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

Actikerall 5 mg/g + 100 mg/g Cutaneous Solution

5 mg of fluorouracil and 100 mg of salicylic acid

Active Ingredient: 1 g of cutaneous solution contains 5 mg of fluorouracil and 100 mg of salicylic acid. Excipient with known effect: 80 mg of dimethyl sulfoxide/g of solution.

Indication: Actikerall is indicated for the topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients.

Dosage and Administration: Cutaneous use only. Apply once daily to the affected area (up to 25 cm^2) until the lesions have completely cleared or for up to a maximum of 12 weeks. If severe side effects occur, reduce the frequency of drug application to three times per week until the side effects improve. If areas of skin with a thin epidermis are treated, the solution should be applied less frequently and the course of therapy monitored more often. Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to eight weeks after treatment cessation. Treatment should be continued, although response is not apparent after the first four weeks. There is experience in treating up to 10 lesions at the same time. Multiple actinic keratoses and surrounding skin can be treated simultaneously, when field treatment is preferred.. The total area of skin being treated at any one time should not exceed 25 cm^2 (5 cm x 5 cm). The treated area should not be covered after application and the solution should be left to dry to form a film over the applied area. Each time Actikerall is reapplied the existing film coating should be removed beforehand by simply peeling it off. Warm water may help to remove the film. Actikerall should not be applied to hairy skin. *Consult SmPC and package leaflet for method of administration.*

Contraindications, Warnings, etc:
Contraindications: Hypersensitivity to the active ingredients or to any other excipients. Contraindicated in pregnancy and lactation. Not be used to treat patients with renal insufficiency; in conjunction with brivudine, sorivudine and analogues. Actikerall must not be allowed to come into contact with the eyes or mucous membranes.
Precautions: Actikerall contains the cytostatic agent 5-fluorouracil. Inhibition, deficiency or decreased activity of dihydropyrimidine dehydrogenase (DPD) can result in accumulation of fluorouracil. If applicable, the determination of DPD enzyme activity is indicated before starting treatment with fluorouracil or other fluoro-pyrimidines. In patients with sensory disturbances (e.g. those with diabetes mellitus) close medical monitoring of the treatment area is required. Patients should be advised to protect the skin against further excessive or cumulative exposure to the sun, especially in the area of skin being actively treated. Actikerall should not be used on bleeding lesions or to treat basal cell carcinoma and Bowen's disease. There is no experience in treating actinic keratosis in areas also affected by another skin disease; treatment outcomes should be taken into account in such cases. This medicinal product contains dimethyl sulfoxide which may be irritant to the skin. The bottle should be closed tightly after use or the solution will dry up quickly and can no longer be used correctly. The solution should not be used if crystals occur. Should not come into contact with textiles or acrylics (e.g. acrylic bathtubs) as the solution may cause permanent stains. Caution flammable: keep away from fire or flames.
Interactions: The enzyme dihydropyrimidine dehydrogenase (DPD) plays an important role in the breakdown of fluorouracil. Nucleoside analogues such as brivudine and sorivudine may lead to a drastic increase in plasma concentrations of fluorouracil or other fluoropyrimidines with associated increase in toxicity. For this reason, an interval of at least 4 weeks between the use of fluorouracil and brivudine, sorivudine and analogues should be observed. In case of accidental concomitant administration of nucleoside analogues such as brivudine and sorivudine, effective measures for reducing fluorouracil toxicity should be taken. Admission to a hospital may be indicated. All necessary measures for protection from systemic infections and dehydration should be introduced. Elevated plasma levels of phenytoin leading to symptoms of phenytoin intoxication have been reported with the concomitant administration of phenytoin and fluorouracil. There is no evidence for relevant systemic absorption of salicylic acid, however absorbed salicylic acid may interact with methotrexate and sulphonylureas.
Pregnancy and lactation: Actikerall is contraindicated in pregnancy and lactation
Ability to drive and use machines: Actikerall has no influence on the ability to drive and use machines.

Adverse Reactions:
Very common: erythema, inflammation, irritation (including burning), pain, pruritus.
Common: at application site - bleeding, erosion, scab, skin exfoliation; headache.
Consult SmPC in relation to other adverse reactions.

Legal Category: POM

Marketing Authorisation Number(s): PL 33016/0015 – *Brown bottle containing 25 ml of solution with brush applicator packed in a carton.*

NHS Cost: £38.30 (excluding VAT)

Marketing Authorisation Holder:
Almirall Hermal GmbH
Scholtzstrasse 3
21465 Reinbek
Germany

Further information is available from:
Almirall Limited
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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 Almirall Ltd.