Summary of Product Characteristics

1. Name of the medicinal product
Metrogel V

2. Qualitative and quantitative composition
Metronidazole 37.5mg/5g

Excipients with known effect:

5 gram of gel contains

Metronidazole.....37.5 mg

For the full list of excipients, see section 6.1

3. Pharmaceutical form
Aqueous gel for cutaneous use.

4. Clinical particulars
4.1 Therapeutic indications
For the treatment of acute inflammatory exacerbation of rosacea.

For the deodorisation of the smell associated with malodorous fungating tumours.

4.2 Posology and method of administration
For the treatment of rosacea:

Posology

For topical administration only.

The average period of treatment is three to four months. The recommended duration of treatment should not be exceeded. However, if a clear benefit has been demonstrated, continued therapy for a further three to four months period may be considered by the prescribing physician depending on the severity of the condition. In clinical studies, topical metronidazole therapy for rosacea has been continued for up to 2 years. In the absence of a clear clinical improvement, therapy should be stopped.

Older people: The dosage recommended in the elderly is the same as that recommended in adults.

Paediatric population: Not recommended. Safety and efficacy have not been established.

Method of administration

Metrogel should be applied in a thin layer to the affected areas of the skin twice daily, morning and evening. Areas to be treated should be washed with a mild

cleanser before application. Patients may use non-comedogenic and non-astringent cosmetics after application of Metrogel.

For the deodorisation of malodorous fungating tumours:

Adults and elderly: Clean the wound thoroughly. Apply the gel over the complete area and cover with a non-adherent dressing. Use once or twice daily as necessary.

Paediatric population: Not recommended

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Metronidazole must not be used in patients with Cockayne syndrome. Cases of severe hepatotoxicity/acute hepatic failure, including cases with a fatal outcome with very rapid onset after treatment initiation in patients with Cockayne syndrome have been reported with products containing metronidazole for systemic use.

4.4 Special warnings and precautions for use
Contact with mucous membranes should be avoided.

Metrogel has been reported to cause lacrimation 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 or discontinue use temporarily and to seek medical advice if necessary. Metronidazole is a nitroimidazole and should be used with care in patients with evidence of, or history of, blood dyscrasia. Exposure of treated sites to ultraviolet (e.g. solarium, sun-lamp) or strong sunlight (including sun-bathing) should be avoided during use of metronidazole. Metronidazole transforms into inactive metabolite due to UV exposure, therefore its efficacy decreases significantly. Phototoxic side-effects haven't been reported in clinical trials in relation to metronidazole. Unnecessary and prolonged use of this medication should be avoided.

Evidence suggests that metronidazole is carcinogenic in certain animal species. There is no evidence to date of a carcinogenic effect in human.

This product contains 50 mg of propylene glycol (E1520) in each gram which is equivalent to 5% w/w and may cause skin irritation. This product also contains hydroxybenzoic acid esters which may cause allergic reactions (possibly delayed) and bronopol which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction
Interaction with systemic medication is unlikely because absorption of metronidazole following cutaneous application of Metrogel is low. Nevertheless,

it should be mentioned that disulfiram-like reactions have been reported in a small number of patients taking metronidazole and alcohol concomitantly. Oral metronidazole has been reported to potentiate the effect of warfarin and other coumarin anticoagulants, resulting in a prolongation of prothrombin time. The effect of topical metronidazole on prothrombin is not known. However, very rare cases of modification of the INR values have been reported with concomitant use of Metrogel and coumarin anticoagulants.

4.6 Fertility, pregnancy and lactation
Pregnancy

There has been no experience to date with the use of Metrogel in pregnant patients. In case of oral administration, metronidazole crosses the placental barrier and enters foetal circulation rapidly. No foetotoxicity was observed after oral metronidazole in either rats or mice. However because animal reproduction studies are not always predictive of human response and since oral metronidazole has been shown to be a carcinogen in some rodents this drug should be used in pregnancy only if clearly needed.

Breast-feeding

After oral administration metronidazole is secreted in breast milk in concentration similar to those found in plasma. Even though blood levels are significantly lower with cutaneous application of Metrogel than those achieved after oral metronidazole in nursing mothers, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into importance of the drug to the mother.

4.7 Effects on ability to drive and use machines
Metrogel has no influence on the ability to drive and use machines.

4.8 Undesirable 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 drug have not been reported with Metrogel. Adverse reactions reported with Metrogel have been only local and mild.

System Organ Class	Frequency	Adverse Drug Reaction
Skin and subcutaneous tissue disorders	Common (≥1/100, < 1/10)	Dry skin, erythema, pruritus, skin discomfort (burning, pain of skin/stinging), skin irritation, worsening of rosacea
	Unknown frequency	Contact dermatitis, swelling face, skin exfoliation

Nervous system disorders	Uncommon (≥ 1/ 1,000, < 1/100)	Hypothesia, paraesthesia, dysgeusia (metallic taste)
Gastrointestinal disorders	Uncommon(≥ 1/ 1,000, < 1/100)	Nausea

Watery eyes have been reported if applied too closely to this area.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

No data exists about overdosage in humans. Acute oral toxicity studies with a topical gel formulation containing 0.75% w/w metronidazole in rats have shown no toxic action with doses of up to 5 g of finished product per kilogram body weight, the highest dose used. This dose is equivalent to the oral intake of 12 tubes of 30g packaging Metrogel for an adult weighing 72 kg, and 2 tubes of Metrogel for a child weighing 12 kg.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Chemotherapeutics for external use

ATC code: D06BX01

The etiology of rosacea is unknown although a variety of hypotheses have been reported.

5.2 Pharmacokinetic properties

The systemic concentration of Metronidazole following the topical administration of 1 g of a 0.75% Metronidazole gel to 10 patients with rosacea ranged from 25 ng/ml (limit of detection), to 66 mg/ml with a mean Cmax of 40.6 ng/ml.

The corresponding mean Cmax following the oral administration of a solution containing 30 mg of metronidazole was 850 ng/ml (equivalent to 212 ng/ml if dose corrected. The mean Tmax for the topical formulation was 6.0 hours compared to 0.97 hours for the oral solution.

5.3 Preclinical safety data

Metronidazole is a well established pharmaceutical active ingredient and to the subject of pharmacopoeial monograph in both the BP and Ph.Eur.

6. Pharmaceutical particulars

6.1 List of excipients

Bronopol BP,

Hydroxybenzoic acid esters,

Hydroxyethylcellulose,

Propylene glycol (E1520),

Phosphoric acid,

Purified water.

6.2 Incompatibilities
Not applicable

6.3 Shelf life
2 years.

6.4 Special precautions for storage
Store between 15°C and 25°C in a dry place.

6.5 Nature and contents of container
Tube: Internally lacquered, membrane sealed aluminium.

Cap: low density polyethylene

Pack sizes: 25 g and 40 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder
iNova Pharmaceuticals (Pty) Ltd

8. Marketing authorisation number(s)
H2022/CTD4036/136ER

9. Date of first authorisation/renewal of the authorisation
4th September 2026

10. Date of revision of the text
4th September 2026