

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rosac

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Metronidazole 0.75 % w/w

3 PHARMACEUTICAL FORM

Gel for cutaneous use.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Rosac is indicated for the treatment acne rosacea

4.2 Posology and method of administration

Apply to the affected skin of the face in a thin film twice daily for eight to nine weeks. Thereafter, further applications may be necessary Adults depending on the severity of the condition.

Elderly patients
As detailed for adults.

Paediatric use
Not recommended.

4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients should not use this product.

4.4 Special warnings and special precautions for use

Avoid contact with the eyes; if eye contact does occur the gel should be washed out carefully with water.

4.5 Interaction with other medicinal products and other forms of interaction

There is evidence to suggest that systemic absorption of metronidazole after topical application is negligible. A small number of patients taking oral metronidazole and alcohol concomitantly have experienced a disulfiram-like reaction.

4.6 Pregnancy and lactation

The safety of Rosac in human pregnancy and lactation has not been established. Animal studies have shown no evidence of teratogenicity or embryo toxicity. It is recommended that the use of Rosac during pregnancy and lactation is avoided.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Dryness or irritation of the skin may be experienced by some patients after application.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The mode of action of topical metronidazole in the treatment of rosacea is not known at present. The most likely mechanism appears to be combined immunosuppressive and anti-inflammatory activity.

5.2 Pharmacokinetic properties

Percutaneous absorption from topical metronidazole gel results in negligible plasma levels of metronidazole. Human studies have shown levels of approximately 70 ng/ml, 100 times lower than levels seen with systemic treatment.

5.3 Preclinical safety data

Metronidazole shows low toxicity in all animal species studied. It has been reported to be mutagenic in some bacteria, but not in human lymphocytes. Micronucleus tests in mice and rats were also negative. This suggests that metronidazole is not a mammalian mutagen. Metronidazole has been in use for many years and its safety in man has been demonstrated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Disodium edetate
Hydroxyethyl cellulose
Benzyl alcohol
Purified water

6.2 Incompatibilities

None.

6.3 Shelf Life

a) For the product as packaged for sale

3 years

b) After first opening the container

Comply with expiry date

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

30 g HDPE tubes.

6.6 Instructions for use and handling

There are no special instructions for use or handling of Rosac.

7 MARKETING AUTHORISATION HOLDER

Stiefel Laboratories (UK) Ltd
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Wooburn Green
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8 MARKETING AUTHORISATION NUMBER

PA 144/35/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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