PATIENT INFORMATION
DUPIXENT® (DU-pix-ent)
(dupilumab)
injection, for subcutaneous use

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 polyps (CRSwNP) in adults and children 12 years of age and older 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).
- with other medicines for the maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and a high number of blood eosinophils (a type of white blood cell that may contribute to your COPD). DUPIXENT is used to reduce the number of flare-ups (the worsening of your COPD symptoms for several days) and can improve your breathing.
- to treat adults and children 2 years of age and older with chronic spontaneous urticaria (CSU), who continue to have hives that are not controlled with H1 antihistamine treatment.
- to treat adults with bullous pemphigoid (BP).
- to treat adults and children 6 years of age and older with allergic fungal rhinosinusitis (AFRS) who have had surgery on their nose or sinuses in the past.

DUPIXENT is not used to relieve sudden breathing problems and will not replace an inhaled rescue medicine **or** to treat any other forms of hives (urticaria).

DUPIXENT works by blocking two proteins that contribute to a type of inflammation that plays a major role in AD, asthma, CRSwNP, EoE, PN, COPD, CSU, BP, and AFRS.

It is not known if DUPIXENT is safe and effective in children with:

- AD under 6 months of age.
- Asthma under 6 years of age.
- CRSwNP under 12 years of age.
- EoE under 1 year of age, or who weigh less than 33 pounds (15 kg).
- PN under 18 years of age.
- COPD under 18 years of age. COPD is most often seen in adults.
- CSU under 2 years of age, or who weigh less than 11 pounds (5 kg).
- BP under 18 years of age. BP is most often seen in adults.
- AFRS under 6 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.
- 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 AD, CRSwNP, EoE, PN, COPD, CSU, BP, or AFRS, and also have asthma

Do not change or stop your other medicines, including corticosteroid medicine or other asthma medicine, without talking to your healthcare provider. This may cause other symptoms that were controlled by those medicines 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 pen is only for use in adults and children 2 years of age and older.
  - The DUPIXENT pre-filled syringe is for use in adults and children 6 months of age and older.
- DUPIXENT is given as an injection under the skin (subcutaneous injection).
- If your healthcare provider decides that you or a caregiver can give the injections of DUPIXENT, 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 children 12 years of age and older, it is recommended that DUPIXENT be given by or under the supervision of an adult. In children 6 months to less than 12 years of age, DUPIXENT should be given by a caregiver.
- **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 2 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 2-week dose schedule from the time you remember to take 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 to.

What are the possible side effects of DUPIXENT?
DUPIXENT can cause serious side effects, including:

- **Allergic reactions. DUPIXENT can cause allergic reactions, including skin 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
  - joint pain
  - swelling of the face, lips, mouth, tongue, or throat
  - hives
  - itching
  - nausea or vomiting
  - cramps in your stomach-area
  - fainting, dizziness, feeling lightheaded
  - skin rash, including rash that looks like a bullseye, painful red or blue bumps under the skin, or red pus-filled spots on the skin

- **Eye problems.** Tell your healthcare provider right away 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. Tell your healthcare provider right away if you get:
  - rash
  - worsening shortness of breath
  - persistent fever
  - chest pain
  - brown or dark colored urine
  - a feeling of pins and needles or numbness of your arms or legs
- **Psoriasis.** This can happen in people with atopic dermatitis and asthma who receive DUPIXENT. Tell your healthcare provider about any new skin symptoms. Your healthcare provider may send you to a dermatologist for an examination if needed.
- **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 problems, including eye and eyelid inflammation, redness, swelling, itching, eye infection, dry eye, and blurred vision
- herpes virus infections
- common cold symptoms (nasopharyngitis)
- cold sores in your mouth or on your lips
- dizziness
- muscle pain
- diarrhea
- pain in the throat (oropharyngeal pain)
- stomach problems (gastritis)
- joint pain (arthralgia)
- trouble sleeping (insomnia)

- high count of a certain white blood cell (eosinophilia)
- viral infection
- back pain
- inflammation inside the nose (rhinitis)
- toothache
- parasitic (helminth) infections
- headache
- urinary tract infection

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 between 36ºF to 46ºF (2ºC to 8ºC).
- 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 (Morristown, NJ 07960) 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: April 2026