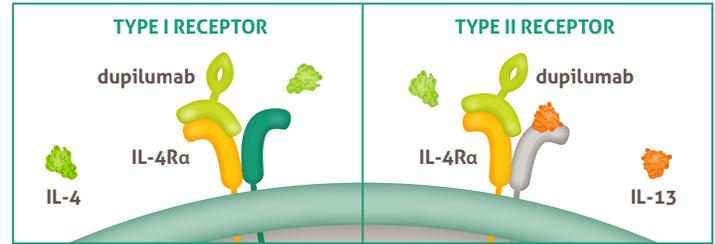


## Dupixent Overview

Dupixent<sup>®</sup> (dupilumab) is a prescription medicine that comes in a single-dose pre-filled syringe that is administered by injection under the skin (subcutaneous injection). In adolescents 12 years of age and older, it is recommended that Dupixent be administered by or under supervision of an adult. It can be self-administered after training by a healthcare professional every other week at different injection sites after an initial loading dose.



Dupixent, created using Regeneron's *VelocImmune*<sup>®</sup> technology, is a human monoclonal antibody specifically designed to inhibit signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two important cytokines that contribute to a type of inflammation that plays a major role in atopic dermatitis (eczema) and asthma. The mechanism of action of Dupixent has not been definitively established.

Dupixent is marketed in the U.S. by Regeneron and Sanofi Genzyme, the specialty care global business unit of Sanofi.

## Dupixent has been approved for the treatment of two distinct inflammatory diseases:

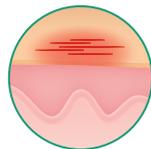


### ATOPIC DERMATITIS

Indicated for people aged 12 years and older with **moderate-to-severe atopic dermatitis** (eczema) whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids. It is not known if Dupixent is safe and effective in children with atopic dermatitis under 12 years of age.

#### WHAT IS ATOPIC DERMATITIS?

Atopic dermatitis, the most common form of eczema, is a chronic inflammatory disease with symptoms often appearing as a rash on the skin.



Inflammation beneath skin during atopic dermatitis flare

Moderate-to-severe atopic dermatitis is characterized by<sup>1</sup>:



Rashes that potentially cover much of the body



Intense, persistent itching  
• Itch is one of the most burdensome symptoms for patients and can be debilitating.<sup>2</sup>



Skin dryness



Cracking, redness, crusting and oozing

There are approximately **300,000-400,000** adults in the U.S. with uncontrolled, moderate-to-severe atopic dermatitis who are most in need. We estimate that the number of adolescent patients most in need is about half of this adult population.<sup>3</sup>

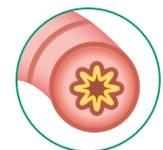


### ASTHMA

Indicated for use with other asthma medicines for the maintenance treatment of **moderate-to-severe asthma** in people aged 12 years and older whose asthma is not controlled with their current asthma medicines. Dupixent is not used to treat sudden breathing problems. It is not known if Dupixent is safe and effective in children with asthma under 12 years of age.

#### WHAT IS ASTHMA?

Asthma is a chronic inflammatory disease that makes it difficult to breathe. It can manifest differently for each person and vary in its symptoms, severity and the treatment required.<sup>4,5</sup>



Inflamed/narrowed airway during asthma attack

Approximately **775,000 to 900,000** people 12 years of age and older in the U.S. with moderate-to-severe asthma have uncontrolled symptoms despite standard of care therapy that may make them suitable for treatment with a biologic therapy.

These patients can experience<sup>6,7</sup>:



Difficulty breathing



Severe asthma attacks



Emergency room visits or hospitalization

## IMPORTANT SAFETY INFORMATION

**Do not use** if you are allergic to dupilumab or to any of the ingredients in DUPIXENT<sup>®</sup>.

Please see additional Important Safety Information on next page and accompanying full [Prescribing Information](#) and [Patient Information](#).

## Important Safety Information (continued)

**Before using DUXIXENT, tell your healthcare provider about all your medical conditions, including if you:**

- have eye problems (if you also have atopic dermatitis)
- have a parasitic (helminth) infection
- are taking oral, topical, or inhaled corticosteroid medicines. **Do not** stop taking your corticosteroid medicines unless instructed by your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine to come back.
- are scheduled to receive any vaccinations. You should not receive a “live vaccine” if you are treated with DUXIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUXIXENT will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known whether DUXIXENT passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. If you are taking asthma medicines, do not change or stop your asthma medicine without talking to your healthcare provider.

**DUXIXENT can cause serious side effects, including:**

- **Allergic reactions (hypersensitivity), including a severe reaction known as anaphylaxis.** Stop using DUXIXENT and tell your healthcare provider or get emergency help right away if you get any of the following symptoms: breathing problems, fever, general ill feeling, swollen lymph nodes, swelling of the face, mouth and tongue, hives, itching, fainting, dizziness, feeling lightheaded (low blood pressure), joint pain, or skin rash.
- **Eye problems.** If you have atopic dermatitis, tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision.
- **Inflammation in your blood vessels:** Rarely, this can happen in people with asthma who receive DUXIXENT. This may happen in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by DUXIXENT. Tell your healthcare provider right away if you have: rash, shortness of breath, persistent fever, chest pain, or a feeling of pins and needles or numbness of your arms or legs.

**The most common side effects include** injection site reactions, pain in the throat (oropharyngeal pain) and cold sores in your mouth or on your lips. Eye and eyelid inflammation, including redness, swelling and itching have been seen in patients who have atopic dermatitis.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DUXIXENT. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Use DUXIXENT exactly as prescribed. DUXIXENT is an injection given under the skin (subcutaneous injection). If your healthcare provider decides that you or a caregiver can give DUXIXENT injections, you or your caregiver should receive training on the right way to prepare and inject DUXIXENT. **Do not** try to inject DUXIXENT until you have been shown the right way by your healthcare provider. In adolescents 12 years of age and older, it is recommended that DUXIXENT be administered by or under supervision of an adult.

Please click [here](#) for the full Prescribing Information. Patient information is available [here](#).

1 Mount Sinai. Patient Care Atopic Dermatitis 2016. <http://www.mountsinai.org/patientcare/healthlibrary/diseasesandconditions/atopicdermatitis#risk>. Accessed October 31, 2016.

2 Zuberbier T, Orlow SJ, Paller AS, et al. Patient perspectives on the management of atopic dermatitis. *J Allergy Clin Immunol*. 2006; 118:226232.

3 Data on file.

4 Global Asthma Network. The Global Asthma Report 2014. Auckland, New Zealand, 2014.

5 Carr TF. Asthma heterogeneity and severity. *World Allergy Organ J*. December 2016.

6 Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2018. Available at: <http://ginasthma.org/download/832/>. Last accessed April 2018.

7 Price D, Fletcher M, van der Molen T. Asthma control and management in 8,000 European patients: the REcognise Asthma and Link to Symptoms and Experience (REALISE) survey. *NPJ Prim Care Respir Med* 2014;24:14009.