Tirbanibulin 10mg/g ointment (Klisyri® ▼) SMC2395[1]

The production of this *Guidelines* card has been commissioned by Almirall Ltd.

Tirbanibulin 10mg/g ointment (Klisyri®) SMC2395[1]

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

Advice: following a full submission

Tirbanibulin (Klisyri®) is accepted for use within NHSScotland.

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

In two phase III studies, a greater proportion of adults with actinic keratosis affecting an area of 25cm^2 on the face or scalp achieved complete clearance when treated with tirbanibulin ointment 1% compared with vehicle.

About the SMC

The Scottish Medicines Consortium (SMC) is part of Healthcare Improvement Scotland, the national healthcare improvement organisation for Scotland. SMC reviews new medicines that have received a licence from the Medicines and Healthcare products Regulatory Agency (MHRA – the licensing body for the UK). SMC also reviews new formulations of, and new ways to use, established medicines. Before a medicine can be prescribed routinely in Scotland, it has to be accepted for use by SMC. SMC advice helps the health service plan for the quick, uniform introduction of beneficial treatments across NHSScotland.

Reference

1. Scottish Medicines Consortium. *tirbanibulin 10mg/g ointment (Klisyri®)* SMC2395. SMC, December 2021. www.scottishmedicines.org.uk/medicines-advice/tirbanibulin-klisyri-full-smc2395/

The production of this *Guidelines* summary card has been commissioned by Almirall Ltd. Almirall Ltd has reviewed the card for technical accuracy and regulatory compliance and supplied the prescribing information.
This summary card only displays the concise guidance; readers are strongly advised to refer to the full guidance at:
www.scottishmedicines.org.uk/medicines-advice/tirbanibulin-klisyri-full-smc2395/

IE-KLI-2100009 © MGP Ltd 2021 Date of preparation: December 2021

Prescribing information can be found on the next page.

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.

Date of First Issue: August 2021
Item code: IE-TIRBA-2100011

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 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