PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME AND DOSAGE FORM

Vari-Hydrocortisone 1 % Cream

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

VARI-HYDROCORTISONE 1 % CREAM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use VARI-HYDROCORTISONE 1 % CREAM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VARI-HYDROCORTISONE 1 % CREAM with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. WHAT VARI-HYDROCORTISONE 1 % CREAM CONTAINS

The active substance is 10 mg hydrocortisone per 1 g cream.

The cream contains chlorocresol 0,1 % m/m as preservative.

The other ingredients are cetomacrogol, cetosterayl alcohol, liquid paraffin, purified water and white soft paraffin.

2. WHAT VARI-HYDROCORTISONE 1 % CREAM IS USED FOR

VARI-HYDROCORTISONE 1 % CREAM is used to relieve the itching, redness,

dryness, crusting, scaling, inflammation and discomfort of various skin conditions.

3. BEFORE YOU USE VARI-HYDROCORTISONE 1 % CREAM

Do not use VARI-HYDROCORTISONE 1 % CREAM

- If you are hypersensitive (allergic) to hydrocortisone or any of the other ingredients (see **WHAT VARI-HYDROCORTISONE 1 % CREAM CONTAINS**).
- If you have any viral infection (herpes simplex, vaccinia or varicella).
- If you have tuberculosis of the skin (an infectious disease caused by the bacteria *Mycobacterium tuberculosis*).
- If you have an acute infection.
- If you are pregnant, planning to become pregnant, or are breastfeeding your baby. If you become pregnant while using VARI-HYDROCORTISONE 1 % CREAM, contact your doctor immediately (see **Pregnancy and breastfeeding**).

Take special care with VARI-HYDROCORTISONE 1 % CREAM

- VARI-HYDROCORTISONE 1 % CREAM is to be used as directed by your doctor. It is for external use only. Avoid contact with the eyes or the area near the eyes.
- If you have inflammation of the skin, especially in the face.
- VARI-HYDROCORTISONE 1 % CREAM should only be used for short periods.

Pregnancy and breastfeeding

If you are pregnant, planning to become pregnant or breastfeeding your baby**,** please consult your doctor, pharmacist or other health care professional for advice before using this medicine.

The use of VARI-HYDROCORTISONE 1 % CREAM is not recommended if you are pregnant or breastfeeding.

Driving and using machinery

VARI-HYDROCORTISONE 1 % CREAM may not cause drowsiness or dizziness. However make sure you know how you react to VARI-HYDROCORTISONE 1 % CREAM before driving a vehicle, operating machinery, or do anything else requiring your attention.

Using other medicines with VARI-HYDROCORTISONE 1 % CREAM

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO USE VARI-HYDROCORTISONE 1 % CREAM

Do not share medicines prescribed for you with any other person.

Always use VARI-HYDROCORTISONE 1 % CREAM exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

VARI-HYDROCORTISONE 1 % CREAM should be applied as a thin film 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.

If you have the impression that the effect of VARI-HYDROCORTISONE 1 % CREAM is too strong or too weak, talk to your doctor or pharmacist.

If you use more VARI-HYDROCORTISONE 1 % CREAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use your VARI-HYDROCORTISONE 1 % CREAM

Apply the missed dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not apply a double dose to make up for a missed dose.

5. POSSIBLE SIDE EFFECTS

VARI-HYDROCORTISONE 1 % CREAM can have side effects.

Not all side effects reported for VARI-HYDROCORTISONE 1 % CREAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using VARI-HYDROCORTISONE 1 % CREAM, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following symptoms of an allergic reaction occur, seek medical help as soon as possible:

Skin rash, redness of the skin, difficulty in breathing, diarrhoea, dizziness.

Consult your doctor if any of these symptoms are severe or become bothersome:

- Burning, itching, irritation or dryness of the skin
- Inflammation of one or more hair follicles
- Abnormal amount of hair growth on the body
- Acne
- Change in skin colour
- Inflammation of the skin

6. STORING AND DISPOSING OF VARI-HYDROCORTISONE 1 % CREAM

- Keep container well-closed.
- Store at or below 25 °C. Protect from light.

- Do not refrigerate.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF VARI-HYDROCORTISONE 1 % CREAM

White aluminium lacquered tubes of 15 g or 20 g with piercing white plastic caps.

8. IDENTIFICATION OF VARI-HYDROCORTISONE 1 % CREAM

VARI-HYDROCORTISONE 1 % CREAM is a homogenous, smooth, white cream free from any visible contaminants.

9. REGISTRATION NUMBER

35/13.4.1/0384

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Barrs Pharmaceutical Industries (Pty) Ltd

10 Inyoni Street

Ndabeni 7405

11. DATE OF PUBLICATION

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