**What is DUPIXENT?**

*DUPIXENT* is a prescription medicine used:

- to treat adults and children 6 months of age and older with moderate-to-severe eczema (atopic dermatitis or AD) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. *DUPIXENT* can be used with or without topical corticosteroids.

- with other asthma medicines for the maintenance treatment of moderate-to-severe asthma in adults and children 6 years of age 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.

- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled.

- to treat adults and children 1 year of age and older with eosinophilic esophagitis (EoE), who weigh at least 33 pounds (15 kg).

- to treat adults with prurigo nodularis (PN).

- *DUPIXENT* works by blocking two proteins that contribute to a type of inflammation that plays a major role in atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, and prurigo nodularis.

- It is not known if *DUPIXENT* is safe and effective in children with atopic dermatitis under 6 months of age.

- It is not known if *DUPIXENT* is safe and effective in children with asthma under 6 years of age.

- It is not known if *DUPIXENT* is safe and effective in children with chronic rhinosinusitis under 16 years of age.

- It is not known if *DUPIXENT* is safe and effective in children with eosinophilic esophagitis under 1 year of age, or who weigh less than 33 pounds (15 kg).

- It is not known if *DUPIXENT* is safe and effective in children with prurigo nodularis under 18 years of age.

Do not use *DUPIXENT* if you are allergic to dupilumab or to any of the ingredients in *DUPIXENT*. See the end of this Patient Information leaflet for a complete list of ingredients in *DUPIXENT*.

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

- have eye problems.

- have a parasitic (helminth) infection.

- are scheduled to receive any vaccinations. You should not receive a “live vaccine” right before and during treatment with *DUPIXENT*.

- are pregnant or plan to become pregnant. It is not known whether *DUPIXENT* will harm your unborn baby.

**Pregnancy Exposure Registry.** There is a pregnancy exposure registry for women who use *DUPIXENT* during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Your healthcare provider can enroll you in this registry. You may also enroll yourself or get more information about the registry by calling 1-877-311-8972 or going to https://mothertobaby.org/ongoing-study/dupixent/.

- are breastfeeding or plan to breastfeed. It is not known whether *DUPIXENT* passes into your breast milk.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**Especially tell your healthcare provider if you:**

- are taking oral, topical, or inhaled corticosteroid medicines

- have asthma and use an asthma medicine

- have atopic dermatitis, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, or prurigo nodularis and also have asthma

**Do not** change or stop your corticosteroid medicine or other asthma medicine without talking to your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine or other asthma medicine to come back.

**How should I use DUPIXENT?**

- See the detailed “Instructions for Use” that comes with *DUPIXENT* for information on how to prepare and inject *DUPIXENT* and how to properly store and throw away (dispose of) used *DUPIXENT* pre-filled syringes and pre-filled pens.

- Use *DUPIXENT* exactly as prescribed by your healthcare provider.

- Your healthcare provider will tell you how much *DUPIXENT* to inject and how often to inject it.

- *DUPIXENT* comes as a single-dose pre-filled syringe with needle shield or as a pre-filled pen.

- The *DUPIXENT* pre-filled syringe is for use in adults and children 6 months of age and older.

- The *DUPIXENT* pre-filled syringe is for use in children 2 years of age and older.

- *DUPIXENT* is given as an injection under the skin (subcutaneous injection).

- If your dose schedule is every week and you miss a dose of *DUPIXENT*: Give the *DUPIXENT* injection as soon as possible and start a new every week dose schedule from the time you remember to take your *DUPIXENT* injection.

- If your dose schedule is every other week and you miss a dose of *DUPIXENT*: Give the *DUPIXENT* injection within 7 days from the missed dose, then continue with your original schedule. If the missed dose is not given within 7 days, wait until the next scheduled dose to give your *DUPIXENT* injection.

- If your dose schedule is every 4 weeks and you miss a dose of *DUPIXENT*: Give the *DUPIXENT* injection within 7 days from the missed dose, then continue with your original schedule. If the missed dose is not given within 7 days, start a new every 4 week dose schedule from the time you remember to take your *DUPIXENT* injection.

- If you inject too much *DUPIXENT*, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

- Your healthcare provider may prescribe other medicines to use with *DUPIXENT*. Use the other prescribed medicines exactly as your healthcare provider tells you.
What are the possible side effects of DUPIXENT?

DUPIXENT can cause serious side effects, including:

• **Allergic reactions.** DUPIXENT can cause allergic reactions that can sometimes be severe. Stop using DUPIXENT and tell your healthcare provider or get emergency help right away if you get any of the following signs or symptoms:
  - breathing problems or wheezing
  - fast pulse
  - fever
  - general ill feeling
  - swollen lymph nodes
  - swelling of the face, lips, mouth, tongue, or throat
  - hives
  - itching
  - cramps in your stomach-area

• **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision, such as blurred vision. Your healthcare provider may send you to an ophthalmologist for an eye exam if needed.

• **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive DUPIXENT. 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 DUPIXENT. Tell your healthcare provider right away if you have:
  - rash
  - worsening shortness of breath
  - chest pain

• **Joint aches and pain.** Joint aches and pain can happen in people who use DUPIXENT. Some people have had trouble walking or moving due to their joint symptoms, and in some cases needed to be hospitalized. Tell your healthcare provider about any new or worsening joint symptoms. Your healthcare provider may stop DUPIXENT if you develop joint symptoms.

The most common side effects of DUPIXENT include:

- injection site reactions
- upper respiratory tract infections
- eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision
- dry eye
- herpes virus infections
- common cold symptoms (nasopharyngitis)
- cold sores in your mouth or on your lips
- high count of a certain white blood cell (eosinophilia)
- dizziness
- muscle pain
- diarrhea
- pain in the throat (oropharyngeal pain)
- gastritis
- joint pain (arthralgia)
- trouble sleeping (insomnia)
- toothache
- parasitic (helminth) infections

The following additional side effects have been reported with DUPIXENT:

- facial rash or redness

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DUPIXENT?

- Store DUPIXENT in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Store DUPIXENT in the original carton to protect from light.
- DUPIXENT can be stored at room temperature up to 77°F (25°C) up to 14 days. Throw away (dispose of) any DUPIXENT that has been left at room temperature for longer than 14 days.
- Do not heat or put DUPIXENT into direct sunlight.
- Do not freeze. Do not shake.

Keep DUPIXENT and all medicines out of the reach of children.

General information about the safe and effective use of DUPIXENT.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DUPIXENT for a condition for which it was not prescribed. Do not give DUPIXENT to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about DUPIXENT that is written for health professionals.

What are the ingredients in DUPIXENT?

**Active ingredient:** dupilumab

**Inactive ingredients:** L-arginine hydrochloride, L-histidine, polysorbate 80, sodium acetate, sucrose, and water for injection.

**REGENERON sanofi**

Manufactured by: Regeneron Pharmaceuticals, Inc., Tarrytown, NY 10591 U.S. License No. 1760

Marketed by: sanofi-aventis U.S. LLC (Bridgewater, NJ 08807) and Regeneron Pharmaceuticals, Inc. (Tarrytown, NY 10591)

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For more information about DUPIXENT, go to www.DUPIXENT.com or call 1-844-DUPIXENT (1-844-387-4936).

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: January 2024