PATIENT INFORMATION LEAFLET

Scheduling status

S4

Proprietary name, strength and pharmaceutical form

LENOVATE CREAM

LENOVATE OINTMENT

Read all of this leaflet carefully before you start using LENOVATE

- Keep this leaflet, you may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- LENOVATE 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 LENOVATE CONTAINS

Each 5 g of LENOVATE CREAM contains 5 mg of betamethasone as betamethasone valerate.

Inactive ingredients:

Chlorocresol, cetyl alcohol, citric acid monohydrate (for pH adjustment), disodium hydrogen phosphate (for pH adjustment), emulsifying wax, liquid paraffin, propylene glycol, purified water

Preservative:

Chlorocresol 0,1 % *m/m*

Each 5 g of LENOVATE OINTMENT contains 5 mg of betamethasone as betamethasone valerate.

Inactive ingredients:

Beeswax, cholesterol, propylene glycol, stearyl alcohol, white soft paraffin

WHAT LENOVATE IS USED FOR

LENOVATE contains a medicine called betamethasone valerate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

LENOVATE is used to help reduce the redness and itchiness of certain non-infected skin problems, such as eczema, psoriasis and dermatitis.

BEFORE YOU USE LENOVATE

Do not use LENOVATE:

- If you are allergic (hypersensitive) to betamethasone or to any inactive ingredients (see WHAT LENOVATE CONTAINS).
- If you have any of the following skin conditions: rosacea (redness of the skin with pimples), acne (pimples), peri-oral dermatitis (skin rash around the mouth), peri-anal and genital pruritus (itching skin conditions around the anus and genital areas), tuberculosis (TB) of the skin or varicose ulcers that form on the skin near varicose veins.
- If you have skin infection caused by a virus (such as herpes simplex, vaccinia or varicella), a fungus (such as candidiasis or tinea) or a bacteria (such as impetigo).
- LENOVATE is not recommended for use on nappy areas or children under the age of one year.
- If you are pregnant.
- Long term use of LENOVATE is not recommended if you have diabetes (high blood sugar) or tuberculosis (TB).

Take special care with LENOVATE:

- If you experience any side effects that become bothersome, stop treatment and consult your doctor.

- If you have an infection of the skin, your doctor may need to prescribe additional treatment.
- LENOVATE IS FOR EXTERNAL USE ONLY.
- LENOVATE should not be applied to any skin crease areas.
- LENOVATE should not be used to treat infections and ulcers of the leg.
- LENOVATE should be used with caution near the eyes.
- LENOVATE may aggravate a skin condition called psoriasis and should be used with caution in this condition.
- LENOVATE should not be used on infants and young children.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby while using LENOVATE, please consult your doctor, pharmacist or other healthcare provider for advice.

Do not use LENOVATE if you are pregnant.

Driving and using machinery:

LENOVATE is not likely to affect your ability to drive or use machines.

Using other medicines with LENOVATE:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of LENOVATE with these medicines may cause undesirable interactions. Please consult with your doctor, pharmacist or healthcare provider for advice if you need to take any other medicines.

HOW TO USE LENOVATE

Always use LENOVATE exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

LENOVATE IS FOR EXTERNAL USE ONLY.

Do not apply LENOVATE in the creases of the skin.

Apply with caution near the eyes.

Wash your hands before and after applying LENOVATE ointment or cream.

LENOVATE ointment: Apply a small quantity gently to the affected areas 2 or 3 times daily or use with air- and water-tight dressings.

LENOVATE cream: Apply gently to the affected areas 2 to 3 times daily.

If you use more LENOVATE than you should:

If by mistake on a few occasions you use more than you should, do not worry. If you apply a lot more or some is accidentally swallowed contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to use LENOVATE:

If you forget to use LENOVATE, apply it as soon as you remember. If it is almost time you are meant to apply LENOVATE again, wait until this time. Do not apply a double amount to make up for the forgotten application.

POSSIBLE SIDE EFFECTS

LENOVATE can have side effects.

Not all side effects reported for LENOVATE are included in this leaflet. Should your general health worsen while using LENOVATE, please consult your doctor, pharmacist or other healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LENOVATE. 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:

- Increased blood pressure in the brain. You may experience intense, throbbing headaches, nausea and vomiting.

Tell your doctor if you notice any of the following:

- a feeling of burning, irritation or itching where LENOVATE is applied,
- veins under the surface of your skin may become more noticeable,
- thinning of the skin,
- drying of the skin,
- skin may bruise or damage more easily,
- loss of elasticity of the skin,
- changes in skin colour,
- stretch marks,
- sweat rash (if the affected area is closed with a dressing),
- worsening and spreading of other infections of the skin,
- Cushingoid features such as weight gain and rounding of the face,
- slow growth in children.

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

STORING AND DISPOSING OF LENOVATE

Store at or below 25 °C.

Store in well closed containers.

Protect from light.

Keep in original packaging until required for use.

Do not use after the expiry date printed on the tube or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

PRESENTATION OF LENOVATE

LENOVATE CREAM and LENOVATE OINTMENT:

15 g is packed in a collapsible, epoxy phenolic lined, aluminium metal tube sealed with a white high-density polyethylene screw-cap and placed in a unit cardboard carton.

500 g is packed in a white round high-density polyethylene jar sealed with a white polypropylene screw-cap.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF LENOVATE

LENOVATE CREAM: A soft, smooth, homogenous, white cream.

LENOVATE OINTMENT: A soft, smooth, translucent whitish ointment.

REGISTRATION NUMBERS

LENOVATE CREAM: 27/13.4.1/0493

LENOVATE OINTMENT: 27/13.4.1/0308

NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMACARE LIMITED

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DATE OF PUBLICATION

Dates of registration:

LENOVATE CREAM: 01 June 1993

LENOVATE OINTMENT: 08 February 1996

Date of the most recently revised approved package insert: 12 December 2019

Botswana:	S2
LENOVATE CREAM:	BOT0600834
LENOVATE OINTMENT:	BOT0600833

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LENOVATE OINTMENT:	04/13.4.1/0116

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