

Diclofenac sodium 3% gel– Abbreviated Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Diclofenac sodium 3% gel

Each gram of gel contains 30 mg diclofenac sodium. **Uses** For the treatment of actinic keratoses (AKs). **Dosage and Administration** Apply to the affected skin areas twice daily and smooth into the skin gently. Amount used depends on the size of the area to be treated. Usually 0.5 g of gel is applied to a 5x5 cm lesion site. The maximum daily amount of 8 grams of product allows simultaneous treatment of up to 200 cm² skin surface area. The usual duration of treatment is 60 to 90 days. Not recommended for use in children and adolescents. **Special Warnings and Precautions** Low systemic absorption of Diclofenac sodium gel, so the likelihood of systemic adverse reactions is small. The possibility of systemic adverse events cannot be excluded if the preparation is used on large areas of skin and over a prolonged period. Use with caution in patients with a history of and/or active gastrointestinal ulceration and/or bleeding, or reduced heart, liver or kidney function. Caution should be used in patients with intracranial haemorrhage and bleeding diathesis. Exposure to direct sunlight and solarium use should be avoided during treatment. If hypersensitivity reactions of the skin occur, treatment must be stopped. Apply only to intact skin, and not to skin wounds, open injuries, infected skin areas or exfoliative dermatitis. The gel must not come into contact with the eyes or mucous membranes and should not be ingested. Discontinue if a (generalised) skin rash develops. Can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing. Contains 15 mg benzyl alcohol in each gram of gel. Benzyl alcohol may cause allergic reactions and mild local irritation. **Contraindications** Hypersensitivity to the active substance or to any of the excipients. Because of the potential for cross-reactions, the gel should not be used in patients who have experienced hypersensitivity reactions such as symptoms as asthma, allergic rhinitis or urticaria to 2-acetoxybenzoic acid (acetylsalicylic acid) or any other non-steroidal anti-inflammatory medicinal products (NSAIDs). Contraindicated in the third trimester of pregnancy. **Interactions with other medicinal products** Systemic absorption is low therefore such interactions unlikely. **Pregnancy, fertility and lactation** During the first and second trimesters of pregnancy, diclofenac should not be used unless clearly necessary. Contraindicated during the last trimester of pregnancy. Only use during lactation under advice from a healthcare professional. Should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period. **Side Effects:** Common: hyperaesthesia, hypertonia, localised paraesthesia, conjunctivitis, dermatitis, eczema, dry skin, erythema, oedema, pruritus, rash, scaly rash, skin hypertrophy, skin ulcer, vesiculobullous rash. Uncommon: eye pain, lacrimation disorder, haemorrhage (skin bleeding), abdominal pain, diarrhoea, feeling sick, alopecia, facial oedema, maculopapular rash, seborrhoea. Please refer to the SmPC for a full list of side effects. **Overdose** Low systemic absorption of topical diclofenac renders overdose unlikely. If the dosage is significantly exceeded when applied to the skin, the gel should be removed (e.g. with a paper towel, to be disposed of in the residual waste) and washed off with water. There have been no reports of clinical cases of overdosage from ingestion of diclofenac-containing gel. Undesirable effects similar to those observed following an overdose of diclofenac tablets can be expected if topical diclofenac is inadvertently ingested (1 tube of 100 g contains the equivalent of 3,000 mg diclofenac sodium). General therapeutic measures normally adopted to treat poisoning with NSAIDs should be used. **Effects on the ability to drive and/or operate machines** No influence on the ability to drive and use machines. **Legal category** POM **Pack size** 50g aluminium tube with original sealing membrane and internal protective lacquer and HDPE screw cap. **Shelf life** 3 years, 6 months after opening. **NHS price** £36.38 per 50g tube. **Marketing Authorisation Holder** Stirling Anglian Pharmaceuticals Ltd, Hillington Park Innovation Centre, 1 Ainslie Road, Hillington Park, Glasgow G52 4RU **Marketing Authorisation Number** PL 42582/0018 Further information is available at medinfo@stirlinganglianpharmaceuticals.com or **0330 1359 499** **Date of preparation:** March 2026

Unique Code: 26-API-002

Adverse events should be reported. Reporting forms and information can be found at <http://yellowcard.mhra.gov.uk> or downloaded from Google Play or the Apple App store. Adverse events should also be reported to **Stirling Anglian Pharmaceuticals** on **0330 1359 499** or by emailing medinfo@stirlinganglianpharmaceuticals.com