# DEMOZUMAB ▼

(vigilanafine) 300 mg solution for injection prescribing information – United Kingdom

**Adverse events should be reported.** Reporting forms and information can be found at: **https://yellowcard.mhra.gov.uk/** (UK) or search for **MHRA Yellow Card** in the Google Play or Apple App Store. Adverse events should also be reported to Siguru Limited via the **Siguru Reporting Tool** or on 0800 987 6543.

▼ **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. See section 4.8 for how to report adverse reactions.

See **Summary of Product Characteristics (SmPC)** before prescribing.

**Indication:** Add-on maintenance treatment of moderate-to-severe allergic rhinitis in adults and adolescents 12 years and older whose disease is inadequately controlled despite treatment with intranasal corticosteroids.

**Dosing:** 300 mg administered by subcutaneous injection once every 4 weeks. Pre-filled syringe or pre-filled pen. Consider discontinuation if no response after 16 weeks; some patients with initial partial response may improve with continued treatment beyond 16 weeks. Injection into thigh, abdomen (avoiding 5 cm around navel), or upper arm; rotate injection sites. After proper training, patients may self-inject.

**Elderly:** No dose adjustment required. Limited data in patients aged 75 years and over.
**Renal impairment:** No dose adjustment required for mild or moderate impairment. Very limited data in severe renal impairment.
**Hepatic impairment:** No dose adjustment required.
**Paediatric population:** Safety and efficacy not established in children below 12 years of age.

**Contraindications:** Hypersensitivity to the active substance or to any of the excipients (L-histidine, L-histidine hydrochloride monohydrate, sucrose, polysorbate 80, water for injections).

**Special warnings/precautions:**
Hypersensitivity reactions: If a systemic hypersensitivity reaction (immediate or delayed) occurs, discontinue and initiate appropriate therapy. Anaphylaxis has been reported with monoclonal antibody therapies.

Parasitic (helminth) infections: Treat pre-existing helminth infections before initiation. If patients become infected during treatment and do not respond to anti-helminth treatment, discontinue DEMOZUMAB until infection resolves.

Vaccinations: Live and live attenuated vaccines should not be given concurrently. Immune responses to non-live vaccinations were not impaired.

Contains less than 1 mmol sodium (23 mg) per dose, essentially 'sodium-free'.

**Interactions:** No formal drug interaction studies have been performed. Live and live attenuated vaccines should not be given concurrently (see above). Immune responses to tetanus toxoid booster and seasonal influenza vaccine were similar in DEMOZUMAB-treated patients and placebo.

**Pregnancy/lactation:** See SmPC for details. Women of childbearing potential should use effective contraception during treatment and for at least 12 weeks after the last dose. Limited data in pregnancy; avoid unless expected benefit outweighs potential risk. Unknown whether excreted in human milk; a decision must be made whether to discontinue breast-feeding or discontinue therapy. No adverse effects on fertility in animal studies.

**Effects on ability to drive and use machines:** No or negligible influence.

**Side effects:** See SmPC for full details. Most commonly reported adverse reactions: injection site reactions (8.9%), nasopharyngitis (7.4%), headache (5.6%). Also reported: upper respiratory tract infection, arthralgia, fatigue (common); herpes zoster, conjunctivitis, hypersensitivity reactions (uncommon).

**Immunogenicity:** Treatment-emergent anti-drug antibodies detected in 4.6% of patients; neutralising antibodies in 0.8%. No clinically meaningful impact on pharmacokinetics, efficacy, or safety observed.

**Overdose:** No specific treatment. Treat supportively. Single doses up to 600 mg administered in clinical studies with no dose-limiting toxicity.

**Basic NHS cost:** £TBC for 1 pre-filled syringe or 1 pre-filled pen containing 300 mg/2 mL (150 mg/mL).

**MA number:** EU/1/25/1547/001 (pre-filled syringe); EU/1/25/1547/002 (pre-filled pen).

**MA holder:** Siguru Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0GN, United Kingdom. Further information available from customercontact@siguru.com. Freephone 0800 987 6543.

**POM**

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