SCHEDULING STATUS: **S2**

1. NAME OF THE MEDICINE

STOPITCH CREAM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 10 g contains:

Hydrocortisone acetate (micronised) 0,1 g

Preservative:

Chlorocresol 0,1 % *m/m*

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM IDENTIFICATION

Cream.

A white homogenous cream with a slight odour of chlorocresol.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

STOPITCH CREAM is indicated in the topical treatment of corticosteroid responsive dermatoses.

4.2 Posology and method of administration

A sufficient quantity of STOPITCH CREAM should be applied to completely cover the affected area. The cream should be massaged gently and thoroughly into the skin. The usual frequency of application is twice daily. For some patients, adequate maintenance therapy when indicated may be achieved with less frequent applications.

4.3 Contraindications

- Known hypersensitivity to the active substance or to any of the excipients listed under Section 6.1.
- Rosacea, acne, peri-oral dermatitis, tuberculosis of the skin and varicose ulcers.
- Skin lesions caused by infection with viruses (e.g. herpes simplex, vaccinia or varicella), fungi (e.g., candidiasis, tinea) or bacteria (e.g., impetigo).

4.4 Special warnings and precautions for use

- If a secondary microbial skin infection is present, suitable concomitant antimicrobial therapy should be instituted.
- STOPITCH CREAM should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced.
- STOPITCH CREAM should be used with caution near the eyes.
- Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, STOPITCH CREAM should not be used during pregnancy.

Safety in lactation has not been established. In the absence of sufficient data, the use during lactation is not recommended. No fertility data available.

4.7 Effects on ability to drive and use machines

The effects of STOPITCH CREAM on the ability to drive and the use of machines is not established.

4.8 Undesirable effects

The undesirable effects listed are based on the MedDRA system organ classes (SOC) classification system. The frequency groupings listed conform to the following convention: 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) and unknown (cannot be estimated from the available data)

System Organ Class	**Frequency**	**Undesirable effect**
Endocrine disorders	Unknown	Adrenal gland suppression (children – severe growth retarded and Cushingoid state)
Psychiatric disorders	Rare	Benign intracranial hypertension
Skin and subcutaneous tissue disorders	Unknown	Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules (see section 4.4)

- Long term continuous treatment with STOPITCH CREAM should be avoided as far as possible as this may cause atrophic changes in the skin leading to thinning, loss

of elasticity, dilation of superficial blood vessels, telangiectasia and ecchymoses. The changes are particularly likely to occur on the face and when using sealed dressings.

- Systemic absorption of the topically applied corticosteroid may occur, particularly under the following conditions:
  - when large quantities are used or when application is made to wide areas of the body or to damaged skin,
  - when the occlusive dressing technique is applied.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity.
Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

A 13.4.1 Dermatological preparations: Corticosteriods with or without anti-infective agents.
WHO ATCC Code: H02AB09 Hydrocortisone

5.1 Pharmacodynamics properties

STOPITCH CREAM has anti-inflammatory, antipruritic, anti-allergic and vasoconstrictive properties.

5.2 Pharmacokinetic properties

None available.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Chlorocresol
- Emulsifying wax
- Liquid paraffin
- Purified water
- White soft paraffin

6.2 Incompatibilities

No information available.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in cool place at or below 25 °C.

6.5 Nature and contents of container

20 g Aluminium tube (Laminated coating on the inside) with a LDPE screw cap (white), packed in a unit carton.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited
1 New Road,
Erand Gardens
Midrand, 1685
Customer Care: 0860 ADCOCK/232625

8. REGISTRATION NUMBER(S):

G2212 (Act 101 of 1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 November 1974

10. DATE OF REVISION OF THE TEXT

10 October 2022

Namibia: NS2 14/13.4.1/0418

Botswana: 1502744 S3