

PACKAGE INSERT

SCHEDULING STATUS:

S3

PROPRIETARY NAME (and dosage form):

ROZEX® GEL

COMPOSITION:

Contains metronidazole 7,5 mg per g, preserved with methylparaben 0,08 % (m/m) and propylparaben 0,02 % (m/m).

Inactive ingredients: Carbomer 940, (Carbopol 980®), propylene glycol, disodium edetate, propylparaben, methylparaben, sodium hydroxide, purified water.

PHARMACOLOGICAL CLASSIFICATION:

A.13.4.2. Dermatologicals – Other.

PHARMACOLOGICAL ACTION:

Metronidazole is an antiprotozoal and antibacterial agent which is active against a wide range of pathogenic micro-organisms. The mechanism of action in rosacea is unknown, but available evidence suggests that the effects may be antibacterial and/or anti-inflammatory.

Pharmacokinetics:

Metronidazole is absorbed after oral administration. The agent is not significantly bound to serum proteins and distributes well to all body compartments with the lowest concentration found in the fat. Metronidazole is excreted primarily in the urine as parent agent, oxidative metabolites and conjugates. Bioavailability studies with ROZEX GEL in rosacea patients treated with 7,5 mg metronidazole applied topically to the face resulted in maximum serum concentrations of 66 nanograms per ml which is approximately 100 times less than those attained after a single oral dose of 250 mg. In most patients at most time points after ROZEX GEL application, serum concentrations of metronidazole were below the detectable limits of the assay (25 ng/ml).

INDICATIONS:

ROZEX GEL is indicated for the treatment of inflammatory papules, pustules and erythema of rosacea.

CONTRA-INDICATIONS:

ROZEX GEL is contra-indicated in individuals with a history of hypersensitivity to metronidazole, parabens or other ingredients of the formulation.

WARNINGS AND SPECIAL PRECAUTIONS:

ROZEX GEL has been reported to cause tearing of the eyes, therefore, contact with the eyes should be avoided. If a reaction suggesting local irritation occurs, patients should be directed to use the medication less frequently, discontinue use temporarily or discontinue use completely.

Metronidazole is a nitroimidazole and should be used with care in patients with evidence of, or history of, blood dyscrasia.

Exposure of metronidazole treated sites to excessive sunlight or artificial sources of ultraviolet irradiation such as sun beds should be avoided.

Effects on ability to drive and use machines:

ROZEX GEL has no or negligible influence on the ability to drive and use machines.

INTERACTIONS:

Medicine interactions are less likely with topical administration but should be kept in mind when ROZEX GEL is prescribed for patients who are receiving anticoagulant treatment. Oral metronidazole has been reported to potentiate the anticoagulant effect of warfarin and other coumarin anticoagulants resulting in a prolongation of prothrombin time (INR).

PREGNANCY AND LACTATION:

Safety and efficacy of ROZEX GEL during pregnancy have not been established. Metronidazole crosses the placental barrier and rapidly enters the foetal circulation. ROZEX GEL should not be used in pregnancy.

Mothers on treatment with ROZEX GEL should not breastfeed their infants.

DOSAGE AND DIRECTIONS FOR USE:

For topical administration only.

Adults: Apply and rub a thin film of ROZEX GEL twice daily, morning and evening, to entire affected areas after washing.

Children: Not recommended.

SIDE EFFECTS:

Because of the minimal absorption of metronidazole and consequently its insignificant plasma concentration after topical administration, the adverse experiences reported with the oral form of the agent have not been reported with ROZEX topical gel. Adverse reactions 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In the event of accidental ingestion, treatment should be symptomatic and supportive.

IDENTIFICATION:

A clear, colourless to light yellow, viscous gel.

PRESENTATION:

ROZEX GEL is packed in lined aluminium tubes containing 30 g gel.

STORAGE INSTRUCTIONS:

Store at room temperature, at or below 25 °C, away from direct heat.

Avoid exposure to temperatures below 4 °C

KEEP OUT OF REACH OF CHILDREN.

FOR EXTERNAL USE ONLY.

REGISTRATION NUMBER:

29/13.4.2/0771

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Galderma Laboratories South Africa (Pty) Ltd
17 Muswell Road South
Bryanston
2021

DATE OF PUBLICATION OF THE PACKAGE INSERT:

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