**Dupixent (Dupilumab) Abbreviated Prescribing Information**

**1) Name and Presentation: Dupixent (Dupilumab) 300 mg Solution for injection in pre-filled syringe and pre-filled pen**. **2) Therapeutic indications Atopic Dermatitis**: 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. **Prurigo Nodularis** Dupixent is indicated for the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy. **Asthma** Dupixent is indicated in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose 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 characterized by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment**. Chronic Rhinosinusitis with nasal polyps (CRSwNP)** Dupixent is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adults with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control. **Eosinophilic Esophagitis:** is indicated for the treatment of eosinophilic esophagitis in adults and adolescents 12 years and older, weighing at least 40 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy. **3) Name and Presentation: Dupixent (Dupilumab) 200 mg Solution for injection in pre-filled syringe and pre-filled pen 4) Therapeutic indications**: **Atopic Dermatitis**: 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. **Asthma** Dupixent is indicated in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose 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 characterized by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), see section 5.1, who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment **5) Posology and Method of administration:** Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment for which dupilumab is indicated**. 6) Posology: Atopic Dermatitis:** The recommended dose of dupilumab for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week administered as subcutaneous injection. The recommended dose of dupilumab for adolescent **patients 12 to 17 years of age**: •Body Weight of Patient less than 60 kg is an initial dose of 400 mg (two 200 mg injections), followed by 200 mg given every other week administered as subcutaneous injection• Body Weight of Patient 60 kg or more is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week administered as subcutaneous injection. The recommended dose of dupilumab for **Children 6 to 11 years patients:** •Body Weight of Patient 15 kg to less than 60 kg is an initial dose of 300 mg (one 300 mg injection) on Day 1, followed by 300 mg on Day 15, with subsequent doses of 300 mg every 4 weeks (Q4W)*, starting 4 weeks after Day 15 dose, (*the dose may be increased to 200 mg Q2W in patients with body weight of 15 kg to less than 60 kg based on physician's assessment). • Body Weight of Patient 60 kg or more is an initial dose of 600 mg (two 300 mg injections) followed by 300 mg every other week (Q2W) administered as subcutaneous injection **Children 6 months to 5 years patients:** •Body weight of patient 5 kg to less than 15 kg is an initial dose of 200 mg followed by 200 mg every 4 weeks (Q4W) •Body weight of patient 15 kg to less than 30 kg is an initial dose of 300 mg followed by 300 mg every 4 weeks (Q4W). Dupilumab can be used with or without topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas. Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment for atopic dermatitis. Some patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks. If dupilumab treatment interruption becomes necessary, patients can still be successfully re-treated**. Prurigo Nodulari**s: The recommended dose of dupilumab for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.

