Prescribing Information: Dupixent (dupilumab) solution for injection in a pre-filled syringe or pen (Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP))

Please refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentations: Dupixent 300 mg, solution for injection in pre-filled pen or syringe, containing 300 mg dupilumab in 2 ml solution (150 mg/ml).

Indication: Dupixent is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adults with severe chronic rhinosinusitis with nasal polyposis (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Dosage and Administration: Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of conditions for which Dupixent is indicated. Dupixent should be administered as subcutaneous (SC) injection, into the thigh or abdomen, except for the 5 cm around the navel. The upper arm can be used if not self-administered. The recommended dose is an initial dose of 300 mg followed by 300 mg given every other week. Dupixent is intended for long-term treatment. Consideration should be given to discontinuing treatment in patients who have shown no response after 24 weeks of treatment for CRSwNP. Some patients with initial partial response may subsequently improve with continued treatment beyond 24 weeks. ***Missed dose:*** See SmPC for more information on missed dose.

Special populations: ***Elderly (≥ 65 years):*** No dose adjustment recommended. ***Renal impairment***: No dose adjustment in patients with mild or moderate renal impairment. Very limited data available in patients with severe renal impairment. ***Hepatic impairment:*** No data available. ***Paediatric population <6 months:*** The safety and efficacy of Dupixent in children below the age of 6 months or a body weight < 5 kg have not been established.***<18 years:*** The safety and efficacy of Dupixent in children with CRSwNP below the age of 18 years have not been established. ***Method of administration:*** The Dupixent pre-filled pen is for use in adult and paediatric patients aged 2 years and older. The Dupixent pre-filled syringe is for use in adult and paediatric patients aged 6 months and older.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions: ***Acute asthma exacerbations:*** Dupixent should not be used to treat acute asthma symptoms or acute exacerbations. Dupixent should not be used to treat acute bronchospasm or status asthmaticus. ***Corticosteroids:*** Systemic, topical, or inhaled corticosteroids should not be discontinued abruptly upon initiation of therapy with Dupixent. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy. ***Hypersensitivity:*** If a systemic hypersensitivity reaction (immediate or delayed) occurs, administration of Dupixent should be discontinued immediately and appropriate therapy initiated. Cases of anaphylactic reaction, angioedema and serum sickness/serum sickness-like reaction have been reported. Anaphylactic reactions and angioedema have occurred from minutes to up to seven days after the Dupixent injection. ***Eosinophilic conditions:*** Cases of eosinophilic pneumonia and vasculitis, consistent with eosinophilic granulomatosis with polyangiitis (EGPA) have been reported. Physicians should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients with eosinophilia. Often these conditions are treated with systemic corticosteroid therapy. These events usually, but not always, may be associated with the reduction of oral corticosteroid therapy. ***Helminth infection:*** Patients with pre-existing helminth infections should be treated before initiating Dupixent. If patients become infected while receiving treatment with Dupixent and do not respond to anti-helminth treatment, treatment with Dupixent should be discontinued until infection resolves. ***Conjunctivitis, dry eye and keratitis related events:*** Patients should be advised to report new onset or worsening eye symptoms to their healthcare provider. Patients treated with Dupixent who develop conjunctivitis that does not resolve following standard treatment or signs and symptoms suggestive of keratitis should undergo ophthalmological examination, as appropriate. ***Patients with comorbid asthma:*** Patients on Dupixent who also have co-morbid asthma, should not adjust or stop their asthma treatments without consultation with their physicians. Patients with comorbid asthma should be monitored carefully following discontinuation of Dupixent. ***Vaccinations:*** Live and live-attenuated vaccines should not be given concurrently with Dupixent as clinical safety and efficacy has not been established. ***Interactions:*** Patients receiving Dupixent may receive concurrent inactive or non-live vaccinations. ***Fertility, pregnancy and lactation:*** Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. There are limited data from the use of Dupixent in pregnant women. Dupixent should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. It is unknown whether Dupixent is excreted in human milk or absorbed systemically after ingestion.

Adverse effects: ***Common (≥1/100 to <1/10):*** Arthralgia, conjunctivitis, conjunctivitis allergic, eosinophilia, injection site reactions (erythema, oedema, pruritis, pain, swelling and bruising), oral herpes. ***Uncommon (≥ 1/1,000 to < 1/100):*** Angioedema, blepharitis, dry eye, eye pruritis, facial rash, keratitis. ***Rare (≥ 1/10,000 to < 1/1,000):*** Anaphylactic reaction, serum sickness reaction, serum sickness-like reaction, ulcerative keratitis. Eye disorders and oral herpes occurred predominately in atopic dermatitis studies. The frequencies for eye pruritus, blepharitis, and dry eye were common and ulcerative keratitis was uncommon in atopic dermatitis studies. ***Serious adverse reactions:*** eczema herpeticum, infections and immunogenicity have also been reported. Prescribers should consult the SmPC in relation to other adverse reactions.

Legal Classification: POM. **List Prices UK:** 2 x pre-filled syringes or pens: £1,264.89**. Marketing Authorisation Holder:** Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. **Marketing Authorisation Numbers**: 2 x 300 mg pre-filled syringe: PLGB 04425/0820; 2 x 300 mg pre-filled pen: PLGB 04425/0771. **Further information is available from:** Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com. **Date of preparation**: June 2024. **Document Number:** MAT-XU-2300829 (v2.0)

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 the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com