Solaraze® Gel

Background Information	Solaraze® gel contains the active ingredient Diclofenac Sodium 3% in a sodium hyaluronate base[1]. It is suitable for topical treatment of superficial lesions for patients suffering actinic keratosis[1].
BNF therapeutic class	Skin: Sun protection and Photodamage[1].
Indication	Actinic keratosis in adults[1].
Dosage and administration	Apply thinly using about 0.5 grams of gel (pea sized amount) per 5 cm x 5cm area twice daily for 60-90 days[1,2,3]. Maximum efficacy has been observed with treatment duration towards the upper end of this range. (BHNFT dermatologists recommend application for a minimum of 90 days).Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy[2].No more than 8 grams of gel should be used per day. BHNFT dermatologists advise concomitant application of emollients both during therapy and for a period of 8 weeks after to avoid dryness of surrounding skin. Avoid sun exposure (including tanning salons) whilst using Diclofenac Sodium 3% gel and always use an appropriate sun protection cream (SPF 30 and above or use suitable protective clothing e.g. sun hat)[3].
Cautions and Contraindication	**Cautions** Apply with gentle massage only[2]. Do not use with occlusive dressings (non-occlusive bandages can be used)[2]. Avoid contact with the eyes, mucous membranes and inflamed or broken skin, discontinue if rash develops or if sensitivity skin reactions occur[1]. Hands should be washed immediately after use[3]. Topical application of large amounts can result in systemic effects including hypersensitivity and asthma[1]. Use with caution in patients with a history of and/or active gastrointestinal ulceration or bleeding, or reduced heart, liver or renal function[2]. Caution should be used in patients with intracranial haemorrhage and bleeding diathesis[2]. Diclofenac sodium 3% gel contains benzyl alcohol so should be used with caution in some ethnic cultures. **Contraindications** Avoid using during pregnancy (contraindicated in third trimester) and breast feeding[2].

	Diclofenac Sodium 3% gel is contraindicated in patients with a known hypersensitivity to diclofenac, benzyl alcohol, macrogol monomethyl ether 350 and/ or sodium hyaluronate.[2] Due to cross-reactions, the gel should not be used by patients who have experienced hypersensitivity reactions such as symptoms of asthma, allergic rhinitis or urticaria, to acetylsalicylic acid or other non-steroidal anti-inflammatory agents[2].
Adverse Drug Reactions & Interactions	Adverse drug reactions include skin reactions such as contact dermatitis, erythema and rash or application site reactions such as inflammation, irritation, pain, blistering, paraesthesia or photosensitivity. In studies there appeared to be no age specific increase or pattern of reactions[2]. Interactions do not normally apply for topical application since systemic absorption is very low[2].
Monitoring	Review: Primary care should review the patient 90 days after treatment commenced. However, complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy[2]. This review should include a discussion around: • Use of all treatments (including concomitant emollients). • Liaising with dermatology regarding side effects, increase in skin infections or changes in patients' condition which may have an impact on treatment. Photographic images both at the start and during treatment are an excellent reference tool and can be forwarded to dermatology for help and advice if it is needed.

Contact names and details

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References

1. *BNF- https://www.medicinescomplete.com/#/content/bnf/_253177925?hspl=solareze#DMD3648411000001100*
2. Solaraze® Summary Product Characteristics- https://www.medicines.org.uk/emc/product/6385
3. Solaraze® Patient Information Leaflet- https://www.medicines.org.uk/emc/files/pil.6385.pdf

Amber with Guidance*= To be initiated and titrated to a stable dose by a specialist prescriber with follow up prescribing and monitoring by primary care where deemed appropriate.*

Development Process

This guidance has been produced following an AMBER-G classification status of Solaraze® Gel by the Barnsley Area Prescribing Committee. This guideline has been subject to consultation and endorsement by the Area Prescribing Committee on 14th August 2019.