Dupilumab can be used with or without topical corticosteroids. PN clinical trial data are available for patients treated up to 24 weeks. Consideration should be given to discontinuing treatment in patients who have shown no response after 24 weeks of treatment for PN. **Asthma**: The recommended dose of dupilumab for adults and adolescents (12 years of age and older) is: • For patients with severe asthma and who are on oral corticosteroids or for patients with severe asthma and co-morbid moderate-to-severe atopic dermatitis, an initial dose of 600 mg (two 300 mg injections), followed by 300 mg every other week administered as subcutaneous injection. • For all other patients, an initial dose of 400 mg (two 200 mg injections), followed by 200 mg every other week administered as subcutaneous injection. 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. **Pediatric Asthma**: The recommended dose of dupilumab for pediatric patients 6 to 11 years of age for subcutaneous administration, Body Weight of Patient 15 kg to less than 30 kg is an Initial and subsequent dose 100mg every other week (Q2W) or 300 mg every four week (Q4W), For 30 kg to less than 60 kg is an Initial and subsequent dose 200 mg every other week (Q2W) or 300 mg every four weeks (Q4W),For 60 Kg or more is an Initial and subsequent dose 200 mg every other week (Q2W) , For pediatric patients (6 to 11 years old) with asthma and co-morbid severe atopic dermatitis, as per approved indication, the recommended dose should be followed Pediatric Atopic Dermatitis dosing. For patients with ***CRSwNP*** the recommended dose of dupilumab for adult patients is an initial dose of 300 mg followed by 300 mg given every other week. Dupilumab 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**. Eosinophilic Esophagitis:** The recommended dose of dupilumab for patients 12 years of age and older is 300 mg given every week (QW). Dupilumab 300 mg QW has not been studied in patients with EoE weighing less than 40 kg. Dupilumab is intended for long-term treatment. Dupilumab 300 mg QW has been studied up to 52 weeks. Dosing beyond 52 weeks has not been studied. **7) Special populations:** The safety and efficacy of dupilumab in children with atopic dermatitis below the age of 6 months have not been established. The safety and efficacy of dupilumab in children with a body weight < 5 kg have not been established. No data are available. The safety and efficacy of dupilumab in children with severe asthma below the age of 6 years have not been established. No data are available. The safety and efficacy in children with CRSwNP below the age of 18 years have not been established. No data are available. The safety and efficacy of dupilumab in children with PN below the age of 18 years have not been established. No data are available. The safety and efficacy of dupilumab in children with EoE below the age of 12 years have not been established. **8) Method of administration: The dupilumab pre-filled pen is not intended for use in children below 12 years of age. For children 6 months to 11 years of age with atopic dermatitis and asthma, the dupilumab pre-filled syringe is the presentation appropriate for administration to this population**. Dupilumab is administered by subcutaneous injection into the thigh or abdomen, except for the 5 cm around the navel. If somebody else administers the injection, the upper arm can also be used. Each pre-filled syringe or pre-filled pen is for single use only. For the initial 600 mg or 400 mg dose, two 300 mg or 200 mg injections should be administered consecutively in different injection sites. It is recommended to rotate the injection site with each injection. Dupilumab should not be injected into skin that is tender, damaged or has bruises or scars. **9) Contraindications:** hypersensitivity to the active substance or to any of the excipients. See full SmPC for full list of excipients **10) Warnings and precautions**: Dupilumab should not be used to treat acute asthma symptoms or acute exacerbations. Dupilumab should not be used to treat acute bronchospasm or status asthmaticus. 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. If systemic hypersensitivity reaction occurs, discontinue administration, and initiate appropriate therapy. Patients with comorbid asthma should be monitored carefully following discontinuation of dupilumab. 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. Contains < 1 mmol Na (23 mg) per 300 mg, i.e. essentially" sodium-free**.** (Kindly refer to the full SmPC for this section) **11) Drug interactions**: The safety and efficacy of concurrent use of Dupixent with live vaccines has not been studied. Immune responses to vaccination were assessed in a study in which patients with atopic dermatitis were treated once weekly for 16 weeks with 300 mg of dupilumab. No adverse interactions between either of the non-live vaccines and dupilumab were noted in the study. Therefore, patients receiving Dupixent may receive concurrent inactivated or non-live vaccinations. In a clinical study of AD patients, the effects of dupilumab on the pharmacokinetics (PK) of CYP substrates were evaluated. The data gathered from this study did not indicate clinically relevant effects of dupilumab on CYP1A2, CYP3A, CYP2C19, CYP2D6, or CYP2C9 activity**. 12) Fertility, pregnancy, and lactation**: **Pregnancy:** There is a limited amount of data from the use of dupilumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). Dupilumab should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. **Breast-feeding**: It is unknown whether dupilumab is excreted in human milk or absorbed systemically after ingestion. A decision must be made whether to discontinue breast-feeding or to discontinue dupilumab therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. **13) Effects on ability to drive**: Dupixent has no or negligible influence on the ability to drive or operate machinery. **14) Undesirable effects:** Atopic dermatitis: observed in clinical trials: *Infections/infestations*: common: conjunctivitis, oral herpes. *Blood/lymphatic system disorders*: common: eosinophilia. *Immune system disorders: uncommon: Angioedema. Rare: Anaphylactic reaction Serum sickness reaction, Serum sickness-like reaction. Eye disorders: common: Conjunctivitis allergic Uncommon: Keratitis, Blepharitis, Eye pruritus, Dry eye. Rare: Ulcerative keratitis*†Musculoskeletal and connective tissue disorders: Common Arthralgia. General disorders/administration site conditions: Common: Injection site reactions (includes erythema, oedema, pruritus, pain, swelling, and bruising). Skin and subcutaneous tissue disorders. Uncommon: Facial rash.* **I**n the long-term OLE atopic dermatitis study (AD-1225) at 3 years, the respective rates of conjunctivitis, keratitis, mean blood eosinophil levels, rates of serious infections, and ADA responses remained similar to those in the dupilumab arm in the placebo controlled atopic dermatitis studies. The long-term safety profile observed in this study up to 3 years was generally consistent with the safety profile of dupilumab observed in controlled

studies. The long-term safety of dupilumab was assessed in 89 adolescent patients who were enrolled in an open-label extension study in moderate-to-severe asthma (TRAVERSE). In this study, patients were followed for up to 96 weeks. The safety profile of dupilumab in TRAVERSE was consistent with the safety profile observed in pivotal asthma studies for up to 52 weeks of treatment **15) Overdose:** There is no specific treatment for Dupixent overdose. In the event of overdosage, monitor the patient for any signs or symptoms of adverse reactions and institute appropriate symptomatic treatment immediately**. 16) Special precautions for storage**: Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original carton to protect from light. **17) Pharmacological properties**: Pharmacotherapeutic group: Other dermatological preparations, agents for dermatitis, excluding corticosteroids: ATC code: D11AH05**. 18) Marketing authorization holder**: Sanofi Winthrop Industrie 82 avenue Raspail 94250 Gentilly France . **Abbreviated Prescribing Information based on approved SmPC dated June 2023**