DUPIXENT® (dupilumab)

DUPIXENT® DOSING GUIDE

for uncontrolled severe eosinophilic or allergic asthma

Selecting the appropriate dose of DUPIXENT using Pharmaceutical Benefits Scheme (PBS) eligibility criteria[1]

Please refer to the Approved Product Information for full prescribing guidance, and the PBS website for complete eligibility criteria and restrictions.

DUPIXENT 200 mg PBS LISTING AND DOSING

DUPIXENT 200 mg is PBS listed for[1]

Uncontrolled severe eosinophilic or allergic asthma

In patients who have documented failure to achieve adequate control with optimised asthma therapy, despite formal assessment of, and adherence to, correct inhaler technique

Recommended dosing schedule:[2]

Loading dose
(two 200 mg injections administered at different sites)

One injection
every two weeks

Remind patients that:

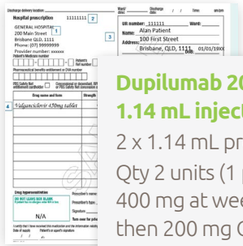
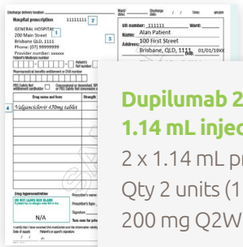
1 pack = 💉💉

Each pack holds two 1.14 mL pre-filled syringes.

- Both syringes from pack 1 (initial script) are used for the loading dose. **Only the first dose requires two injections (at different sites).**
- They need to collect pack 2 (repeat 1) after receiving the loading dose.
- One syringe from pack 2 is administered at week 2, and the second syringe at week 4.
- They need to collect pack 3 at week 4, refilling every four weeks thereafter as all subsequent doses are administered as one injection every two weeks.

DUPIXENT 200 mg PBS QUICK REFERENCE GUIDE

PBS item codes, forms and prescription requirements for patients eligible for DUPIXENT 200 mg

Patient type	Form	PBS item code: Public (S100)	PBS item code: Private (S100)	Prescription requirements
INITIAL New to DUPIXENT*	PB075	12309W	12313C	 **Dupilumab 200 mg/ 1.14 mL injection,** 2 x 1.14 mL pre-filled syringes Qty 2 units (1 pack) and 8 repeats 400 mg at week 0, then 200 mg Q2W
CHANGE Switch from other biologic to DUPIXENT	PB285			
CONTINUING Continue on DUPIXENT	PB076	12318H	12316F	 **Dupilumab 200 mg/ 1.14 mL injection,** 2 x 1.14 mL pre-filled syringes Qty 2 units (1 pack) and 5 repeats 200 mg Q2W

PBS authority application forms can be accessed from

www.serviceaustralia.gov.au/organisations/health-professionals/forms

Please refer to the PBS website for complete eligibility criteria and restrictions.
*Biologic naïve or commencing DUPIXENT after 12-month break from a biologic. Q2W, once every two weeks.

DUPIXENT 300 mg PBS LISTINGS AND DOSING

DUPIXENT 300 mg is PBS listed for[1]

Uncontrolled severe eosinophilic or allergic asthma

In patients who have documented failure to achieve adequate control with optimised asthma therapy, despite formal assessment of, and adherence to, correct inhaler technique

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Who are oral corticosteroid (OCS) dependent, defined as receiving regular maintenance OCS in the last 6 months with a stable daily OCS dose between 5–35 mg of prednisolone or equivalent over the 4 weeks prior to treatment initiation

Recommended dosing schedule:[2]

Loading dose
(two 300 mg injections administered at different sites)

One injection
every two weeks

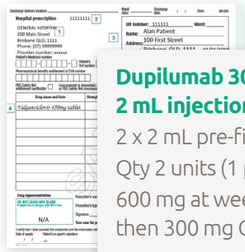
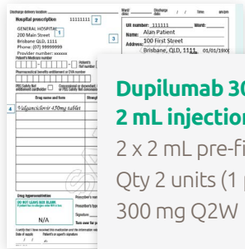
Remind patients that:

Each pack holds two 2 mL pre-filled syringes.

