TAKHZYRO® ▼ (lanadelumab) 300 mg solution for injection
PRESCRIBING INFORMATION FOR GREAT BRITAIN (ENGLAND, SCOTLAND, WALES)
Refer to the Summary of Product Characteristics (SmPC) before prescribing
Presentation: Pre-filled syringe (PFS): 300 mg lanadelumab in 2 ml solution.
Indication: Routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients 12 years and older.
Dosage and administration: TAKHZYRO should be initiated under the supervision of a physician experienced in the management of patients with HAE. Posology: The recommended starting dose is 300 mg lanadelumab every 2 weeks. In stably attack-free patients on treatment, a dose reduction of 300 mg lanadelumab every 4 weeks may be considered, especially in patients with low weight. Missed doses: If a dose of TAKHZYRO is missed, the patient should be instructed to administer the dose as soon as possible ensuring at least 10 days between doses. Refer to the SmPC for more information on posology. Method of administration: Subcutaneous administration only.
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Warnings and precautions: Traceability: Name and batch number of the administered product should be clearly recorded. Hypersensitivity: Hypersensitivity reactions have been observed. In the case of a severe hypersensitivity reaction, administration must be stopped immediately, and appropriate treatment initiated. General: TAKHZYRO is not intended for treatment of acute HAE attacks, individualised treatment should be initiated with an approved rescue medication in the event of a breakthrough HAE attack. Interference with coagulation test: Lanadelumab can increase activated partial thromboplastin time (aPTT) due to an interaction of lanadelumab with the aPTT assay, this increase is not associated with bleeding adverse events in treated patients. Sodium: This medicinal product contains less than 1mmol sodium (23 mg) per vial, essentially 'sodium-free'.
Interactions: No dedicated drug-drug interactions have been conducted, based on the characteristics of lanadelumab, no pharmacokinetic interactions with co-administered medicinal products are expected.
Fertility, pregnancy and lactation: As a precaution it is preferable to avoid the use of lanadelumab during pregnancy and in the few days following childbirth. If clinically needed, lanadelumab can be administered during breast-feeding.
Undesirable effects: Very common (≥1/10): Injection site reactions (includes erythema, bruising, discomfort, haematoma, haemorrhage, pruritus, swelling, induration, paraesthesia, reaction, warmth, oedema and rash). Common (≥1/100 to <1/10): Hypersensitivity (includes pruritus, discomfort and tingling of tongue), dizziness, rash maculo-papular, myalgia, alanine and aspartate aminotransferase increased.
Refer to the SmPC for details on full side effect profile and interactions.
UK Basic NHS price: PFS: £12,420. **Legal classification**: POM. **Marketing authorisation number:** PLGB 54937/0020. **Business responsible for sale and supply:** Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom. **PI approval code**: pi-02058.
Date of preparation: June 2022.

▼This medicinal product is subject to additional monitoring. 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 Takeda at: AE.GBR-IRL@takeda.com

TAKHZYRO® ▼ (lanadelumab) 300 mg solution for injection
PRESCRIBING INFORMATION FOR NORTHERN IRELAND
Refer to the Summary of Product Characteristics (SmPC) before prescribing
Presentation: Pre-filled syringe (PFS): 300 mg lanadelumab in 2 ml solution.
Indication: Routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients 12 years and older.
Dosage and administration: TAKHZYRO should be initiated under the supervision of a physician experienced in the management of patients with HAE. Posology: The recommended starting dose is 300 mg lanadelumab every 2 weeks. In stably attack-free patients on treatment, a dose reduction of 300 mg lanadelumab every 4 weeks may be considered, especially in patients with low weight. Missed doses: If a dose of TAKHZYRO is missed, the patient should be instructed to administer the dose as soon as possible ensuring at least 10 days between doses. Refer to the SmPC for more information on posology. Method of administration: Subcutaneous administration only.
Contraindications: Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Traceability: Name and batch number of the administered product should be clearly recorded. Hypersensitivity: Hypersensitivity reactions have been observed. In the case of a severe hypersensitivity reaction, administration must be stopped immediately, and appropriate treatment initiated. General: TAKHZYRO is not intended for treatment of acute HAE attacks, individualised treatment should be initiated with an approved rescue medication in the event of a breakthrough HAE attack. Interference with coagulation test: Lanadelumab can increase activated partial thromboplastin time (aPTT) due to an interaction of lanadelumab with the aPTT assay, this increase is not associated with bleeding adverse events in treated patients. Sodium: This medicinal product contains less than 1mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.
Interactions: No dedicated drug-drug interactions have been conducted, based on the characteristics of lanadelumab, no pharmacokinetic interactions with co-administered medicinal products are expected. **Fertility, pregnancy and lactation:** As a precaution it is preferable to avoid the use of lanadelumab during pregnancy and in the few days following childbirth. If clinically needed, lanadelumab can be administered during breast-feeding.
Undesirable effects: Very common (≥1/10): Injection site reactions (includes pain, erythema, bruising, discomfort, haematoma, haemorrhage, pruritus, swelling, induration, paraesthesia, reaction, warmth, oedema and rash). Common (≥1/100 to <1/10): Hypersensitivity (includes pruritus, discomfort and tingling of tongue), dizziness, maculopapular rash, myalgia, alanine and aspartate aminotransferase increased. **Refer to the SmPC for details on full side effect profile and interactions**.
UK basic NHS price: PFS: £12,420. **Legal classification**: POM. **Marketing authorisation number:** EU/1/18/1340/004. **Business responsible for sale and supply:** Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom. **PI approval code:** pi-02069.
Date of preparation: June 2022.

▼This medicinal product is subject to additional monitoring. 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 Takeda at: AE.GBR-IRL@takeda.com