DUPIXENT®
(dupilumab) Injection
200mg · 300mg

DUPIXENT® (dupilumab) Backgrounder

DUPIXENT Overview

- DUPIXENT® (dupilumab) is a prescription medicine used:
  - to treat adults with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. It is not known if DUPIXENT is safe and effective in children with atopic dermatitits under 18 years of age.
  - 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 helps prevent severe asthma attacks (exacerbations) and can improve your breathing. DUPIXENT may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing. 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.
- DUPIXENT, created using Regeneron's *VelocImmune*® 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 and asthma.
- DUPIXENT comes in a prefilled syringe and can be self-administered as a subcutaneous (under the skin) injection every other week after an initial loading dose, which is injected into different injection sites. If a healthcare provider decides that a patient or caregiver can give the injections of DUPIXENT, they should receive training on the right way to prepare and inject DUPIXENT. DUPIXENT **should not** be injected until the patient/caregiver has been shown the right way by his or her healthcare provider. In adolescents with asthma 12 years of age and older, it is recommended that DUPIXENT be administered by or under supervision of an adult.
- DUPIXENT is marketed in the U.S by Regeneron and Sanofi Genzyme, the specialty care global business unit of Sanofi.

DUPIXENT Clinical Trial Programs

- **Atopic dermatitis** – The FDA's approval of DUPIXENT in moderate-to-severe atopic dermatitis was based on the global LIBERTY AD clinical program including three Phase 3 pivotal trials known as SOLO 1, SOLO 2 and CHRONOS that compared the use of DUPIXENT with placebo, either alone (SOLO 1 or SOLO 2) or with topical corticosteroids (CHRONOS), in adults with uncontrolled moderate-to-severe atopic dermatitis.
  - The primary endpoints were met in all Phase 3 atopic dermatitis trials.
  - The most common adverse events in atopic dermatitis that occurred in at least one percent with DUPIXENT treatment included injection site reactions, eye and eyelid inflammation including redness, swelling, and itching, and cold sores in the mouth or on the lips.
- **Asthma** – The FDA's approval of DUPIXENT as add-on asthma maintenance treatment is based on the LIBERTY ASTHMA clinical program that evaluated more than 2,800 adults and adolescents (12 years of age and older) living with uncontrolled moderate-to-severe asthma in three randomized, placebo-controlled, multicenter trials.
  - Two trials were in patients on medium- or-high dose inhaled corticosteroid (ICS) with at least one controller and up to two additional controller medications and the third trial was in oral steroid-dependent patients who used daily oral corticosteroids in addition to high dose inhaled corticosteroids plus an additional controller.
  - DUPIXENT demonstrated efficacy across four clinically important disease measures, which were lung function, severe exacerbations, oral steroid use and health-related quality of life.
  - Injection site reactions, pain in the throat (oropharyngeal pain), and cold sores in the mouth or on the lips were the most common side effects in the Dupixent groups compared to placebo.

Important Safety Information

Do not use if you are allergic to dupilumab or to any of the ingredients in DUPIXENT®.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information and Patient Information.

SANOFI REGENERON

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What is Moderate-to-Severe 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.
- Moderate-to-severe atopic dermatitis is characterized by rashes that potentially cover much of the body and intense, persistent itching and skin dryness, cracking, redness, crusting, and oozing.[1] Itch is one of the most burden symptoms for patients and can be debilitating.[2]
- Of the adults with uncontrolled moderate-to-severe atopic dermatitis in the United States, it is estimated that approximately 300,000 are most in need of additional treatment options.[3]

What is Moderate-to-Severe Asthma with an eosinophilic phenotype or oral corticosteroid dependence?

- 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.[4,5]
- 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 experience difficulty breathing and are at risk of severe asthma attacks (exacerbations) requiring emergency room visits or hospitalizations.[6,7]
- An eosinophilic phenotype means a patient has elevated levels of eosinophils, a type of white blood cell, in the blood.
- Oral corticosteroid dependent asthma means a patient is taking daily oral steroids to try to control their asthma symptoms. Oral corticosteroids can provide relief for severe, short-term symptoms. However, their chronic use is limited to the most severe patients due to long-term risk-benefit profile.[8,9]

Scientific History and Discovery

- Following the discovery of IL-4 and IL-13, several studies confirmed these proteins are important contributors to a type of inflammation that plays a major role in a number of diseases including atopic dermatitis and asthma.
- Regeneron and Sanofi recognized the need to develop an antibody that inhibits the overactive signaling of IL-4 and IL-13.

Important Safety Information (continued)

Before using DUPIXENT, 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 DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known whether DUPIXENT 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.

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Important Safety Information (continued)

DUPIXENT can cause serious side effects, including:

- **Allergic reactions (hypersensitivity), including a severe reaction known as anaphylaxis.** Stop using DUPIXENT 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 DUPIXENT. This happens 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 DUPIXENT. 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 DUPIXENT. 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, or call 1-800-FDA-1088.

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

Please click here for the full Prescribing Information. Patient information is available here.

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