SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

Brand name: MORORATE

Product name: Mometasone Furoate Cream

Strength: 1mg

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

Mometasone Furoate

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

Each gram contains Mometasone Furoate 1mg

3. PHARMACEUTICAL FORM

White cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mometasone Furoate Cream is a medium potency corticosteroid indicated for the treatment of inflammatory and pruritic manifestations of psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis.

4.2 Posology/Dosage and method of administration

Adults, including elderly patients and Children: A thin layer of Mometasone Furoate Cream should be applied to the affected areas of skin once daily.

Use of topical corticosteroids in children or on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

Mometasone Furoate Cream is not recommended for children under the age of 2

4.3 Contraindication

Mometasone Furoate Cream is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions. Mometasone Furoate Cream should not be used on wounds or on skin which is ulcerated. Mometasone Furoate Cream should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids or to any of the ingredients in this medicine.

4.4 Special warnings and precautions for use

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of therapy. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can likewise be generated in some sufferers by systemic absorption of topical corticosteroids while on treatment.

People applying a topical steroid to a large surface area or to areas under occlusion must be assessed regularly for evidence of HPA axis suppression. This might be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free cortisol tests.

In a study reviewing the effects of mometasone furoate cream on the hypothalamic-pituitary-adrenal (HPA) axis, 15 grams were applied two times daily for 7 days to six grownup patients by having psoriasis or atopic dermatitis. The balm was applied without occlusion to at least 30 % of the body surface. The results show that the medicine created a slight decreasing of adrenal corticosteroid secretion.

4.5 Interaction with other drug products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

During pregnancy and lactation treatment with Mometasone Furoate Cream should be performed only on the physician's order.

Then however, the application on large body surface areas or over a prolonged period should be avoided. There is inadequate evidence of safety in human pregnancy. Like other topically applied glucocorticoids, Mometasone Furoate Cream should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus. It is not known whether topical administration of corticosteroids could

result in sufficient systemic absorption to produce detectable quantities in breast milk. Mometasone Furoate Cream should be administered to nursing mothers only after careful consideration of the benefit/risk relationship. If treatment with higher doses or long term application is indicated, breast-feeding should be discontinued.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

A few people may find that they suffer from some of the following side effects after using Mometasone Furoate Cream: allergic skin reactions ,bacterial and secondary skin infections , acne, inflammation and/ or infection of the hair follicles ,thinning of the skin ,red marks with associated prickly heat , loss of skin colour, burning , stinging , itching , tingling, excessive hair growth , softening of the skin and stretch marks .Other adverse effects that may occur with topical corticosteriods are dry skin, skin irritation, dermatitis, dermatitis around the mouth, and small dilated blood vessels.

4.9 Overdose

Topically applied mometasone furoate cream USP, 0.1% can be absorbed in sufficient amounts to produce systemic effects .

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mometasone furoate exhibits marked anti-inflammatory activity and marked anti-psoriatic activity in standard animal predictive models.

In the croton oil assay in mice, mometasone was equipotent to betamethasone valerate after single application and about 8 times as potent after five applications.

In guinea pigs, mometasone was approximately twice as potent as betamethasone valerate in reducing m.ovalis-induced epidermal acanthosis (i.e. anti-psoriatic activity) after 14 applications.

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Studies in humans indicate that approximately 0.4% of the

applied dose of mometasone furoate cream 0.1% enters the circulation after 8 hours of contact on normal skin without occlusion. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of local irritation, single and repeated dose toxicity, genotoxicity, and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hexylene glycol , Titanium Dioxide, Aluminum Starch Octenylsuccinate, White Beeswax, White Soft Paraffin , Hydrogenated Soybean Lecithin , Phosphoric acid , 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:5g, 15g

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

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E-mail: export@frontpharm.com

9. NAFDAC REGISTRATION NUMBER(S)