- Both syringes from pack 1 (initial script) are used for the loading dose. **Only the first dose requires two injections (at different sites).**
- They need to collect pack 2 (repeat 1) after receiving the loading dose.
- One syringe from pack 2 is administered at week 2, and the second syringe at week 4.
- They need to collect pack 3 at week 4, refilling every four weeks thereafter as all subsequent doses are administered as one injection every two weeks.

DUPIXENT 300 mg PBS QUICK REFERENCE GUIDE

PBS item codes, forms and prescription requirements for patients eligible for DUPIXENT 300 mg

Patient type	Form	PBS item code		Prescription requirements
		Public (S100)	Private (S100)	
INITIAL New to DUPIXENT*	PB075	12293B	12310X	 **Dupilumab 300 mg/ 2 mL injection,** 2 x 2 mL pre-filled syringes Qty 2 units (1 pack) and 8 repeats 600 mg at week 0, then 300 mg Q2W
CHANGE Switch from other biologic to DUPIXENT	PB285			
CONTINUING Continue on DUPIXENT	PB076	12302L	12294C	 **Dupilumab 300 mg/ 2 mL injection,** 2 x 2 mL pre-filled syringes Qty 2 units (1 pack) and 5 repeats 300 mg Q2W

PBS authority application forms can be accessed from

www.serviceaustralia.gov.au/organisations/health-professionals/forms

*Biologic naïve or commencing DUPIXENT after 12-month break from a biologic. Q2W, once every two weeks.

KEY TIMEPOINTS FROM INITIATION THROUGH TO CONTINUATION OF THERAPY[1]

INITIAL COURSE
32 weeks (1 + 8 repeats)

Loading dose
(two injections administered at different sites)

One injection
every two weeks

To ensure treatment continuity and approval of a continuation prescription prior to the end of the course, assess the patient's response to treatment around week 28: (1) **complete ACQ-5**, (2) **review OCS dose**, (3) **submit PBS application form and PBS prescription** (1 + 5 repeats)

Initial PBS form and prescription completed and approved before starting DUPIXENT treatment

CONTINUATION COURSE 24 weeks
(1 + 5 repeats)

One injection
every two weeks

To ensure treatment continuity and approval of a continuation prescription prior to the end of the course, assess the patient's response to treatment around week 18: (1) **complete ACQ-5**, (2) **review OCS dose**, (3) **submit PBS application form and PBS prescription** (1 + 5 repeats)

Initial PBS form and prescription completed and approved before starting DUPIXENT treatment

ADMINISTRATION AND STORAGE

DUPIXENT is intended for use under the guidance of a healthcare provider[2]

- DUPIXENT can be self-injected at home after training in subcutaneous injection technique.
- Physicians or nurses should provide proper training to patients and/or caregivers on the storage, preparation and administration of DUPIXENT prior to use, according to the instruction leaflet inside the pack.
- No additional monitoring requirements after administration are mentioned in the Product Information. Additional hospital protocols may apply.[2]

Please review PBS website for complete eligibility criteria and restrictions.

DUPIXENT storage instructions[2]

- DUPIXENT should be stored in a refrigerator (2°C to 8°C) until ready to use. Do not freeze.
- If necessary, DUPIXENT may be kept at room temperature (up to 25°C) for up to 14 days. Do not store above 25°C. After removal from the refrigerator, DUPIXENT must be used within 14 days or discarded.
- Store DUPIXENT in the original carton to protect from light. Do not expose to heat. Do not shake.

Please review the DUPIXENT Product Information for full dosage, administration and storage instructions.

Download a copy of the DUPIXENT severe asthma PBS prescribing guide for more information.

PBS Information: Authority required. Refer to PBS schedule for full Authority Required Information.

Please review full Product Information before prescribing. Full Product Information is available from sanofi-aventis australia pty ltd at http://www.guildlink.com.au/gc/ws/sw/pi.cfm?product=swpdupix or by contacting 1800 818 806.

