PACKAGE LEAFLET: INFORMATION FOR THE USER

Flutarzole®
0,05% w/w cream, Fluticasone propionate

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Flutarzole®

1.2. Composition

Active substance: Fluticasone propionate.
Excipients: Paraffin liquid, Isopropyl myristate, Cetostearyl alcohol, Cetomacrogol 1000, Propylene glycol, Imidurea, Sodium phosphate, Citric acid monohydrate, Water purified.

1.3. Pharmaceutical form

Cream.

1.4. Quantitative composition

Each g of cream contains 0,5 mg of fluticasone propionate (0,05% w/w).

1.5. Nature and contents of the container

Each carton contains one tube of 30 g cream and a leaflet.

1.6. Pharmacotherapeutic category

Topical corticosteroid

1.7. Marketing Authorization Holder

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1.8. Manufacturer

Pharmaceutical Industry PROEL Epam. G. Koronis S.A.

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1. General information

Flutarzole® cream is indication for the relief of inflammatory and itchy skin conditions that respond to corticosteroids.

2.2. Indications

Treatment of inflammatory skin conditions:
Flutarzole® cream is indicated for adults, children and infants older than 3 months, that do not respond to less potent corticosteroids for the relief of inflammatory and itchy skin conditions that respond to corticosteroids, such as:
- Eczema including atopic, children and nummular (discoid) eczema
- prurigo nobularis
- Psoriasis (excluding widespread plaque psoriasis)
- Neurodermatitis including lichen simplex chronicus
- Lichen planus
- Seborrheic dermatitis
- Irritant or allergic contact dermatitis
- Discoid lupus erythematosus
- An adjunct to systemic steroid therapy in generalised erythroderma
- Insect bite reactions
- Miliaria

Reduction of recurrence risk for chronic recurrent atopic eczema:
Flutarzole® cream is indicated for the reduction of the risk of recurrence for chronic recurrent atopic eczema, once an acute episode is effectively cured.

2.3. Contraindications

Hypersensitivity to any of the excipients of the product
Rosacea
Acne vulgaris
Perioral dermatitis
Primary dermal infectious diseases (e.g., simple herpes, varicella)
Perianal and genital itching
The use of dermatological preparations that contain fluticasone propionate is not indicated for the treatment of primary infectious skin lesions caused by fungal or bacterial infections and dermatosis for infants younger than three months, including dermatitis and rushes from diapers.
Topical corticosteroids should not be used in cases of undiagnosed dermatopathy. Also, use should be avoided on ulcers and burns because they may prevent healing.

2.4. Special warnings and precautions for use

2.4.1. General

Due to possible adverse events from potential absorption, caution is needed when applied to large areas of skin or in prolonged administration, especially in children, patients with severe renal impairment, prone to hemorrhage and in imminent vaccinations.
Prolonged treatment of large quantities or extensive use in large areas of the skin should be avoided especially in infants and young children this may lead to suppression of adrenal function. Children and infants have a larger ratio of skin surface versus body weight comparing to adults and children can respectively absorb larger quantities of topical corticosteroids and will therefore be more susceptible to systemic toxicity.
When applied **Flutarzole®** cream the minimum quantity that will have therapeutic result should be used.

Do not use topical corticosteroids beyond three weeks without a re-evaluation from a specialist.
After repeated application for at least 10-15 days, temporary deduction or loss of efficacy of the corticosteroid may occur due to tachyphylaxis. This phenomenon is restored after a few days or week of discontinuation.
The skin of the face is more susceptible than the skin in other body parts to show atrophies after prolonged treatment with high potency topical corticosteroids. This should be taken into account when treating dermatoses such as psoriasis, discoid lupus erythematous and severe eczema.
When occlusive dressing is applied, thorough skin cleaning should be recommended to prevent possible infection.
It may cause cataract or glaucoma when used near the eye bulb for extensive time.
Caution is needed if the product will be used on the eye lids not to get inside the eye in order to avoid the risk of local irritation or glaucoma.
Topical steroids may be dangerous in psoriasis for some reasons that include possible relapse when the treatment is discontinued, development of tolerance to the treatment, the risk of generalized pustular psoriasis and the occurrence of local or systemic toxicity due to deterioration of the function of skin barrier. If the product will be used in psoriasis, it is important to get close supervision by a specialist.
When treating inflamed lesion that are infected, the proper antimicrobial therapy should also be used. Any extension of the infection requires discontinuation of the topical corticotherapy and systemic administration of antimicrobial drugs.
Bacterial infection is more susceptible to a warm and humid environment which can be created with occlusive dressing. For this reason the skin should be thoroughly cleaned before a new occlusive dressing is applied.

2.4.2. Elderly

See section 2.3 “Contraindications” and section 2.4 “Special warnings and precautions for use”.

