Prescribing Information: Dupixent (dupilumab) solution for injection in a pre-filled syringe or pen (Atopic Dermatitis and Prurigo Nodularis)

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).

Indications: Dupixent is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. Dupixent is indicated for the treatment of severe atopic dermatitis in children 6 months to 11 years old who are candidates for systemic therapy. Dupixent is indicated for the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy.

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. Dupixent can be used with or without topical corticosteroids. ***Adults:*** the recommended initial dose of Dupixent is 600 mg (two 300 mg injections), followed by 300 mg given every other week (EOW). ***Adolescents (12-17 years) with body weight <60 kg:*** the recommended initial dose of Dupixent is 400 mg (two 200 mg injections), followed by 200 mg EOW. ***Adolescents (12-17 years) with body weight ≥60 kg:*** the recommended initial dose of Dupixent is 600 mg (two 300 mg injections) followed by 300 mg EOW. ***Children 6 to 11 years of age with body weight 15 kg to <60 kg:*** the recommended initial dose of Dupixent is 300 mg on Day 1, followed by 300 mg on Day 15. Subsequent doses of 300 mg every 4 weeks (Q4W) starting 4 weeks after Day 15 dose. The dose may be increased to 200mg EOW in these patients based on physician's assessment. ***Children 6 to 11 years of age with body weight ≥ 60 kg:*** the recommended initial dose of Dupixent is 600 mg (two 300 mg injections), followed by 300 mg EOW. ***Children 6 months to 5 years of age with body weight of 5 kg to <15 kg:*** the recommended initial dose of Dupixent is 200 mg (one 200 mg injection). Followed by subsequent doses 200mg every 4 weeks (Q4W). ***Children 6 months to 5 years of age with body weight of 15kg to less than 30kg:*** the recommended initial dose of Dupixent is 300mg (one 300 mg injection). Followed by subsequent doses of 300 mg every 4 weeks (Q4W).

Adults (with PN): The recommended dose of Dupixent for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week. Dupixent can be used with or without topical corticosteroids. ***Missed dose:*** See SmPC for more information on missed dose.

Special populations: ***Elderly patients (⩾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 PN 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. The Dupixent pre-filled pen is not intended for use in children below 2 years of age.

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

Warnings and Precautions: ***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. Anaphylactic reactions and angioedema have occurred from minutes up to seven days post injection. ***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. ***Comorbid asthma:*** Patients with 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 Dupixent 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 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 Price:** ***NI*****:** 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**: May 2024. **Document number:** MAT-IE-2400127 (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 UK-drugsafety@sanofi.com
In Ireland: www.hpra.ie email: medsafety@hpra.ie Adverse events should also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600. Alternatively, send via email to IEPharmacovigilance@sanofi.com