Adtralza® ▼ (tralokinumab) Prescribing Information for the United Kingdom

Prescribing Information for Adtralza® ▼ (tralokinumab) 150 mg solution for injection in pre-filled syringe and Adtralza® ▼ (tralokinumab) 300 mg solution for injection in pre-filled pen

Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.org.uk/emc) before prescribing.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. **Indications:** Treatment of moderate-to-severe atopic dermatitis in adult and adolescent patients 12 years and older who are candidates for systemic therapy. **Active ingredients:** Each pre-filled syringe contains 150 mg of tralokinumab in 1 mL solution (150 mg/mL). Each pre-filled pen contains 300 mg of tralokinumab in 2 mL solution (150 mg/mL). **Dosage and administration:** *Posology:* The recommended dose of tralokinumab for adult and adolescent patients 12 years and older is an initial dose of 600 mg (four 150 mg injections by pre-filled syringe or two 300 mg injections by pre-filled pen) followed by 300 mg (two 150 mg injections by pre-filled syringe or one 300 mg injection by pre-filled pen) administered every other week as subcutaneous injection. Every fourth week dosing may be considered for patients who achieve clear or almost clear skin after 16 weeks of treatment. The probability of maintaining clear or almost clear skin may be lower with every fourth week dosing. Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment. Some patients with initial partial response may subsequently improve further with continued treatment every other week beyond 16 weeks. Tralokinumab can be used with or without topical corticosteroids. The use of topical corticosteroids, when appropriate, may provide an additional effect to the overall efficacy of tralokinumab. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas. *Missed dose:* If a dose is missed, the dose should be administered as soon as possible and then dosing should be resumed at the regular scheduled time. *Special populations:* No dose adjustment is recommended for elderly patients, patients with renal impairment or patients with hepatic impairment. For patients with high body weight (>100 kg), who achieve clear or almost clear skin after 16 weeks of treatment, reducing the dosage to every fourth week might not be appropriate. The safety and efficacy of tralokinumab in children below the age of 12 years have not yet been established. *Method of administration:* Subcutaneous use. The pre-filled syringe and pen should not be shaken. After removing the pre-filled syringes or pre-filled pens from the refrigerator, they should be allowed to reach room temperature by waiting for 30 minutes before injecting a pre-filled syringe or 45 minutes before injecting a pre-filled pen. Tralokinumab is administered by subcutaneous injection into the thigh or abdomen, except the 5 cm around the navel. If somebody else administers the injection, the upper arm can also be used. For the initial 600 mg dose, four 150 mg tralokinumab injections or two 300 mg tralokinumab injections, should be administered consecutively in different injection sites within the same body area. It is recommended to rotate the injection site with each dose. Tralokinumab should not be injected into skin that is tender, damaged or has bruises or scars. A patient may self-inject tralokinumab or the patient's caregiver may administer tralokinumab if their healthcare professional determines that this is appropriate. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** If a systemic hypersensitivity reaction (immediate or delayed) occurs, administration of tralokinumab should be discontinued and appropriate therapy initiated. Patients treated with tralokinumab who develop conjunctivitis that does not resolve following standard treatment should undergo ophthalmological examination. Patients with pre-existing helminth infections should be treated before initiating treatment with tralokinumab. If patients become infected while receiving tralokinumab and do not respond to antihelminth treatment, treatment with tralokinumab should be discontinued until infection resolves. Live and live attenuated vaccines should not be given concurrently with tralokinumab. **Interactions:** See SmPC for full details on interactions. **Fertility, pregnancy and lactation:** There is limited data from the use of tralokinumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of tralokinumab during pregnancy. It is unknown whether tralokinumab is excreted in human milk or absorbed systemically after ingestion. Animal studies did not show any effects on male and female reproductive organs and on sperm count, motility and morphology. **Side effects:** *Very common (≥1/10):* Upper respiratory tract infections. *Common (≥1/100 to <1/10):* conjunctivitis, conjunctivitis allergic, eosinophilia, injection site reaction. Please see SmPC for full list of side effects. **Precautions for storage:** Store in a refrigerator (2°C-8°C). Do not freeze. Store in the original package in order to protect from light. **Legal category:** POM. **Marketing authorisation number and holder:** *Pre-filled syringe:* PLGB 05293/0182, EU/1/21/1554/002. *Pre-filled pen:* PLGB 05293/0189, EU/1/21/1554/004. LEO Pharma A/S, Ballerup, Denmark. **Basic NHS price:** *4 pre-filled syringes:* £1,070 (each syringe contains 150 mg of tralokinumab in 1 mL solution (150 mg/mL)). *2 pre-filled pens:* £1,070 (each pen contains 300 mg of tralokinumab in 2 mL solution (150 mg/mL)). **Last revised:** January 2024. **Reference number**: MAT-70774.

Reporting of Suspected Adverse Reactions

Adverse events should be reported.

Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow card in the Google Play or Apple App Store.

