Klisyri®▼ (tirbanibulin) PRESCRIBING INFORMATION

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

Klisyri 10 mg/g ointment

Active Ingredient: Each gram of ointment contains 10 mg of tirbanibulin. Each sachet contains 2.5 mg of tirbanibulin in 250 mg ointment. Excipients with known effects: Propylene glycol 890 mg/g ointment

Indication: Klisyri is indicated for the field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.

Dosage and Administration: Tirbanibulin ointment should be applied to the affected field on the face or scalp once daily for one treatment cycle of 5 consecutive days. A thin layer of ointment should be applied to cover the treatment field of up to 25cm^2. *Consult SmPC and package leaflet for full method of administration.*

Contraindications, Precautions and Warnings:
Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of SmPC. *Precautions:* Contact with the eyes should be avoided. Tirbanibulin ointment may cause eye irritation. In the event of accidental contact with the eyes, the eyes should be rinsed immediately with large amounts of water, and the patient should seek medical care as soon as possible. Tirbanibulin ointment must not be ingested. If accidental ingestion occurs, the patient should drink plenty of water and seek medical care. Tirbanibulin ointment should not be used on the inside of the nostrils, on the inside of the ears, or on the lips. Application of tirbanibulin ointment is not recommended until the skin is healed from treatment with any previous medicinal product, procedure or surgical treatment and should not be applied to open wounds or broken skin where the skin barrier is compromised. Local skin reactions in the treated area, may occur after topical application. Treatment effect may not be adequately assessed until resolution of local skin reactions. Due to the nature of the disease, excessive exposure to sunlight (including sunlamps and tanning beds) should be avoided or minimised. Tirbanibulin ointment should be used with caution in immunocompromised patients. Changes in the appearance of actinic keratosis could suggest progression to invasive squamous cell carcinoma. Propylene glycol may cause skin irritation. *Consult SmPC and package leaflet for more information.*
Fertility, pregnancy and lactation: No human data on the effect of tirbanibulin ointment on fertility are available. Tirbanibulin ointment is not recommended during pregnancy and in women of childbearing potential not using contraception. It is unknown whether tirbanibulin/metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. *Consult SmPC and package leaflet for more information.*

Adverse Reactions: *Very common* (≥1/10)*:* Application site - erythema; exfoliation; scab; swelling; erosion.
Common (≥1/100 to <1/10): Application site - pain, pruritus and vesicles. *Consult SmPC and package leaflet for further information.*

Legal Category:
Ireland: POM
Subject to prescription which may not be renewed (A).
United Kingdom & Northern Ireland: POM

Price:
Ireland: Price to wholesaler
United Kingdom & Northern Ireland: UK NHS Cost: £59.00 (excluding VAT).

Marketing Authorisation Numbers:
Ireland and Northern Ireland: EU/1/21/1558/001
Great Britain: PLGB 16973/0043

Marketing Authorisation Holder:
Almirall, S.A., Ronda General Mitre, 151
08022 Barcelona, Spain

Further information available from:
Almirall Limited, Harman House, 1 George Street, Uxbridge, Middlesex, UB8 1QQ, UK.

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UK and UK(NI)-Adverse events should be reported.
Reporting forms and information can be found at MHRA
https://yellowcard.mhra.gov.uk
Adverse events should be also reported to
Almirall Ltd. Tel. 0800 0087 399

IE-Adverse events should be reported.
Reporting forms and information can be found at HPRA
Website: www.hpra.ie.
Adverse events should be also reported to
Almirall Ltd. Tel. +353 (0) 1431 9836