SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

Brand name: Aksocort

Product name: Hydrocortisone Cream

Strength: 10mg

Pharmaceutical: Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration, The active substance should be declared by its recommended INN. Accompanied by itssalt or hydrate form if relevant

Hydrocortisone

Quantitative Declaration, The quantity of the active substance must be expressed per dosage unit.

Each gram contains Hydrocortisone 10mg

3. PHARMACEUTICAL FORM

White cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Hydrocortisone Cream is used for reducing itching, redness, and swelling associated with many skin conditions.

4.2 Posology/Dosage and method of administration

FOR EXTERNAL USE ONLY.

For itching of skin irritation and rashes: adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.

For external anal and genital itching: adult: When practical, clean the affected area with mild soap and water and rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before applying. Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: ask a doctor.

4.3 Contraindication

Do not use if allergic to any ingredient in hydrocortisone cream.

4.4 Special warnings and precautions for use

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 so 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.

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.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity.

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.

4.5 Interaction with other drug products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

There is no evidence against use in lactating women. However, caution should be exercised when Hydrocortisone Cream is administered to nursing mothers. In this event, the product should not be applied to the chest area.

4.7 Effects on ability to drive and use machines

Hydrocortisone Cream has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following local side 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 and miliaria.

4.9 Overdose

Symptoms may include Skin irritation, rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth etc. It may be harmful if swallowed. Contact your doctor, or emergency room immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction in the vascular component of the inflammatory response and reduction in the formation of inflammatory fluid and cellular exudates. The granulation reaction is also decreased due to the inhibition effect of Hydrocortisone on connective tissue. Stabilisation of most cell granules and lysomal membranes decreases the mediators involved in inflammatory response and reduces release of enzymes in prostaglandin synthesis. The vasoconstrictor action of Hydrocortisone may also contribute to its anti-inflammatory activity.

5.2 Pharmacokinetic properties

Absorption: Topically applied steroids are absorbed to a significant extent only if applied to broken skin, to very large areas, or under occlusive dressings.

Distribution: Corticosteroids are rapidly distributed to all body tissues. They cross the placenta and may be excreted in small amounts in breast milk

Metabolism: Hydrocortisone is etabolized mainly in the liver, but also the kidney, to various degraded and hydrogenated forms such as tetra hydrocortisone.

Elimination: Hydrocortisone is excreted in the urine, mostly conjugated as glucuronides. Only very small amounts of unchanged hydrocortisone are excreted.

5.3 Preclinical safety data

Adverse effects of Hydrocortisone are due to its effects on electrolyte balance, metabolism and particularly adrenal suppression. Topical use of Hydrocortisone has only rarely been associated with systemic side effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glyceryl Monostearate, Cetyl Alcohol, White soft paraffin, Liquid Paraffin, Span60, Polyaorbate 60, Methylparaben, Propylparaben, Edetate Disodium, Propylene Glycol, Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C in dry place away from sunlight.

Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Collapsible aluminum tube having a screw threaded neck finish sealed with an aluminum membrane. Each tube is supplied with a white polyethylene screw cap which has a piercing tip to puncture open the aluminum membrane on the neck.

Pack size: 20g

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE F PRODUCT REGISTRATION

Applicant: AKSO PHARMACEUTICAL NIGERIA LIMITED..

Adress: No. 320, Odusami Street, off Wempco Road, Ogba , Lagos Nigeria

E-mail: 506798052@qq.com

Contact person : Brian Fu

Tel: 09118269061

8. DRUG PRODUCT MANUFACTURER

Manufacturer name: FRONT PHARMACEUTICAL PLC

Physical address: No.369 Baocheng Road, Xuancheng Economic and Technical Development Zone, Anhui, China
Tel: 86-0563-2625199
Fax: 86-0563-2625199
E-mail: export@frontpharm.com

9. NAFDAC REGISTRATION NUMBER(S)