Soolantra 10mg/g cream Prescribing Information (UK and Ireland)

Presentation: 10mg/g ivermectin cream

Indications: Topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients.

Dosage and Administration: One application per day for up to 4 months. The treatment course may be repeated. It can be applied as monotherapy or as part of combination treatment. Treatment should be discontinued after 3 months if no improvement. Apply a pea sized amount to each of the 5 areas of the face: forehead, chin, nose, each cheek. Cutaneous use only. Apply only to the face; avoiding the eyes, lips and mucosa. Hands should be washed immediately after application.

Contraindications: Hypersensitivity to the active substance or any excipients.

Precautions and Warnings: Soolantra has not been studied in patients with renal or hepatic impairment. Caution should be exercised in patients with severe hepatic impairment. Contains cetyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis), methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed) and propylene glycol which may cause skin irritation.

Interactions: No interaction studies have been performed.
Caution is advised when ivermectin is administered concomitantly with potent CYP3A4 inhibitors as the plasma exposure may be significantly increased. **Pregnancy and Lactation:** Soolantra is not recommended during pregnancy. A risk to a suckling child cannot be excluded; a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Soolantra therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Undesirable Effects: In clinical trials the most common adverse reactions were typically mild to moderate in severity, and usually decreased when treatment was continued. Adverse reactions include: **Common (≥1/100 to <1/10):** Skin burning sensation; **Uncommon (≥1/1,000 to <1/100):** Skin irritation, pruritus, dry skin, rosacea aggravation; **Unknown frequency:** Erythema, dermatitis contact (allergic or irritant), swelling face, increased transaminases.

Packaging Quantities and Cost:
UK: 30g £18.29, 45g £27.43
Ireland: 30g €23.50
MA Number: UK: PL 10590/0063, Ireland: PA 22743/015/001
Legal Category: POM
Marketing Authorisation Holder:
UK: Galderma (UK) Ltd, Meridien House, 69-71 Clarendon Road, Watford, Herts, WD17 1DS, Telephone: +44 (0) 1923 208950
Ireland: Galderma International S.A.S.,Tour Europlaza, La Défense 4, 20 Avenue André Prothin, 92927, France
Date of Revision: August 2021

Adverse events should be reported
Adverse Event Reporting
For the UK: Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for Yellow Card in the Google Play or Apple App Store.
For Ireland: HPRA Pharmacovigilance Website: www.hpra.ie
Adverse events should also be reported to Galderma (UK) Ltd, Email: Medinfo.uk@galderma.com; Tel: +44 (0) 1923 208950