PROPOSED PATIENT INFORMATION LEAFLET (clean)

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME AND DOSAGE FORM

Vari-Betamethasone Cream, 0,1 g per 100 g

Read all of this leaflet carefully before you start using VARI-BETAMETHASONE CREAM.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- VARI-BETAMETHASONE CREAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT VARI-BETAMETHASONE CREAM CONTAINS

The active substance is 0,1 g betamethasone per 100 g cream.

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

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

2. WHAT VARI-BETAMETHASONE CREAM IS USED FOR

VARI-BETAMETHASONE CREAM is used for the relief of inflammatory and pruritic manifestations (itchy effects) of corticosteroid-responsive dermatoses.

3. BEFORE YOU USE VARI-BETAMETHASONE CREAM

Do not use VARI-BETAMETHASONE CREAM

- If you are hypersensitive (allergic) to betamethasone or to any of the other ingredients (see **WHAT VARI-BETAMETHASONE CREAM CONTAINS**).
- If you have rosacea (a chronic inflammatory disorder involving especially the skin of the nose, forehead and cheeks).
- If you have acne (an inflammatory disease of the skin, usually in the face).
- If you have peri-oral dermatitis (a common skin problem in the area around the mouth).
- If you have peri-anal or genital pruritus (itching in the rectal or vaginal area).
- If you have tuberculosis of the skin (an infectious disease caused by the bacteria *Mycobacterium tuberculosis*).
- If you have varicose ulcers (wounds that are thought to occur due to improper functioning of valves in the veins, usually of the legs).
- If you have any viral infection (e.g. herpes simplex, vaccinia or varicella).
- If you have any fungal infection (e.g. candidiasis or tinea).
- If you have a bacterial infection (impetigo, a contagious bacterial skin infection usually of children, characterised by the eruption of superficial pustules).

- VARI-BETAMETHASONE CREAM should not be used in the nappy areas of infants or for any skin disorders in children under the age of one year.
- If you are pregnant, planning to become pregnant, or are breastfeeding your baby. If you become pregnant while using VARI-BETAMETHASONE CREAM, contact your doctor immediately (see **Pregnancy and breastfeeding**).

Take special care with VARI-BETAMETHASONE CREAM

- VARI-BETAMETHASONE CREAM should be discontinued if you experience unfavourable reactions.
- VARI-BETAMETHASONE CREAM should only be used for short periods.
- VARI-BETAMETHASONE 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.
- VARI-BETAMETHASONE CREAM should not be used in skin folds.
- VARI-BETAMETHASONE CREAM should never be used if you have infection, except in conjunction with effective cancer treatment. Stop using VARI-BETAMETHASONE CREAM if you experience any spread of infection.
- If you have inflammation of the skin, especially in the face.

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-BETAMETHASONE CREAM is not recommended if you are breastfeeding.

Driving and using machinery

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

Using other medicines with VARI-BETAMETHASONE CREAM

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

4. HOW TO USE VARI-BETAMETHASONE CREAM

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

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

VARI-BETAMETHASONE CREAM should be applied as a thin film to completely cover the affected area two or three times per day until improvement occurs. It may then be possible to maintain improvement by applying once a day or even less often.

VARI-BETAMETHASONE CREAM is especially appropriate for moist or weeping surfaces.

VARI-BETAMETHASONE CREAM should be used for short courses only, as prolonged and intensive treatment may cause side effects.

Your doctor will tell you how long your treatment with VARI-BETAMETHASONE CREAM will last.

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

If you use more VARI-BETAMETHASONE 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 apply VARI-BETAMETHASONE 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-BETAMETHASONE CREAM can have cause side effects.

Not all side effects reported for VARI-BETAMETHASONE CREAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using VARI-BETAMETHASONE 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:

- Stretch marks on the skin
- Dryness, thinning of the skin
- Loss of skin elasticity
- Small dilated blood vessels near the surface of the skin or mucous membranes
- Purple discolouration of the skin
- Change in skin colour
- Excessive growth of hair on the body.

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

6. STORING AND DISPOSING OF VARI-BETAMETHASONE CREAM

- Store at or below 25 °C protected from light in a well-closed container.
- 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-BETAMETHASONE CREAM

15 g and 50 g aluminium lacquered tube with piercing cap.

500 g brown HDPE jar with a white polypropylene cap.

8. IDENTIFICATION OF VARI-BETAMETHASONE CREAM

VARI-BETAMETHASONE CREAM is a white, smooth, homogeneous cream free from any visible contaminants.

9. REGISTRATION NUMBER

34/13.4.1/0430

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Barrs Pharmaceutical Industries (Pty) Ltd

10 Inyoni Street

Ndabeni 7405

Cape Town

11. DATE OF PUBLICATION

Date of registration: 20 February 2002

Date of approval: To be advised.