2.4.3. Pregnancy

Fluticasone propionate may be administered during pregnancy only if the expected benefit justifies the potential risk to the fetus. In such a case it should not be administered in large quantities or for a long time.

2.4.4. Lactation

When the use of corticosteroids during breast-feeding is considered necessary by the physician, the amount of the drug and the duration of treatment should be kept minimum.

2.4.5. Children

Only for children and infants older than three months, who do not respond to less potent corticosteroids. (See also section 2.3 “Contraindications” and section 2.4 “Special warnings and precautions for use”).

2.4.6. Effect on the ability to drive and use of machines

None known.

2.4.7. Special warnings about the excipients

Flutarzole® cream contains imidurea as an excipient, which releases traces of formaldehyde as degradation product. Formaldehyde may cause allergic sensitization on the skin or skin irritation at contact.

2.5. Interactions with other medicines or substances

None known.

2.6. Posology – Method of application

Treatment of inflammatory dermotopathies:
For adults, children and infants older than 3 months: apply a small amount of cream on the affected area once or twice daily (see also section "2.4 Special warnings and precaution for use")

Reduction of recurrence risk for chronic recurrent atopic eczema:
Once an acute episode has been treated effectively, the application rate should be reduced to once daily, twice per week without overlapping.
The application should be continued in all areas previously affected or in areas known to be recurring. This practice should be combined with the daily use of soothing products. The condition should be re-evaluated frequently (see section 2.4)

2.7. Overdose – Management

Acute overdose is not possible to occur, nevertheless in cases of prolonged overdose or misuse, characteristics of hypercorticosteroidism may occur as with other corticosteroids (class effect) and in such cases the treatments should be gradually discontinued. However, due to the risk of acute adrenal suppression, this should be done under medical supervision.

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2.8. Possible side effects

Adverse events are listed below by system organ class and by frequency. Frequencies are defined as follows: Very common (>1/10), common (>1/100, 1<10), uncommon (>1/1.000, <1/100), rare (>1/10.000, <1/1.000), and very rare (<1/10.000) including isolated reports.

Infections and infestations
Very rare: Secondary infection,
Secondary infection has been reported with the use of corticosteroids, especially when occlusive dressing is applied or in skin folds.

Immune system disorders
Very rare: Hypersensitivity.
In case hypersensitivity symptoms occur treatment should be immediately discontinued.

Endocrine disorders
Very rare: Hypercorticosteroidism symptoms.
Prolonged use of large quantities of corticosteroids or treatment of extensive skin areas may cause adequate systemic absorption and present hypercorticosteroidism signs and symptoms.
This effect is most likely to occur in infants and children and if occlusive dressing applied. In infants and babies, diapers can act as occlusive dressing (see section 2.4)

Vascular disorders
Very rare: Dilation of superficial blood vessels.
Prolonged and intensive treatment with potent corticosteroid preparations may cause dilation of superficial blood vessels.

Skin and subcutaneous tissue disorders
Common: pruritus.
Uncommon: local burning.
Very rare: Skin thinning, striae, hypertrichosis, pigmentation changes, allergic contact dermatitis, exacerbation of underlying symptoms, pustular psoriasis.

In clinical trials, local burning and pruritus have been reported in frequencies comparable to those reported for the placebo or the reference medicine.
Prolonged and intense treatment with high potency corticosteroid preparations, may cause skin atrophy disorders such as thinning, striae, hypertrichosis, pigmentation changes.
Exacerbation of signs and symptoms of dermatopathy and allergic contact dermatitis have been reported with the use of corticosteroids.
Treatment of psoriasis with corticosteroids (or discontinuation of treatment) may cause pustular form of the disease.

2.9 What you should know in case you forget to take one dose

If you should use this medicine for long time and you forget a dose, you should receive it as soon as you remember. If it is about the time for your next dose, do not take the missed dose, continue your treatment plan.
Do not take double dose.

2.10 What should the patient know about the expiration date

Expiration date is mentioned in outer and immediate container.
Do not use after the expiration date.

2.11 Special warnings about the storage of the product

Store below 25ºC.

2.12 Date of last revision of this leaflet

15 April 2011.

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment with this medicine you experience any problem or issue, contact immediately your doctor or pharmacist.
- If you have any questions regarding the information for this product, its use or about the medical condition that you suffer, you should ask your doctor or pharmacist.
- This product will be safe and effective if it is used exactly according to instructions provided.
- For your own safety it is highly recommended that you read carefully all information provided for the prescribed medicine.
- Do not store medicines in bathroom lockers, as the high temperature and the humidity may degrade the product which may be harmful to your health.
- Store the product in the original packaging.
- If your doctor instructed you to stop the use of this product, dispose the remaining product and do not use it.
- Do not keep the medicine you do not need any more or those that are expired.
- Keep all medicines in safe place out of reach and sight of children.

4. PRESCRIBING INFORMATION

This medicine is subjected to medicinal prescription.