PATIENT INFORMATION LEAFLET FOR

REPIVATE

SCHEDULING STATUS: S4

REPIVATE (15 mg/ 15 g, cream)

Betamethasone

Read all of this leaflet carefully before you start using REPIVATE.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- REPIVATE 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.

What is in this leaflet

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

1. What REPIVATE is and what it is used for

- REPIVATE contains a cortisone-type medicine which is used on the skin to reduce redness and itchiness caused by certain skin problems.
- REPIVATE is used to treat skin problems that are not infected and respond to cortisone type medicines.

2. What you need to know before you use REPIVATE

Do not use REPIVATE:

- if you are hypersensitive (allergic) to betamethasone or any of the other ingredients of REPIVATE (listed in section **6**),
- if your healthcare provider has diagnosed you with an infective disease called herpes simplex (sore blisters around mouth, genitals, or rectum area), varicella (chickenpox), vaccinia (smallpox, which causes rash, fever, head, and body aches) or tuberculosis,
- if you are pregnant,
- in infants or young children,
- on skin infections or leg ulcers,
- on itchiness without redness or itching in the area around your genital organs, anus, or mouth.

Warnings and precautions

Take special care with REPIVATE:

- if there is a worsening of your condition during use consult your doctor – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment,
- REPIVATE is for use only on the skin. Avoid contact with the eyes. Use with caution on facial skin and only for short periods,

- do not use REPIVATE more often or for a longer time than your doctor recommends,
- do not use REPIVATE in any skin crease areas,
- if you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your doctor unless your doctor has previously advised you to do so. 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,
- do not use REPIVATE on large areas of the body, as this will increase the amount absorbed,
- do not use REPIVATE under bandages and plasters or if skin is damaged,
- REPIVATE should not be used in nappy areas and ideally should not be used in infants and young children at all.

Children and adolescents

Children and adolescents who must use REPIVATE should be followed closely by their doctor, since REPIVATE is absorbed through the skin and can affect growth or cause other unwanted effects.

Other medicines and REPIVATE

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

Pregnancy, breastfeeding, and fertility

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 using REPIVATE.

Driving and using machines

It is not always possible to predict to what extent REPIVATE 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 REPIVATE affects them.

REPIVATE contains methyl paraben and propyl paraben.

REPIVATE cream contains methyl paraben and propyl paraben which may cause allergic reactions (possibly delayed).

3. How to use REPIVATE

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

Always use REPIVATE exactly as your doctor or pharmacist has told. Check with your doctor or pharmacist if you are not sure.

Apply a thin film of REPIVATE to cover the affected area and massage in gently, usually twice or three times a day or as directed by your doctor.

Your doctor will tell you how long your treatment with REPIVATE will last. Do not stop treatment early. If you have an impression that the effect of REPIVATE is too strong or too weak, tell your doctor or pharmacist.

If you use more REPIVATE than you should

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

If you forget to use REPIVATE

If you forget to use your cream at the right time, use it again at your next dose as usual.

Do not use a double dose to make up for forgotten individual applications.

If you stop using REPIVATE

If you stop using REPIVATE, you will lose the effects of this medicine. You should not stop using this medicine unless your doctor tells you as your symptoms may return.

4. Possible side effects

REPIVATE can have side effects.

Not all side effects reported for REPIVATE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using REPIVATE, please consult your health care provider for advice.

If any of the following happens, stop using REPIVATE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions that include rash, itching, hives, swelling of the tongue, lips or face, tightness of the chest, and wheezing or difficulty breathing,
- red, scaly pus-filled bumps (if spread throughout the body).

These are all very serious side effects. If you have them, you may have had a serious reaction to REPIVATE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- steroid withdrawal reaction:

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,

- slowed growth,
- weight gain with fat accumulating in the stomach area, the face, and between the shoulders accompanied by stretch marks, easy bruising, and sometimes acne,
- higher than normal blood sugar results or sugar is detected in your urine,
- poor or reduced vision,
- high blood pressure,
- depression, problems sleeping and aggressiveness,
- hair loss.

These effects are more common in children and/or when you have had an infection or accident whilst using REPIVATE.

- the appearance of multiple tiny blood vessels that cause threadlike red lines or patterns on the skin,
- thinning, drying, wrinkling skin, easy bruising of the skin.

These effects are more common with long term use or with use on the face or when used with an air and water-tight dressing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- itchy, burning, painful sensation on the area of skin where the cream was applied.

Less frequent side effects:

- allergic skin reactions,
- skin reddening,
- raised, itchy skin,
- excessive hair growth,
- infection of the treatment area.

Side effects with unknown frequency:

- headache that worsens when lying down and is accompanied by nausea, vomiting and sight disturbances.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. 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 or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of REPIVATE.

5. How to store REPIVATE

- Store all medicines out of reach of children.

- Store at or below 25 °C.
- For external use only.
- Store in the original container.
- Keep the container in the outer carton.
- Do not use after the expiry date stated on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets). **PIL Guideline**

6. Contents of the pack and other information

What REPIVATE contains

The active substance is betamethasone.

Each 15,0 g of cream contains 15,0 mg betamethasone.

Each 500,0 g of cream contains 500,0 mg betamethasone.

The other ingredients are: cetostearyl alcohol, liquid paraffin, methyl paraben, propyl paraben, sodium lauryl sulphate, sorbitan mono oleate, propylene glycol, citric acid monohydrate, disodium hydrogen ortho phosphate anhydrous purified water and yellow soft paraffin.

Preservatives: Methyl paraben 0,12 % *m/m*

Propyl paraben 0,04 % *m/m*

What REPIVATE looks like and contents of the pack

A white cream with no visible foreign particles.

REPIVATE is packed in a 20 g aluminium tube or 500 g plastic jar.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662

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