

## PRESCRIBING INFORMATION

(Please consult the Summary of Product Characteristics (SmPC) before prescribing.)

### Solaraze™ 3% Gel 30 mg/g diclofenac sodium

**Active Ingredient:** Each gram contains 30 mg diclofenac sodium (3% w/w). For full list of excipients, see section 6.1.

**Indication:** For the treatment of actinic keratosis (AK).

**Dosage and Administration:** Solaraze is applied locally to the affected area twice daily. Normally 0.5 grams (the size of a pea) of the gel is used on a 5 cm x 5 cm lesion site. The maximum daily amount of 8 grams of product allows simultaneous treatment of up to 200 cm<sup>2</sup> skin surface area. The usual duration of therapy is from 60 to 90 days. Optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. *Consult SmPC and package leaflet for method of administration.*

#### **Contraindications, Special warnings etc:**

**Contraindications:** Hypersensitivity to diclofenac sodium or to any of the excipients. Patients with a history of hypersensitivity reactions such as symptoms of asthma, allergic rhinitis, urticaria, acetylsalicylic acid or other non-steroidal anti-inflammatory agents. Contraindicated in third trimester of pregnancy.

**Special warnings, etc.:** The possibility of systemic adverse events from application of topical diclofenac cannot be excluded if the preparation is used on large areas of skin and over a prolonged period (see product information on systemic forms of diclofenac). This product should be used with caution in patients with a history of and/or active gastrointestinal ulceration or bleeding, or reduced heart, liver or renal function. Caution should be used in patients with intracranial haemorrhage and bleeding diathesis. Direct sunlight, including solarium, should be avoided during treatment. Solaraze should not be applied to skin wounds, infections or exfoliative dermatitis. It should not be allowed to come into contact with the eyes or mucous membranes and should not be ingested. Discontinue the treatment if sensitivity reactions or a generalised skin rash develop after applying the product. Should not be used with an airtight occlusive dressing.

**Interactions:** Since systemic absorption of diclofenac from a topical application is very low, such interactions are very unlikely.

**Pregnancy and lactation:** Not recommended in pregnancy or lactation unless clearly necessary. *Consult SmPC.* If diclofenac is

used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low (< 30% of the body surface) and duration of treatment as short as possible (not longer than 3 weeks). Contraindicated during the third trimester of pregnancy and not to be applied to breasts of nursing mothers.

**Ability to drive and use machines:** Cutaneous application of topical diclofenac has no influence on the ability to drive and use machines.

#### **Undesirable Effects:**

*These are ranked under heading of frequency using the following convention: very common (>1/10); common (≥1/100 <1/10); uncommon (≥1/1,000 <1/100); rare (≥1/10,000 <1/1,000); very rare (<1/10,000).*

**Common:** Conjunctivitis, application site reactions (including inflammation, irritation, pain and tingling or blistering at the treatment site), hyperaesthesia, hypertonia, localised paraesthesia, dermatitis (including contact dermatitis), eczema, dry skin, erythema, oedema, pruritus, rash, scaly rash, skin hypertrophy, skin ulcer, vesicubullous rash. **Very rare:** Gastrointestinal haemorrhage, renal failure, asthma. Topical application of large amounts may lead to systemic effects including all types of hypersensitivity. *Consult SmPC in relation to other side-effects.*

#### **Legal Category:** POM

**Product Authorisation Number(s):** PL 16973/0012

#### **NHS cost (excluding VAT):**

£38.30 – 50 g tube

£76.60 – 100 g tube

#### **Marketing Authorisation Holder:**

Almirall S.A., Ronda General Mitre, 151, 08022 Barcelona Spain.

#### **Further information is available from:**

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Solaraze is a trademark.

**Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Almirall Ltd.**