PRESCRIBING INFORMATION
Zyclara 3.75% cream
(Imiquimod)
Please refer to Summary of Product Characteristics (SmPC) before prescribing**.**

Indications: Zyclara is indicated for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate.
Presentation: Each sachet contains 9.375 mg of imiquimod in 250 mg cream (3.75%.) Each gram of cream contains 37.5 mg of imiquimod.
Dosage and administration: Apply up to 2 sachets, once daily, before bedtime to the skin of the affected treatment area for two treatment cycles of 2 weeks each separated by a 2-week no-treatment cycle or as directed by the physician. The treatment area is the full face or balding scalp. A transient increase in actinic keratosis counts may be observed during treatment. Treatment should be continued for the full treatment course even if all actinic keratosis appear to be gone. Response to therapy has to be determined after regeneration of the treated skin. Lesions that do not respond completely after the second treatment cycle should be carefully re-evaluated and one additional 2-week treatment of Zyclara may be considered.Local skin reactions in the treatment area are in part anticipated and common due to its mode of action. A rest period of several days may be taken if required by the patient's discomfort or severity of the local skin reaction. The safety and efficacy of imiquimod in AK in children and adolescents below the age of 18 years have not been established. Patients with hepatic or renal impairment should be monitored under the close supervision of an experienced physician. For external use only. Contact with eyes, lips, and nostrils should be avoided. The treatment area should not be bandaged or otherwise occluded. Once daily before bedtime apply as a thin film to the entire treatment area and rub in until the cream vanishes. Leave on the skin for approximately 8 hours; during this period, showering and bathing should be avoided. Before applying the cream, the patient should wash the treatment area with mild soap and water and allow the area to dry thoroughly. This wash process is then repeated after the treatment period is completed. Partially-used sachets should be discarded and not reused. In case a dose is missed, patients should wait until the forthcoming night to apply Zyclara and then continue with the regular schedule. The cream should not be applied more than once daily. Each treatment cycle should not be extended beyond 2 weeks due to missed doses or rest periods.
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Warning and Precautions: Lesions clinically atypical for AK or suspicious for malignancy should be biopsied to determine appropriate treatment. Not recommended until the skin has healed after any previous medicinal products or surgical treatment. Use of sunscreen is encouraged, and patients should minimise or avoid exposure to natural or artificial sunlight. Not recommended for the treatment of AK lesions with marked hyperkeratosis or hypertrophy as seen in cutaneous horns. During therapy and until healed, affected skin is likely to appear noticeably different from normal skin. Local skin reactions are common but generally decrease in intensity during therapy or resolve after cessation of therapy. Rarely, intense local inflammatory reactions including skin weeping or erosion can occur after only a few applications. There is an association between the complete clearance rate and the intensity of local skin reactions. These local skin reactions may be related to the stimulation of local immune response. Imiquimod has the potential to exacerbate inflammatory conditions of the skin. If required by the patient's discomfort or the intensity of the local skin reaction, a rest period of several days may be taken. Treatment can be resumed after the skin reaction has moderated. The intensity of the local skin reactions tend to be lower in the second cycle than in the first treatment cycle. Flu-like systemic signs and symptoms may accompany, or even precede, intense local skin reactions and may include fatigue, nausea, fever, myalgias, arthralgias, and chills. An interruption of dosing or dose adjustment should be considered. Patients with reduced haematologic reserve should be monitored under the close supervision of an experienced physician Patients with cardiac, hepatic or renal impairment were not included in clinical trials. Caution should be exercised in these patients. Use with caution in immunocompromised patients and/or patients with autoimmune conditions and consider balancing the benefit of treatment for these patients with the risk associated either with the possibility of organ rejection or graft-versus-host disease or a possible worsening of their autoimmune condition. Stearyl alcohol and cetyl alcohol may cause local skin reactions. Benzyl alcohol may cause allergic reactions and mild local irritation. Methyl parahydroxybenzoate (E 218), and propyl parahydroxybenzoate (E 216) may cause allergic reactions (possibly delayed).

Interactions with other medicinal products: No interaction studies have been performed. use with caution in patients who are receiving immunosuppressive drugs. Avoid using with any other imiquimod creams in the same treatment area.

Pregnancy and lactation: No data is available on the use of Zyclara during exposed pregnancies or breast feeding and there is no data on the risk to human fertility. Caution should be exercised when prescribing.

Effects on ability to drive and use machines: Zyclara has no or negligible influence on the ability to drive and use machines.

Undesirable effects:

Very common: Skin reactions: erythema, scab, skin exfoliation, skin oedema, skin ulcer, skin hypopigmentation. Application site reactions: erythema, scabbing, skin exfoliation, skin oedema, skin ulcer, skin hypopigmentation, dryness and application site discharge.

Common: Herpes simplex, lymphadenopathy, anorexia, increased blood glucose, insomnia, headache, dizziness, nausea, diarrhoea, vomiting, dermatitis, myalgia, arthralgia, application site reaction, pruritus, pain, swelling, burning, irritation and rash, fatigue, pyrexia, influenza-like illness, pain, chest pain.

Uncommon: Infection, pustules, depression, irritability, conjunctival irritation, eyelid oedema, nasal congestion, pharyngo laryngeal pain, dry mouth, face oedema, abdominal and back pain, pain in extremity. Application site dermatitis, bleeding, papules, paraesthesia, hyperaesthesia, inflammation, scar, skin breakdown, vesicles and warmth, asthenia, chills, lethargy, discomfort, inflammation.

Rare: Exacerbation of autoimmune conditions, remote site dermatologic reaction.

Frequency not known: Skin infection, decreased haemoglobin, decreased white blood cell count, decreased neutrophil count, decreased platelet count, increased hepatic enzyme, alopecia, erythema multiforme, Steven Johnson syndrome, cutaneous lupus erythematosus, skin hypopigmentation.

Legal Category: POM **Marketing Authorisation number:** EU/1/12/783/002

MAH: Viatris Healthcare Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland

NHS price: Pack of 28 sachets £54.75 **Date of revision of prescribing information: June 2024**

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The SmPC for this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm and from Viatris Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com.

Please continue to report suspected adverse drug reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report adverse drug reactions online via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can report via some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) or by calling the Commission on Human Medicines (CHM) free phone line: 0800-731-6789. Adverse reactions/events should also be reported to MAH at e-mail address: pv.uk@viatris.com.