For the use only of a Registered Medical Practitioner or Hospital or a Laboratory

▼Abbreviated Prescribing Information

Dupilumab 150 mg/ml solution for Injection

DUPIXENT®

Pre-filled syringe with needle shield

Name and Presentation: Each single-use pre-filled syringe with needle shield contains 300 mg dupilumab in 2 mL solution (150 mg/ml). Dupilumab is a fully human monoclonal antibody against interleukin (IL)- 4 receptor alpha that inhibits IL-4/IL-13 signaling and is produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology. **Therapeutic indications:** Dupixent® is indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. **Posology:** Dupixent® is administered by subcutaneous injection. 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. Based on individual therapeutic response, the dosage may be increased to 300 mg given weekly. Missed Dose: If a dose is missed administer the dose as soon as possible. Thereafter resume dosing at the regular scheduled time. **Method of administration:** For the initial 600 mg dose, administer two 300 mg Dupixent® injections consecutively in different injection sites. Dupixent® is intended for use under the guidance of a healthcare provider. A patient may self-inject Dupixent® or the patient's caregiver may administer Dupixent®. Dupixent® is self-administered by subcutaneous injection into the thigh or abdomen, except for the 2 inches (5 cm) around the navel, using a single-use pre-filled syringe. If somebody else administers the injection, the upper arm can also be used. It is recommended to rotate the injection site with each injection. Dupixent® should not be injected into skin that is tender, damaged or has bruises or scars. **Contraindications:** hypersensitivity to the active substance or to any of the excipients. Refer package insert for full list of excipients. **Warnings and precautions:** *Hypersensitivity:* If a systemic hypersensitivity reaction occurs, administration of Dupixent® should be discontinued immediately and appropriate therapy initiated. One case of serum sickness-like reaction and one case of serum sickness reaction, both considered serious, have been reported in clinical trials following the administration of Dupixent®. *Conjunctivitis:* Conjunctivitis occurred more frequently in atopic dermatitis patients who received Dupixent®. Most patients with conjunctivitis recovered or were recovering during the treatment period. Patients should report new onset or worsening eye symptoms to their healthcare provider. *Helminth Infection:* Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if Dupixent® will influence the immune response against helminth infections. Treat patients with pre- existing helminth infections before initiating Dupixent®. If patients become infected while receiving treatment with Dupixent® and do not respond to anti-helminth treatment, discontinue treatment with Dupixent® until infection resolves. **Drug interactions:** *Live vaccines:* Live vaccines should not be given concurrently with Dupixent®. *Non-Live Vaccines:* 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. After 12 weeks of dupilumab administration, patients were vaccinated with a Tdap vaccine (T cell-dependent, Adacel®) and a meningococcal polysaccharide vaccine (T cell-independent, Menomune®) and immune responses were assessed 4 weeks later. Antibody responses to both tetanus vaccine and meningococcal polysaccharide vaccine were similar in dupilumab-treated and placebo-treated patients. No adverse interactions between either of the non-live vaccines and dupilumab were noted in the study. *Interactions with CYP450 Substrates:* In a clinical trial of AD patients, the effects of dupilumab on the PK of CYP substrates was evaluated. The data gathered from this study did not indicate a clinically relevant effect of dupilumab on CYP1A2, CYP3A, CYP2C19, CYP2D6, or CYP2C9 activity. **Fertility, pregnancy and lactation:** Dupixent should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. 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. **Effects on ability to drive:** Dupixent has no or negligible influence on the ability to drive or operate machinery. **Undesirable effects:** *Infections/infestations*: common: conjunctivitis, oral herpes. *Blood/lymphatic system disorders*: common: eosinophilia. *Immune system disorders:* very rare: serum sickness/serum sickness-like reactions. *Nervous system disorders*: common: headache. *Eye disorders*: common: allergic conjunctivitis, eye pruritus, blepharitis. *General disorders/administration site conditions*: very common: injection site reactions. Asthma: *Immune system disorders:* very rare: anaphylactic reaction. *General disorders/administration site conditions*: injection site erythema, injection site edema, injection site pain, injection site pruritus. **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. **Special precautions for storage:** Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original carton to protect from light.

For full prescribing information please write to: Sanofi Healthcare India Pvt. Ltd., Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400 072

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