Adverse events should also be reported to Drug Safety at LEO Pharma by calling +44 (0)1844 347333 or e-mail: medical-info.uk@leo-pharma.com

Further information can be found in the Summary of Product Characteristics or from:
LEO Pharma, Building 5, Foundation Park, Roxborough Way, Maidenhead, Berkshire SL6 3UD, UK.
e-mail: medical-info.uk@leo-pharma.com

Date of preparation: January 2024
UK/IE MAT-70675

Adtralza®▼(tralokinumab) Prescribing Information for the Republic of Ireland

Prescribing Information for Adtralza®▼(tralokinumab) 150 mg solution for injection in pre-filled syringe and Adtralza®▼(tralokinumab) 300 mg solution for injection in pre-filled pen

Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.ie) before prescribing.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. **Indications:** Treatment of moderate-to-severe atopic dermatitis in adult and adolescent patients 12 years and older who are candidates for systemic therapy. **Active ingredients:** Each pre-filled syringe contains 150 mg of tralokinumab in 1 mL solution (150 mg/mL). Each pre-filled pen contains 300 mg of tralokinumab in 2 mL solution (150 mg/mL). **Dosage and administration:** *Posology:* The recommended dose of tralokinumab for adult and adolescent patients 12 years and older is an initial dose of 600 mg (four 150 mg injections by pre-filled syringe or two 300 mg injections by pre-filled pen) followed by 300 mg (two 150 mg injections by pre-filled syringe or one 300 mg injection by pre-filled pen) administered every other week as subcutaneous injection. Every fourth week dosing may be considered for patients who achieve clear or almost clear skin after 16 weeks of treatment. The probability of maintaining clear or almost clear skin may be lower with every fourth week dosing. Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment. Some patients with initial partial response may subsequently improve further with continued treatment every other week beyond 16 weeks. Tralokinumab can be used with or without topical corticosteroids. The use of topical corticosteroids, when appropriate, may provide an additional effect to the overall efficacy of tralokinumab. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas. *Missed dose:* If a dose is missed, the dose should be administered as soon as possible and then dosing should be resumed at the regular scheduled time. *Special populations:* No dose adjustment is recommended for elderly patients, patients with renal impairment or patients with hepatic impairment. For patients with high body weight (>100 kg), who achieve clear or almost clear skin after 16 weeks of treatment, reducing the dosage to every fourth week might not be appropriate. The safety and efficacy of tralokinumab in children below the age of 12 years have not yet been established. *Method of administration:* Subcutaneous use. The pre-filled syringe and pen should not be shaken. After removing the pre-filled syringes or pre-filled pens from the refrigerator, they should be allowed to reach room temperature by waiting for 30 minutes before injecting a pre-filled syringe or 45 minutes before injecting a pre-filled pen. Tralokinumab is administered by subcutaneous injection into the thigh or abdomen, except the 5 cm around the navel. If somebody else administers the injection, the upper arm can also be used. For the initial 600 mg dose, four 150 mg tralokinumab injections or two 300 mg tralokinumab injections, should be administered consecutively in different injection sites within the same body area. It is recommended to rotate the injection site with each dose. Tralokinumab should not be injected into skin that is tender, damaged or has bruises or scars. A patient may self-inject tralokinumab or the patient's caregiver may administer tralokinumab if their healthcare professional determines that this is appropriate. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** If a systemic hypersensitivity reaction (immediate or delayed) occurs, administration of tralokinumab should be discontinued and appropriate therapy initiated. Patients treated with tralokinumab who develop conjunctivitis that does not resolve following standard treatment should undergo ophthalmological examination. Patients with pre-existing helminth infections should be treated before initiating treatment with tralokinumab. If patients become infected while receiving tralokinumab and do not respond to antihelminth treatment, treatment with tralokinumab should be discontinued until infection resolves. Live and live attenuated vaccines should not be given concurrently with tralokinumab. **Interactions:** See SmPC for full details on interactions. **Fertility, pregnancy and lactation:** There is limited data from the use of tralokinumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of tralokinumab during pregnancy. It is unknown whether tralokinumab is excreted in human milk or absorbed systemically after ingestion. Animal studies did not show any effects on male and female reproductive organs and on sperm count, motility and morphology. **Side effects:** *Very common (≥1/10):* Upper respiratory tract infections. *Common (≥1/100 to <1/10):* conjunctivitis, conjunctivitis allergic, eosinophilia, injection site reaction. Please see SmPC for full list of side effects. **Precautions for storage:** Store in a refrigerator (2°C-8°C). Do not freeze. Store in the original package in order to protect from light. **Legal category:** POM. **Marketing authorisation number and holder:** *Pre-filled syringe:* EU/1/21/1554/002. *Pre-filled pen:* EU/1/21/1554/004. LEO Pharma A/S, Ballerup, Denmark. **Last revised:** January 2024. **Reference number:** MAT-70775.

Reporting of Suspected Adverse Reactions

Adverse events should be reported.

Reporting forms and information can be obtained from:
HPRA Pharmacovigilance, Website: www.hpra.ie

Adverse events should also be reported to Drug Safety at LEO Pharma by calling +353 1 4908924 or e-mail medical-info.ie@leo-pharma.com

Further information can be found in the Summary of Product Characteristics or from:
LEO Pharma, Cashel Road, Dublin 12, Ireland. e-mail: medical-info.ie@leo-pharma.com
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