Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Natcort cream (mometasone furoate 0.1 % w/w cream)

2. Qualitative and quantitative composition

Each NATCORT CREAM tube contains mometasone furoate 0.1 % w/w cream.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Cream.

White coloured, homogeneous cream, non- gritty and non-greasy on application to the skin.

4. Clinical particulars

4.1 Therapeutic indications

Mometasone Furoate 0.1% w/w Cream is indicated for the treatment of inflammatory pruritic manifestations of and psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis in adults and children aged 2 to 18 years.

4.2 Posology and method of administration

Posology

A thin film of Mometasone Furoate 0.1% w/w Cream should be applied to the affected areas of skin once daily.

Method of administration

One fingertip unit (a line from the tip of an adult index finger to the first crease) is enough to cover an area twice the size of an adult hand. 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.

Paediatric population

Mometasone Furoate 0.1% w/w Cream is not recommended for use in children below 2 years of age as the safety and efficacy of Mometasone Furoate 0.1% w/w Cream in this age group has not been established.

4.3 Contraindications

Hypersensitivity to the active substance mometasone furoate, or other corticosteroids or to any of the excipients listed in section 6.1.

Mometasone Furoate 0.1% w/w 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 0.1% w/w Cream should not be used on wounds or on skin which is ulcerated**.**

4.4 Special warnings and precautions for use

If irritation or sensitisation develop with the use of Mometasone Furoate 0.1% w/w Cream, treatment should be withdrawn and appropriate therapy instituted.Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

Systemic absorption of topical corticosteriods can produce reversible hypothalamicpituitaryadrenal(HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorp tion of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. As the safety and efficacy of Mometasone Furoate 0.1% w/w Cream in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin, in flexures and with polythene occlusion. If used in childhood, or on the face, occlusion should not be used. If used on the face, courses should be limited to 5 days and occlusion should not be used. Long term continuous therapy should be avoided in all patients irrespective of age.

Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of centralised 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.

As with all potent topical glucocorticoids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning. This can be prevented by slow reduction of the treatment, for instance continue treatment on an intermittent basis before discontinuing treatment.

Hyperglycaemia and glucosuria can occur in some patients after topical application due to systemic absorption.

Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing.

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.

Mometasone Furoate 0.1% w/w Cream topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract

4.5 Interaction with other medicinal products and other forms of interaction

Co-administered drugs that inhibit CYP3A (e.g., cobicistat, ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on, i.a., the dose of the corticosteroid and the potency of the CYP3A inhibitor.

4.6 Fertility, pregnancy, and lactation

During pregnancy and lactation treatment with Mometasone Furoate 0.1% w/w 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. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation.

There are no adequate and well-controlled studies with Mometasone Furoate 0.1% w/w Cream in pregnant women and therefore the risk of such effects to the human foetus is unknown. However as with all topically applied glucocorticoids, the possibility that foetal growth may be affected by glucocorticoid passage through the placental barrier should be considered. There may therefore be a very small risk of such effects in the human foetus. Like other topically applied glucocorticoids, Mometasone Furoate 0.1% w/w Cream should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus.

Breast-feeding

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Mometasone Furoate 0.1% w/w 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 0.1% w/w Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed in Table 1 according to MedDRA system organ class and in decreasing frequency defined as follows:

Very common (≥ 1/10) Common (≥ 1/100 to < 1/10)

Uncommon (≥ 1/1,000 to < 1/100) Rare (≥ 1/10,000 to < 1/1,000) Very rare

(<1/10,000)

Not known (frequency cannot be estimated from the available data)

Table 1: Treatment-related adverse reactions reported by body system and frequency	
Infections and infestations Not known Very rare	 Infection, furuncle Folliculitis
Nervous system disorders Not known Very rare	 Paraesthesia Burning sensation
Skin and subcutaneous tissue disorders Not known Very rare	 Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy Pruritus
General disorders and administration site conditions Not known **Eye disorders** Not known	 Application site pain, application site reactions Vision, blurred (see also section 4.4)

Local adverse reactions reported infrequently with topical dermatalogic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, miliaria and telangiectasiae.

Paediatric population

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal axis suppression and Cushing's syndrome than mature patients because of a larger skin surface to body weight ratio.

Chronic corticosteroids therapy may interfere with the growth and development of children.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and

poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Excessive, prolonged use of topical corticosteroids may suppress hypothalamic-pituitary- adrenal function resulting in secondary adrenal insufficiency which is usually reversible.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of applications or to substitute for a less potent steroid.

The steroid content of each container is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticoids, potent (group III)

ATC code: D07AC13

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

Pharmacokinetic studies have indicated that systemic absorption following topical application of mometasone furoate cream 0.1% is minimal, approximately 0.4% of the applied dose in man, the majority of which is excreted within 72 hours following application.

Characterisation of metabolites was not feasible owing to the small amounts present in plasma and excreta.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

- Cetomacrogol 1000 BP
- Chlorocresol BP
- Cetosteryl Alcohol BP
- White Soft Paraffin BP
- Sodium dihydrogen phosphate BP
- Light Liquid Parafin BP
- Purified Water BP

6.2 Incompatibilities
Not applicable

6.3 Shelf life
36 months from the date of manufacture.

6.4 Special precautions for storage:
Store below 30℃

6.5 Nature and contents of container
10 grams cream packed in collapsible Aluminium tubes embossed with batch number, manufacturing date and expiry dates packed in unit box with an insert

6.6 Special precautions for disposal and other handling:
No special requirements.

7. Marketing authorization holder and manufacturing site addresses
Marketing authorization holder:

Company Name;	National Pharmacy Ltd,
Address:	P.O.Box 17843-005,
Country:	Nairobi

Manufacturing site address:

Company Name:	ZAIN PHARMA LIMITED
Adress:	Plot No. 209/13741, Colchester Park, Godown No. 1,2,3, P.O. Box 100167-00101, Nairobi ,
Country:	Kenya.

8. Marketing authorization number
CTD9410

9. Date of first registration
22/08/2023

10. Date of revision of the text:
14/09/2023

11. Dosimetry:
Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals:
Not Applicable