Prescribing Information: Dupixent (dupilumab) solution for injection in a pre-filled syringe or pen (Asthma)
Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentations: Dupixent 200 mg solution for injection in a pre-filled syringe or pen, containing 200 mg of dupilumab in 1.14 ml solution (175 mg/ml) or Dupixent 300 mg solution for injection in a pre-filled syringe or pen, containing 300 mg of dupilumab in 2 ml solution (150 mg/ml).
Indication: Dupixent is indicated in adults and adolescents (>12 years old) as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment. Dupixent is indicated in children 6 to 11 years old as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.
Dosage and Administration: Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of asthma. 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. Dupixent can be used with or without topical corticosteroids. ***Adults and adolescents:*** an initial dose of 400 mg (two 200 mg injections), followed by 200 mg every other week (EOW). ***Children 6 to 11 years of age with body weight 15 kg to < 30 kg:*** 300 mg every four weeks (Q4W). ***Children 6 to 11 years of age with body weight 30 kg to < 60 kg:*** 200 mg EOW or 300 mg Q4W. ***Children 6 to 11 years of age with body weight ≥ 60 kg:*** 200 mg EOW. Children 6 to 11 years of age with asthma and co-morbid severe atopic dermatitis should follow the recommended dose as per the approved atopic dermatitis indication. ***Patients with severe asthma, who are on oral corticosteroids or, have co-morbid moderate-to-severe atopic dermatitis, or adults with co-morbid severe chronic rhinosinusitis with nasal polyposis:*** an initial dose of 600 mg (two 300 mg injections consecutively in different injection sites), followed by 300 mg EOW. Patients receiving concomitant oral corticosteroids may reduce their steroid dose once clinical improvement with dupilumab has occurred. Steroid reductions should be accomplished gradually. Dupilumab is intended for long-term treatment. The need for continued therapy should be considered at least on an annual basis as determined by physician assessment of the patient's level of asthma control. ***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:* The safety and efficacy of dupilumab in children with severe asthma below the age of 6 years have not been established.
Method of administration: The dupilumab pre-filled pen is not intended for use in children below 12 years of age.
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Warnings and Precautions: ***Acute asthma exacerbations:*** Dupilumab should not be used to treat acute asthma symptoms, acute exacerbations, acute bronchospasm or status asthmaticus. ***Corticosteroids:*** Systemic, topical, or inhaled corticosteroids should not be discontinued abruptly upon initiation of therapy with dupilumab. 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. Biomarkers of type 2 inflammation may be suppressed by systemic corticosteroid use. This should be taken into consideration to determine type 2 status in patients taking oral corticosteroids. ***Hypersensitivity:*** If a systemic hypersensitivity reaction (immediate or delayed) occurs, administration of Dupixent should be discontinued immediately and appropriate therapy initiated. Anaphylactic reactions and angioedema have occurred from minutes to up to seven days. ***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. Patients may present with serious systemic eosinophilia sometimes presenting with clinical features of eosinophilic pneumonia or vasculitis consistent with eosinophilic granulomatosis with polyangiitis. 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 promptly report new onset or worsening eye symptoms to their healthcare provider. Sudden changes in vision or significant eye pain that does not settle warrant urgent review. Patients treated with Dupixent who develop conjunctivitis or dry eye 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 dupilumab who also have comorbid 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:*** Concurrent use of live and live attenuated vaccines with dupilumab should be avoided as clinical safety and efficacy have 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 Reactions: ***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 predominantly in atopic dermatitis studies. ***Serious adverse reactions:*** eczema herpeticum and immunogenicity have also been reported. ***Adolescents (12-17 years):*** The safety profile of Dupixent in adolescents aged 12-17 years

followed through week 52 and through a long-term study was similar to the safety profile from studies in adults with asthma. ***Children (6-11 years):*** the additional adverse reaction of enterobiasis was reported in 1.8% in the dupilumab groups and none in the placebo group. All enterobiasis cases were mild to moderate and patients recovered with anti-helminth treatment without dupilumab treatment discontinuation. Eosinophilia (blood eosinophils ≥ 3,000 cells/mcL or deemed by the investigator to be an adverse event) was reported in 6.6% of the dupilumab groups and 0.7% in the placebo group. Most eosinophilia cases were mild to moderate and not associated with clinical symptoms. These cases were transient, decreased over time, and did not lead to dupilumab treatment discontinuation. Prescribers should consult the SmPC in relation to other adverse reactions.

Legal Classification: POM. **List Price:** 4 week pack containing 2 x pre-filled syringes or pens: £1,264.89. **Marketing Authorisation Holder:** Sanofi Genzyme, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. **Marketing Authorisation Numbers**: 2 x 200 mg pre-filled syringe: PLGB 04425/0874; 2 x 300 mg pre-filled syringe: PLGB 04425/0820. 2 x 200 mg pre-filled pen: PLGB 04425/0875; 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**: February 2024. **Document Number:** MAT-XU-2400390 (v1.0)

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 UKdrugsafety@sanofi.com

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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:* The safety and efficacy of dupilumab in children with severe asthma below the age of 6 years have not been established. ***Method of administration:*** The dupilumab pre-filled pen is not intended for use in children below 12 years of age.
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adults with asthma. ***Children (6-11 years):*** the additional adverse reaction of enterobiasis was reported in 1.8 % in the dupilumab groups and none in the placebo group. All enterobiasis cases were mild to moderate and patients recovered with anti-helminth treatment without dupilumab treatment discontinuation. eosinophilia (blood eosinophils ≥ 3,000 cells/mcL or deemed by the investigator to be an adverse event), was reported in 6.6 % of the dupilumab groups and 0.7% in the placebo group. Most eosinophilia cases were mild to moderate and not associated with clinical symptoms. These cases were transient, decreased over time, and did not lead to dupilumab treatment discontinuation. Prescribers should consult the SPC in relation to other adverse reactions.

Legal Classification: POM. **List Price:** ***NI:*** 4 week pack containing 2 x pre-filled syringes or pens: £1,264.89. ***IE:*** Price on application. **Marketing Authorisation Holder:** Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France. **Marketing Authorisation Numbers**: 2 x 200 mg pre-filled syringe: EU/1/17/1229/010; 2 x 300 mg pre-filled syringe: EU/1/17/1229/006. 2 x 200 mg pre-filled pen: EU/1/17/1229/014; 2 x 300 mg pre-filled pen: EU/1/17/1229/018. **Further information is available from: *NI*:** Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com. ***IE:*** Sanofi, 18 Riverwalk, Citywest Business Campus, Dublin 24 or contact IEmedinfo@sanofi.com. **Date of Preparation**: January 2024. **Document number:** MAT-IE-2400005(v1.0).

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