For Healthcare Professionals Only

Prescribing Information will be available at this meeting

MF-CTCL ACADEMY

WEBINAR

NOVEMBER

16

16:00-17:00 (UK/RoI Time)

RECORDATI RARE DISEASES GROUP
Focused on the Few™

This webinar meeting is initiated and funded by Recordati Rare Diseases

MF-CTCL patient journeys from diagnosis to treatment: An interactive session on clinical cases

PANEL OF PRESENTERS:

Dr Ulrike WEHKAMP (Germany)
Dr Marco ARDIGO (Italy)

AGENDA

The complexity of the diagnosis	**Dr U. WEHKAMP**
The challenges of therapeutic options	**Dr M. ARDIGO**
Questions & Answers	

If you are interested in attending this meeting please contact Libby Kennedy, Senior Multi Channel Account Manager on behalf of Recordati Rare Diseases: email: Libby.Kennedy@staroutico.com Phone: +44 1225 697095, for virtual meeting registration and joining details

RRDIRE-099-001
October 2021

EMEA-LAC/HQ/PRO/LED/HCP/Aug-21/350

Ledaga® (chlormethine) 160 micrograms/g gel
Please refer to full Summary of Product Characteristics (SmPC) before prescribing

Name of Medicinal Product: Ledaga 160 micrograms/g gel. **Composition:** Each gram of gel contains chlormethine hydrochloride equivalent to 160 micrograms of chlormethine. **Indication:** Ledaga is for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MFtype CTCL) in adult patients. **Dosage and administration** *(adults, including elderly)*: Treatment with Ledaga should be initiated by an appropriately experienced physician. A thin film of Ledaga should be applied once daily to affected areas of the skin. Treatment with Ledaga should be stopped for any grade of skin ulceration or blistering, or moderately severe or severe dermatitis (e.g., marked skin redness with oedema). Upon improvement, treatment with Ledaga can be restarted at a reduced frequency of once every 3 days. If reintroduction of treatment is tolerated for at least 1 week, the frequency of application can be increased to every other day for at least 1 week and then to once daily application if tolerated. Ledaga is for topical application to the skin. Instructions for use should be followed carefully by patients or caregivers when applying Ledaga. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions for use:** Contact with mucous membranes, especially those of the eyes, must be avoided. Exposure of mucous membranes such as the oral mucosa or nasal mucosa causes pain, redness, and ulceration, and these may be severe. Exposure of the eyes to chlormethine causes pain, burns, inflammation, photophobia, and blurred vision. Blindness and severe irreversible anterior eye injury may occur. Patients should be advised of action to be taken if any mucous membrane exposure occurs. Patients should be assessed during treatment for skin reactions such as dermatitis (e.g., redness, swelling, inflammation), pruritus, blisters, ulceration, and skin infections. The face, genitalia, anus, and intertriginous skin are at increased risk of skin reactions to topical chlormethine. For dose modification information in case of skin reactions, refer to SmPC. Skin-directed therapies for MF-type CTCL have been associated with secondary skin cancers, although the specific contribution of chlormethine has not been established. Patients should be monitored for development of skin cancers during and after discontinuation of treatment with chlormethine. Direct skin contact with Ledaga should be avoided in individuals other than the patient. Risks of secondary exposure may include skin reactions, mucosal injury, and skin cancers. Recommended application instructions should be followed to prevent secondary exposure. The medicinal product contains propylene glycol and butylhydroxytoluene, which may cause skin irritation (e.g., contact dermatitis). In addition, butylhydroxytoluene has been reported to cause irritation to the eyes and mucous membranes. **Fertility, pregnancy and lactation:** Ledaga is not recommended in women of childbearing potential not using contraception, nor for use during pregnancy. A decision must be made whether to discontinue breast-feeding or to discontinue Ledaga therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the breast-feeding mother. **Side effects:** *Very common (≥ 1/10);* Dermatitis, skin infections, pruritus. *Common (≥ 1/100 to < 1/10);* Hypersensitivity, skin ulceration and blistering, skin hyperpigmentation. **Please consult the full SmPC for further information**. **Marketing Authorisation Numbers:** EU/1/16/1171/001. **Legal Classification**: POM. **Price:** 60g tube £1000.00. **Name and Address of the Business Responsible for Sale**: Recordati Rare Diseases UK Ltd., Origin, Western Road, Bracknell RG12 1US. Further information is available on request. **Date Prescribing Information Revised**: October 2020. OEUK-LED-001-V2

Adverse events should be reported. Reporting forms and information can be found at (UK) www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. (Ireland) Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance www.hpra.ie. Adverse events should also be reported to Recordati Rare Diseases at Tel: +44 (0) 1491 414 333 or RRDpharmacovigilance@recordati.com