UK Prescribing Information

(Please refer to full Summary of Product Characteristics before prescribing)

Duac® Once Daily 10mg/g + 30mg/g Gel (clindamycin phosphate 1%, benzoyl peroxide 3% - Duac 3%) and **Duac® Once Daily 10mg/g + 50mg/g Gel** (clindamycin phosphate 1%, benzoyl peroxide 5% - Duac 5%).

Indication: Topical treatment of mild to moderate acne vulgaris, particularly inflammatory lesions. **Dosage and administration**: Adults and adolescents (aged >12 years): Apply thin layer once daily (evening) to affected area after washing. Wash hands after use. Reduce frequency or temporarily interrupt if drying or peeling occurs. Do not exceed more than 12 weeks of continuous use. Contra-indications: Hypersensitivity to clindamycin, lincomycin, benzoyl peroxide or any of the excipients. **Precautions**: Avoid contact with mouth, eyes, mucous membranes and irritated/broken skin. Caution advised in sensitive areas; history of regional enteritis, ulcerative colitis or antibiotic-associated colitis; atopic patients due to skin drying effect; and with concomitant topical acne therapy. Discontinue if severe local irritancy; prolonged or significant diarrhoea; or abdominal cramps. Minimise exposure to sun/sunlamps. Resistance to clindamycin or cross-resistance may occur with other antibiotics. Avoid contact with hair or coloured fabrics due to bleaching. Pregnancy and lactation: Safety in human pregnancy and breastfeeding is not established. Careful risk/benefit assessment required. Do not apply to breast area if used during lactation. Side effects: For full details see SPC. 3%: Application site pruritus, dermatitis. 3% & 5%: Application site erythema, peeling, dryness, burning sensation, photosensitivity, headache, application site pain, allergic reactions including anaphylaxis, diarrhoea, haemorrhagic diarrhoea, pseudomembranous colitis, abdominal cramps. Legal category: POM. NHS list price: 3% Tube: 30g £13.14; 5% Tube: 25g £10.95, 50g £21.89. **Market authorisation details**: Product licence (PL) number 3% PL 19494/0251; 5% PL 19494/0075. PL holder: GlaxoSmithKline UK Limited, Stockley Park West, Uxbridge, Middlesex, UB11 1BT. Last date of revision: January 2015.

Duac® Once Daily Gel is a registered trademark of Stiefel, a GSK company.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Stiefel, a GSK company on 0800 221 441.

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