1. Name of the medicinal product

Clobetasol Propionate Cream 25g

Cream (Semisolid)

2. Qualitative and quantitative composition

Each gram of cream contains Clobetasol Propionate 0.05%$^{w}/_{w}$

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Cream (Semisolid)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Clobetasol Propionate is a very potent topical corticosteroid. Topical Corticosteroids are also referred to as topical steroids. It helps to reduce swelling and irritation.
Clobetasol Propionate cream is used to help reduce the redness and itchiness of certain skin problems. These skin problems include:

- Frequently relapsing eczema
- Psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales), excluding widespread plaque psoriasis
- Discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp causing scaring and increased sensitivity of the affected skin to sunlight)
- Dermatitis and other skin conditions that have not responded to milder steroid creams or ointments.

4.2 Posology and method of administration

Posology

Clobetasol Propionate Cream, USP 0.05% is a super-high potency corticosteroid formulation indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. Clinical Clobetasol propionate belongs to the most potent class of topical corticosteroids (Group IV) and prolonged use may result in serious undesirable effects. If treatment with a local corticosteroid is clinically justified beyond 4 weeks, a less potent corticosteroid preparation should be considered.

Repeated but short courses of clobetasol propionate may be used to control exacerbations. Creams are especially appropriate for moist or weeping surfaces.

Method of Administration

Topical

Creams are especially appropriate for moist or weeping surfaces, it should be applied topically.

Apply a small amount of cream to the areas of skin which are inflamed. Then gently rub it into the skin until it has disappeared. If you are using this preparation, use it regularly twice daily for one week only, unless you have been directed otherwise by your doctor.

The amount of topical steroid cream that you should apply is commonly measured by fingertip units (FTUs). One FTU is the amount of cream that is squeezed out along an adult's fingertip (that is, from the very end of the finger to the first crease in the finger). As a guide, one FTU is enough to cover an area twice the size of an adult hand. Your doctor or pharmacist will give an idea of how many FTUs you will need to cover the area of your skin which is affected.

Do not use for more than 4weeks without talking to your doctor. If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment. After you have applied Clobetasol propionate, remember to wash your hands (Unless your hands are the treated area).

Use in Children

Do not use this medicine on children under 1year of age.

- It is especially important in children not to exceed the prescribed amount
- A course of treatment for a child over the age of 1 year should not normally last more than 5days unless your doctor has told you to use it for longer. Your doctor may want to see the child every week, whilst using the cream.
- Dressing or bandages should not be used on children where the cream is applied.

4.3 Contraindications

Clobetasol is contraindicated in dermatoses in children under one year of age, including dermatitis and nappy eruptions.

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

The following conditions should not be treated with Clobetasol Propionate: Untreated cutaneous infections, Rosacea, Acne vulgaris, Pruritus without inflammation, Perianal and genital pruritus, Perioral dermatitis.

4.4 Special warnings and precautions for use

Talk to your doctor or pharmacist before using Clobetasol Cream If:

- You experience newly developed bone pain or worsening of previous bone symptoms during a treatment with Clobetasol Cream especially if you have been using Clobetasol cream for a prolonged time or repeatedly.
- You use other oral/topical medication(s) containing corticosteroids or medication intended to control your immune system (e.g. for autoimmune disease or after a transplantation). Combining Clobetasol with these medicines may result in serious infections
- You have previously had an allergic reaction with another steroid.
- You are applying the cream on broken or damaged skin or within skin folds.
- You are applying to a large surface area.
- You have psoriasis, your doctor will want to see you more often
- You are using around a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- You are applying near eyes or eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye.
- You are applying to thin skin such as the face, as Clobetasol Cream may cause skin thinning.
  Use on the face should be limited to 5days.
  Dressings or bandages should not be used on the face where the cream is applied.
  Contact your doctor if you experience blurred vision or other visual disturbances.
  If an infection develops during the use of this medicine, talk to your doctor or pharmacist.
  If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

  Children
- Do not use this medicine in children under 1year of age.
- Avoid continuous treatment for a long period of time in infants and children over 1year of age, as their skin is thinner than adults and as a result may absorb larger amounts.
- Use on children should be limited to 5days and reviewed weekly
- Dressings or bandages should not be used on children where the cream is applied.

