

<b>Applicant:</b>	<b>GALDERMA LABORATORIES SOUTH AFRICA (PTY) LTD.</b>
<b>Proprietary name:</b>	<b>ROZEX® GEL</b>
<b>Dosage form and strength:</b>	<b>Gel (7,5 mg per g)</b>
<b>Registration Number</b>	<b>29/13.4.2/0771</b>

## **PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S3

### **ROZEX® GEL**

Metronidazole 7,5 mg per g gel

#### **Read all of this leaflet carefully before you start using ROZEX® GEL**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ROZEX® GEL 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 ROZEX® GEL is and what it is used for
2. What you need to know before you start using ROZEX® GEL
3. How ROZEX® GEL is used
4. Possible side effects
5. How to store ROZEX® GEL
6. Contents of the pack and other information

#### **1. What ROZEX® GEL is and what it is used for**

ROZEX® GEL is a dermatological preparation.

ROZEX® GEL is used for the treatment of rosacea.

It helps to treat the pimples, pustules (spots) and redness found with this condition.

ROZEX® GEL contains the active substance metronidazole.

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Metronidazole belongs to a group of medicines called antiprotozoal and antibacterial agents and has been shown to help to control infection and inflammation in certain skin problems, such as rosacea.

## **2. What you need to know before you use ROZEX® GEL**

Always tell your health care provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before using this medicine.

### **Do not use ROZEX® GEL**

- If you are allergic to metronidazole or any of the other ingredients of this medicine (see section 6 for other ingredients). An allergic reaction may include a rash or itching.

### **Warnings and precautions**

Take special care with ROZEX® GEL:

- Avoid contact with the eyes and mucous membranes.
- If a reaction suggesting local irritation occurs, use the medication less frequently, discontinue use temporarily or discontinue use until further instruction from your health care professional.
- If you have evidence of, or a history of, blood dyscrasia (serious blood disorder).
- If you are taking anticoagulant therapy such as warfarin.
- Avoid excessive sunlight or artificial sources of ultraviolet irradiation such as sun beds.

#### *Children*

Do not use ROZEX® GEL in children.

### **Other medicines and ROZEX® GEL**

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

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### **Pregnancy and Breastfeeding**

If you are pregnant, 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 this medicine.

ROZEX® GEL should not be used in pregnancy.

#### *Breastfeeding*

Do not use ROZEX® GEL if you are breastfeeding.

### **Driving and using machines:**

ROZEX® GEL should not affect your ability to drive or use machines.

ROZEX® GEL contains carbomer 940, (Carbopol 980®), propylene glycol, disodium edetate, propylparaben, methylparaben and sodium hydroxide. Propylene glycol can be irritating to the skin. Propyl parahydroxybenzoate and methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

### **3. How ROZEX® GEL is used**

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

Always use ROZEX® GEL exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

- For topical administration only.
- Adults: Apply and rub a thin film of ROZEX® GEL twice daily, morning and evening, to the entire affected area after washing.
- Children: Not recommended

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

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#### **If you use more ROZEX® GEL 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 use more ROZEX® GEL than you should, or in the rare event that you accidentally swallow any ROZEX® GEL, consult your doctor or pharmacist.

#### **4. Possible side effects**

ROZEX® GEL can have side effects.

Not all side effects reported for ROZEX® GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this ROZEX® GEL, please consult your doctor, pharmacist or other healthcare professional for advice.

Side-effects reported with ROZEX® GEL include watery (tearing) eyes if the gel is applied too closely to this area, transient redness and mild dryness, burning and skin irritation.

ROZEX® GEL may cause the following side effects:

Frequent side-effects:

- Dry skin
- Redness of skin
- Itching
- Skin discomfort (burning, pain of skin or stinging)
- Skin irritation
- Worsening of rosacea

Less frequent side-effects:

- Hypoesthesia (numbness)
- Paraesthesia (tingling sensation)
- Metallic taste

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- Nausea

Frequency unknown side-effects:

- Contact dermatitis
- Skin exfoliation

Swelling face has also been reported during post-marketing surveillance with unknown frequency.

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 or pharmacist. 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 ROZEX® GEL.

### **5. How to store ROZEX® GEL**

Store all medicines out of reach of children.

For external use only.

Do not use after the expiry date stated on the tube and carton. The expiry date refers to the last day of that month.

Store at or below 25 °C, away from direct heat. Avoid exposure to temperatures below 4 °C.

Return all unused medicine to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What ROZEX® GEL contains:**

The active substance is metronidazole, 7.5 mg per g.

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The gel is preserved with methyl parahydroxybenzoate (E218) and propylparaben propyl parahydroxybenzoate (E216).

The other ingredients are:

carbomer 940 (carbopol 980), disodium edetate, propylene glycol, sodium hydroxide solution and purified water.

**What ROZEX® GEL looks like and contents of the pack**

ROZEX® GEL is a clear, colourless to light yellow, viscous gel which may turn slightly brown over time.

*Pack contains:*

ROZEX® GEL is available in aluminum tubes containing 30 g of gel.

**Holder of Certificate of registration:**

Galderma Laboratories South Africa (Pty) Ltd

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