SCHEDULING STATUS: **S2**

STOPITCH CREAM (cream)

Hydrocortisone Acetate (micronised) 0,1 g/10 g

Read all of this leaflet carefully because it contains important information for you:

STOPITCH CREAM is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use STOPITCH CREAM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share STOPITCH CREAM with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet:

1. What STOPITCH CREAM is and what it is used for.
2. What you need to know before you use STOPITCH CREAM
3. How to use STOPITCH CREAM
4. Possible side effects
5. How to store STOPITCH CREAM
6. Contents of the pack and other information

1. What STOPITCH CREAM is and what it is used for:

STOPITCH CREAM contains the active substance hydrocortisone acetate (micronised). This is a corticosteroid cream for use on the skin. STOPITCH CREAM is indicated in the topical relief of skin irritation and inflammation.

2. What you need to know before you use STOPITCH CREAM

Do not use STOPITCH CREAM, if you are/have:

- Allergic to the active substance (hydrocortisone acetate (micronised)) or to any of the excipients listed in section 6,
- Small, red, pus-filled bumps on the face,
- Acne,
- Inflammation of the skin around the mouth,
- Painful, small, abnormal, swelling of skin lesions most often found on the face around the nose, eyelids, lips, cheeks, ears and neck associated with tuberculosis
- A wound on the leg or ankle caused by abnormal or damaged veins.
- Skin lesions caused by infection with viruses, fungi or bacteria.

Warnings and Precautions

Take special care with STOPITCH CREAM:

- If a secondary microbial skin infection is present, appropriate antibiotic treatment needs to be started.
- Be careful when using it on any skin defect or lesion on the face. It should only be used for short periods as it will cause the affected area to become red. Small bumps (papules) and pustules may appear and may be scaly.
- Should be used with caution near the eyes.
- If your condition worsens during use, consult a pharmacist or doctor – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.
- If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream/ointment without consulting a pharmacist or doctor. If your condition has resolved and on recurrence the redness

extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Other medicines and STOPITCH CREAM:

Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)

- None known.

Pregnancy, breastfeeding & Fertility:

STOPITCH CREAM should not be used in pregnancy. In the absence of sufficient data, the use during lactation is not recommended. No fertility data available. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking STOPITCH CREAM.

Driving and using machines:

The effects of STOPITCH CREAM on the ability to drive and use of machines is not established. It is not always possible to predict to what extent STOPITCH CREAM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which STOPITCH CREAM affects them.

3. How to use STOPITCH CREAM

Do not share medicines prescribed for you with any other person.
Always use STOPITCH CREAM exactly as described in this leaflet or as your health care professional has told you. Check with your health care professional if you are not sure.

The usual dose is:

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, appropriate maintenance treatment, when needed, may be achieved with less frequent applications.

If you use more STOPITCH CREAM than you should:

Side effects will be precipitated or be of increased severity. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining cream with you so the doctor will know what you have taken.

If you forget to use STOPITCH CREAM:

Use your next dose at your regular time.
Do not use a double dose to make up for forgotten individual doses.

4. Possible Side Effects

STOPITCH CREAM can have side effects.

Not all side effects reported for STOPITCH CREAM are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking STOPITCH CREAM, please consult your health care provider for advice.

Tell your doctor if you notice any of the following side effects:

Unknown frequency side effects:

- Adrenal gland suppression - when the adrenal glands don't make enough of the hormones cortisol and aldosterone in children this may cause a severe growth delay and a condition in which there is too much cortisol in the body
- 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

Rare frequency side effects:

- Benign intracranial hypertension - high pressure in the brain

If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you have any side effects, talk to your health care professional.

You can report side effects to the Adcock Ingram Pharmacovigilance department by e-mail to Adcock.Aereports@adcock.com , fax to +27 86 553 0128 or call 011 635 0134.You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of STOPITCH CREAM.

5. How to store STOPITCH CREAM:

Store in cool place at or below 25 °C.

Store in well-closed containers and protect from light.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton / tube.

Return all unused medicine to your pharmacist for proper disposal.
Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What STOPITCH CREAM contains:

The active ingredients are:
Each 10 g contains:
Hydrocortisone acetate 0,1 g

Preservative: Chlorocresol 0,1 % *m/m*
The other ingredients are: emulsifying wax, liquid paraffin, purified water, white soft paraffin.

What STOPITCH CREAM looks like and contents of the pack:

A white homogenous cream with a slight odour of chlorocresol.

20 g Aluminium tube with a white LDPE screw cap (white), packed in a unit carton.

Holder of the certificate of registration:

Adcock Ingram Limited

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Customer Care: 0860 ADCOCK/232625

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