Dupixent (dupilumab) MINIMUM PRODUCT INFORMATION. INDICATIONS: Atopic dermatitis: Adults and adolescents. Treatment of moderate to severe atopic dermatitis in patients aged 12 years and older who are candidates for chronic systemic therapy. Not intended for episodic use. Children 6 to 11 years of age. Dupixent is indicated for the treatment of severe atopic dermatitis in patients aged 6 to 11 years old who are candidates for chronic systemic therapy. Dupixent is not intended for episodic use. **Moderate to severe asthma:** Add on maintenance treatment in patients aged 12 years and older with moderate to severe asthma with type 2 inflammation (elevated eosinophils or elevated FeNO). Indicated as maintenance therapy for oral corticosteroid dependent asthma. **Chronic rhinosinusitis with nasal polyposis (CRSwNP):** Dupixent is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). **DOSAGE AND ADMINISTRATION Atopic dermatitis – Adults:** Initial dose of 600 mg by subcutaneous injection (two 300 mg injections consecutively in different injection sites), followed by 300 mg given every other week. Refer to full PI for preparation, handling and administration. Treatment should be initiated and supervised by a dermatologist or immunologist. **Atopic Dermatitis – Paediatric and Adolescent patients aged 6-17 years: Patients 15 kg to <30 kg:** Initial dose of 600 mg (two 300 mg injections consecutively in different injection sites) followed by 300 mg every four weeks. **Patients 30 kg to < 60 kg:** Initial dose of 400 mg (two 200 mg injections consecutively in different injection sites) followed by 200 mg given every other week. **Patients ≥ 60 kg:** Initial dose of 600 mg by subcutaneous injection (two 300 mg injections consecutively in different injection sites) followed by 300 mg given every other week. **Asthma: Moderate to severe asthma:** Initial dose of 400 mg by subcutaneous injection (two 200 mg injections consecutively in different injection sites) followed by 200 mg given every other week. Refer to full PI for preparation, handling and administration. Oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid severe chronic rhinosinusitis with nasal polyposis: Initial dose of 600 mg by subcutaneous injection (two 300 mg injections consecutively in different injection sites) followed by 300 mg given every other week. **Chronic Rhinosinusitis with Nasal Polyposis:** The recommended dose of Dupixent for adult patients is an initial dose of 300 mg followed by 300 mg given every other week. Dupixent 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 improve with continued treatment beyond 24 weeks. If after 24 weeks of treatment a patient's disease is stable, Dupixent may be given at a dose of 300 mg every four weeks in patients with CRSwNP who do not have comorbid asthma. **CONTRAINDICATIONS:** Hypersensitivity to dupilumab or any of its excipients. **PRECAUTIONS:** Record the tradename and the batch number to improve traceability. Hypersensitivity, angioedema, helminth infections, conjunctivitis and keratitis, comorbid asthma, concomitant atopic conditions, eosinophilic conditions, acute asthma or deteriorating disease, gradual corticosteroid dose reduction. Refer to full PI. INTERACTIONS: Live vaccines, No safety data on co-administration with other immunomodulators. Refer to full PI. **ADVERSE EFFECTS:** Atopic dermatitis: Injection site reactions, conjunctivitis, conjunctivitis allergic, oral herpes, conjunctivitis bacterial, herpes simplex, eosinophilia, eye pruritus, blepharitis, dry eye, hypersensitivity – refer to full PI. **Moderate to severe asthma:** Injection site reactions, oropharyngeal pain, eosinophilia – refer to full PI. **Chronic Rhinosinusitis with Nasal Polyposis:** Injection site reactions, injection site swelling, conjunctivitis – refer to full PI. Post marketing experience: Angioedema, arthralgia, keratitis, ulcerative keratitis, facial rash. **NAME OF SPONSOR:** sanofi-aventis australia pty ltd, 12-24 Talavera Road, Macquarie Park, NSW 2113. Based on Full Product Information with TGA date of approval of 17 August 2021. Date of Preparation: 19 October 2021.

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

References: 1. Australian Government Department of Health. Pharmaceutical Benefits Scheme. Available at https://www.pbs.gov.au/medicine/item/12291X-12292Y-12293B-12294C-12302L-12309W-12310X-12313C-12316F-12318H (accessed April 2021). **2.** Australian Approved Product Information for DUPIXENT (dupilumab). 17 August 2021.

Sanofi and Regeneron are collaborating in a global development program and commercialisation for DUPIXENT.

sanofi-aventis australia pty ltd trading as Sanofi ABN 31 008 558 807. Talavera Corporate Centre, Building D, 12–24 Talavera Road, Macquarie Park, NSW 2113. www.sanofi.com.au. Date of preparation: March 2022. MAT-AU-2200875. 2200162.

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DUPIXENT® (dupilumab)