

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

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 or pharmacist.
- **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.

1. WHAT ROZEX GEL CONTAINS:

The active substance is metronidazole.

The gel is preserved with methylparaben 0,08 % (m/m) and propylparaben 0,02 % (m/m).

The other ingredients are carbomer 940 (carbopol 980), disodium edetate, methyl paraben, propyl paraben, propylene glycol, sodium hydroxide solution and purified water.

2. WHAT ROZEX GEL IS USED FOR:

ROZEX GEL is used for the treatment of rosacea.

3. BEFORE YOU USE ROZEX GEL:

Do not use ROZEX GEL:

- If you have a history of hypersensitivity (allergy) to metronidazole, parabens or any other ingredients that are contained in **ROZEX GEL**.

Take special care with ROZEX GEL:

- Avoid contact with the eyes.
- 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).
- Avoid excessive sunlight or artificial sources of ultraviolet irradiation such as sun beds.
- If you are taking anticoagulant therapy such as warfarin.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using ROZEX GEL.

Pregnancy

If you are pregnant or think you may be pregnant, do not use **ROZEX GEL** unless your doctor has told you that you can.

ROZEX GEL should not be used in pregnancy.

Breastfeeding

Do not use ROZEX GEL if you are breastfeeding.

Using other medicines with ROZEX GEL.

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

4. **HOW TO USE ROZEX GEL:**

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.

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.

5. **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 using **ROZEX GEL**, please consult your doctor, pharmacist or other health care 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.

6. STORING AND DISPOSING OF 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.

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

7. PRESENTATION OF ROZEX GEL:

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

8. IDENTIFICATION OF ROZEX GEL

ROZEX GEL is a clear, colourless to light yellow, viscous gel.

9. REGISTRATION NUMBER:

29/13.4.2/0771

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Galderma Laboratories South Africa (Pty) Ltd

17 Muswell Road South

Bryanston

2021

11. DATE OF PUBLICATION:

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