DUPIXENT® (dupilumab)

TARGETED LONG-TERM CONTROL[4]

Prescribing Information

Dupixent (dupilumab) solution for injection in pre-filled syringe. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Dupixent 300 mg solution for injection in pre-filled syringe, containing 300 mg of dupilumab in 2 ml (150 mg/ml). **Indication:** Dupixent is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy. **Dosage and Administration:** Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of atopic dermatitis. For adult patients, the recommended initial dose of Dupixent is 600 mg (two 300 mg injections), followed by 300 mg given every other week. Dupixent should be administered as subcutaneous injection, into the thigh or abdomen, except for the 5 cm around the navel. The upper arm can be used if administered by somebody other than the patient. Dupixent can be used with or without topical corticosteroids. Topical calcineurin inhibitors should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas. ***Missed dose:*** If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time. ***No or partial response:*** Discontinuation of treatment should be considered in patients who have shown no response after 16 weeks of treatment. Some patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks. Patients and/or caregivers should be trained on the preparation and administration of Dupixent prior to use according to the Instructions for Use (IFU) section in the package leaflet. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Precautions:** ***Traceability:*** In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. ***Hypersensitivity:*** If a systemic hypersensitivity reaction (immediate or delayed) occurs, administration of Dupixent should be discontinued immediately and appropriate therapy initiated. ***Helminth infection:*** Patients with known helminth infection were excluded from the clinical trials. Dupixent may influence the immune response against helminth infections by inhibiting IL-4/IL-13 signaling. 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 related events:*** Patients treated with Dupixent who develop conjunctivitis that does not resolve following standard treatment should undergo ophthalmological examination. ***Comorbid asthma:*** Safety and efficacy of Dupixent have not been established in the treatment of 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. ***Interactions:*** There are no data on the use of Dupixent with live vaccines. Results from one study show that antibody responses to tetanus vaccine and meningococcal polysaccharide vaccine were similar in dupilumab-treated patients and placebo-treated patients. No adverse interactions between vaccine and dupilumab were noted. Patients receiving Dupixent may receive concurrent inactive or non-live vaccinations. One study evaluating the pharmacokinetic effects of dupilumab on CYP substrates did not indicate clinically relevant effects of dupilumab on CYP1A2, CYP3A, CYP2C19, CYP2D6 or CYP2C9 activity. **Undesirable Effects:** ***Very common (≥ 1/10):*** Injection site reactions. ***Common (≥ 1/100 to < 1/10):*** Conjunctivitis, Oral herpes, Eosinophilia, Headache, Conjunctivitis allergic, Eye pruritus, Blepharitis. ***Very rare (< 1/10,000):*** Serum sickness/serum sickness-like reactions. ***Serious adverse reactions:*** Eczema herpeticum, infections and immunogenicity have also been reported. Please consult the Summary of Product Characteristics for a comprehensive description of adverse reactions associated with Dupixent. **Pregnancy, Lactation and Fertility:** There are limited data from the use of dupilumab in pregnant women. Animal studies do not indicate harmful effects. Dupixent should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. 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 Dupixent therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. Animal studies showed no impairment of fertility. **Legal Classification:** POM **List Price UK:** 4 week pack containing 2 x pre-filled syringes £1,264.89, 12 week pack containing 6 x pre-filled syringes £3,794.66 **List Price IE:** Price on Application **Marketing Authorisation Holder:** Sanofi-Aventis groupe - 54, rue La Boétie, 75008 Paris, France **Marketing Authorisation Numbers:** EU/1/17/1229/001-008 **Further information is available from:** ***UK:*** Medical Information Department, Sanofi, One Onslow Street, Guildford, Surrey, GU1 4SY Tel: 0845 372 7101 ***IE:*** Sanofi, 18 Riverwalk, Citywest Business Campus, Dublin 24 or contact IEmedinfo@sanofi.com Tel: 01 403 5600 **Date of Revision:** October 2017

Dupixent is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported.

In the UK: **Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard**

Adverse events should also be reported to Sanofi Tel: 0800 0902314. Alternatively, send via E-mail to UK-drugsafety@sanofi.com

In Ireland: **Reporting forms and information can be found at: www.hpra.ie, E-mail: medsafety@hpra.ie**

Adverse events should also be reported to Sanofi Ireland Tel: 01 403 5600. Alternatively, send via E-mail to IEPharmacovigilance@sanofi.com

References: 1. © NICE [2018] Dupilumab for treating moderate to severe atopic dermatitis. Available from: https://www.nice.org.uk/guidance/TA534/chapter/1-Recommendations. Date accessed: May 2019. All rights reserved. Subject to notice of rights. NICE guidance is prepared for the National Health Service in England. All NICE guidance is subject to regular review and may be updated or withdrawn. NICE accepts no responsibility for the use of its content in this product/publication. **2.** Scottish Medicines Consortium. Dupilumab (Dupixent). Available from: https://www.scottishmedicines.org.uk/medicines-advice/dupilumab-dupixent-fullsubmission-smc2011/. Date accessed: May 2019. **3.** DUPIXENT Summary of Product Characteristics. **4.** Blauvelt A, et al. *Lancet.* 2017;389(10086):2287–2303.

Sanofi and Regeneron are collaborating in a global development programme and commercialisation for Dupixent.

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