Clobetasol Propionate Cream contains:

Cetostearyl alcohol and propylene glycol.

Propylene glycol may cause skin irritation. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis)

The Active substance is Clobetasol Propionate

The other ingredients are Cetomacrogol 1000, Cetostearyl alcohol, Glyceryl monostearate, Liquid paraffin (Heavy), Propylene glycol, Benzyl Alcohol, Citric acid, Sodium citrate and purified water.

Paediatric population

In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur. Children are more susceptible to develop atrophic changes with the use of topical corticosteroids.

Duration of treatment for children and infants

Courses should be limited if possible to five days and reviewed weekly. Occlusion should not be used.

Infection risk with occlusion

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Use in Psoriasis

Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalized pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

Concomitant infection

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 administration of appropriate antimicrobial therapy.

Application to the face

Application to the face is undesirable as this area is more susceptible to atrophic changes.

If used on the face, treatment should be limited to 5 days.

Application to the eyelids

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataract and glaucoma might result from repeated exposure. If clobetasol does enter the eye, the affected eye should be bathed in copious amounts of water.

Visual disturbance

Visual disturbance has been 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.

Clobetasol cream contains paraffin. Instruct patients not to smoke or go near naked flames due to the 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole.

4.6 Fertility, pregnancy and lactation

Pregnancy

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breast-feeding

If you do use clobetasol cream when breast feeding, do not use it on your breast area to ensure that the baby does not accidentally take clobetasol cream in their mouth.

The safe use of topical corticosteroids during lactation has not been established.

Fertility

There are no data in humans to evaluate the effect of topical corticosteroids on fertility

Clobetasol administered subcutaneously to rats had no effect upon mating performance; however, fertility was decreased at the highest dose (see section 5.3).

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of clobetasol on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical clobetasol.

4.8 Undesirable effects

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class are very rare: Infections and infestation (oppourtunistic infection), Immune System Disorders (Hypersensitivity, generalized rash), Endocrine Disorders, Skin and subcutaneous tissue disorders (Common: Pruritus, local skin burning/skin pain; uncommon: skin atrophy, striae; Very rare: Skin thinning, skin wrinkling, skin dryness, pigmentation changes).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the risk/benefit balance of the medicinal product.

4.9 Overdose

If you apply too much or if accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible. Topically applied clobetasol may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic over dosage or misuse the features of hypercortisolism may occur (see section 4.8) In the event of overdose, clobetasol should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical Corticosteroid Group IV, **ATC code:** D07AD01

Mechanism of action

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

5.2 Pharmacokinetic properties

Absorption

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Mean peak plasma clobetasol propionate concentrations of 0.63 mg/ml occurred in one study eight hours after the second application (13 hours after an initial application) of 25g clobetasol propionate 0.05% cream to normal individuals with healthy skin. Following the application of a second dose of 25g clobetasol propionate cream 0.05% mean peak plasma concentrations were slightly higher than the ointment and occurred 10 hours after application.

Distribution

The use of Pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolized, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

The active ingredient of Clobetasol Propionate Cream is a well-known constituent of medicinal products and its safety is well documented. The results of pre- clinical studies do not add anything of relevance for therapeutic purposes.

6. Pharmaceutical particulars

6.1 List of excipients

Clobetasol Propionate
Cetomacrogol 1000
Cetostearyl alcohol
Glyceryl monostearate
Liquid Paraffin (Heavy)
Propylene glycol
Benzyl Alcohol
Citric Acid (monohydrate)
Sodium Citrate (Trisodium citrate dihydrate)
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture.

6.5 Nature and contents of container

Collapsible Aluminium tube with a screw cap

Pack size: 25g

6.6 Special precautions for disposal and other handling

Patients should be advised to wash their hands after applying Clobetasol Propionate Cream unless it is the hands that are being treated.

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

7.0 APPLICANT/MANUFACTURER

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