

OVIXAN® 1 mg/g cream (mometasone furoate) PRESCRIBING INFORMATION

Please refer to the SmPC before prescribing.

Presentation: Each g of cream contains 1 mg mometasone furoate (0.1% w/w). Excipients with known effect: propylene glycol (E1520) and cetostearyl alcohol. See SmPC for full list. **Indication:** Treatment of inflammatory and pruritic manifestations of psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis. **Dose and administration:** *Adults including elderly and Children:* Apply a thin film to the affected areas of skin once daily. Use in children or on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days. **Contraindications:** Hypersensitivity to active substance mometasone furoate, to other corticosteroids, or to any excipients. Facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritus, napkin eruptions, bacterial (e.g. impetigo, pyoderma), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions. Should not be used on wounds or on skin which is ulcerated. **Special warnings and precautions:** Strong steroid. Discontinue if irritation or sensitization develop. If an infection develops, use the appropriate antifungal or antibacterial agent. If no prompt improvement occurs, discontinue the corticosteroid until the infection is controlled. Systemic absorption of topical corticosteroids can cause hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, hyperglycemia, and glucosuria, especially in children. Not recommended for children under 2 years old. Patients using corticosteroids on large areas or under occlusion should be monitored for HPA axis suppression. Long-term use, especially on large or damaged areas, can lead to local and systemic toxicity. Avoid occlusion when treating children or the face; and limit use to 5 days. Avoid sudden withdrawal after long-term use to prevent rebound dermatitis. Do not use around the eyes due to the risk of glaucoma or cataracts. Fabrics in contact with the product may present a fire hazard. Long-term use can lead to withdrawal symptoms, such as intense redness and burning, particularly in delicate areas like the face. If symptoms return after treatment, consider withdrawal reactions and seek specialist advice. See SmPC for further details. **Pregnancy and lactation:** Use during pregnancy and lactation only if the potential benefit justifies the potential risk. Animal studies show topical corticosteroids can cause foetal abnormalities. Although human risk is unknown, foetal growth effects cannot be ruled out. Avoid prolonged use and large area application during pregnancy. Discontinue breastfeeding if high doses or long-term treatment are required. **Undesirable effects:** *Very rare (<1/10 000):* folliculitis, burning sensation, pruritus. *Frequency not known:* infection, furuncle, paraesthesia, dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy, withdrawal reactions (redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules), application site pain, application site reactions, vision blurred. See SmPC for a full list of undesirable effects. **Legal Category:** POM. **Basic UK NHS cost:** £4.40/£14.10 per 30g/100g tube. **Market authorization (MA) number:** PLGB 34942/0004. **MA holder:** Biofrontera Bioscience GmbH, Hemmelrather Weg 201, 51377 Leverkusen, Germany. **Date of preparation of PI:** Nov 2025.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Biofrontera Pharma GmbH on +49 214 876 32 66