 Pharmacokinetic properties

Pharmacokinetic data for the rat and the dog indicate rapid elimination and extensive metabolic clearance. Bioavailability is very low after topical or oral administration, due to limited absorption through the skin or from the gastrointestinal tract, and because of extensive first-pass metabolism. Distribution studies have shown that only minute traces of orally administered compound reach the systemic circulation, and that any systemically available radiolabel is rapidly eliminated in the bile and excreted in the faeces.

Fluticasone propionate does not persist in any tissue, and does not bind to melanin. The major route of metabolism is hydrolysis of the S-fluoromethyl carbothioate group, to yield a carboxylic acid (GR36264), which has very weak glucocorticoid or anti-inflammatory activity. In all test animal species, the route of excretion of radioactivity is independent of the route of administration of radiolabelled fluticasone propionate.

Excretion is predominantly faecal and is essentially complete within 48 hours.

In man, too, metabolic clearance is extensive, and elimination is consequently rapid.

Thus drug entering the system circulation via the skin will be rapidly inactivated. Oral bioavailability approaches zero, due to poor absorption and extensive first-pass metabolism. Therefore systemic exposure to any ingestion of the topical formulation will be low.

5.3 Preclinical safety data

Non-clinical studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, fertility and general reproductive performance revealed no special hazard for humans, other than that anticipated for a potent steroid.

Reproductive studies suggest that subcutaneous administration of fluticasone propionate to pregnant animals at doses much higher that the human topical dose can result in abnormalities of foetal development including cleft palate/lip.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol Cetostearyl Ether
Cetostearyl Alcohol
Isopropyl Myristate
Paraffinum Liquidum
Purified Water
Propylene Glycol (E-1520)
Citric Acid Monohydrate
Disodium Phosphate Anhydrous
Imidazolinyl Urea

6.2 Incompatibilities

None reported.

6.3 Shelf life

3 years.

Shelf life after first opening: 6 months

6.4 Special precautions for storage

Do not store above 30ºC

6.5 Nature and contents of container

30 g of cream contained in an aluminium tube with white high-density polypropylene screw cap.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Aspire Pharma Ltd
Unit 4 Rotherbrook Court
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Hampshire
GU32 3QG
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 35533/0205

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/10/2012

10 DATE OF REVISION OF THE TEXT

22/07/2024