

Academy Allergy Asthma and Sinus Center

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DUPIXENT (dupilumab) Injection Consent Form

Indications

DUPIXENT is a prescription medicine used:

to treat people 12 years of age and older 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. 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.

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 number 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.

FDA approved DUPIXENT for the treatment of Nasal Polyps.

Dr. Patel owns or has owned more than 50 stocks such as McDonald's, Macey, Regeneron which is who makes Dupixent, Rosh and many others. Dr. Patel will prescribe not only the most effective but the cheapest medications for you. If you want Dr. Patel to find other alternatives then what Dr. Patel recommended please tell him and he will discuss different options.

Important Safety Information

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

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 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.

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 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, 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. DUPIXENT is an injection given under the skin (subcutaneous injection). 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 12 years of age and older, it is recommended that DUPIXENT be administered by or under the supervision of an adult.

Characteristics of Biologic Therapies for T2 High Asthma					
	Omalizumab	Dupilumab	Benralizumab	Mepolizumab	Reslizumab
FDA approval status	Approved, ≥6 years of age	Pending	Approved, ≥12 years of age	Approved, ≥12 years of age	Approved, ≥18 years of age
Mechanism of action	Binds to IgE (at Fcε3), which prevents IgE binding to the FcεR1 receptor on mast cells, basophils, dendritic cells and other key inflammatory cells.	Binds to IL-4Rα, which inhibits both IL-4 and IL-13 signaling.	Binds to the IL-5Ra on eosinophils and basophils leading to antibody-dependent cell-mediated cytotoxicity of these cells.	Binds to IL-5	Binds to IL-5
Route	Subcutaneous	Subcutaneous	Subcutaneous	Subcutaneous	Intravenous
Frequency	Every 2 to 4 weeks	Every two weeks	Every 4 weeks for the first three doses then every 8 weeks	Every four weeks	Every four weeks
Dose	Based on IgE and body weight (~0.016 mg/kg/IU/mL)	Likely 300 mg (fixed)	30 mg (fixed), pre-filled syringes	100 mg (fixed)	3.0 mg/kg (weight-based)
Biomarkers	Efficacy better with elevated eosinophils or FeNO	Efficacy better with elevated eosinophils or FeNO	Blood eosinophils ≥ 300 cells/μL	Blood eosinophils ≥ 150 cells/μL at initiation OR ≥ 300 cells/μL within the previous year	Blood eosinophils ≥ 400 cells/μL
Reduction in asthma exacerbations	Yes	Yes	Yes	Yes	Yes
Improvements in pulmonary functions	Minimal or mixed effect	Yes	Yes	Yes, especially in patients with very elevated eosinophil levels	Yes
Asthma symptom score and quality of life improvements vs placebo	Yes	Yes in Phase 2b study	Varied	Varied	Varied
Corticosteroid sparing effect	Data mixed	Not published	Yes	Yes	Data mixed

As outlined in the above table, Dupixent has helped patients in numerous ways such as relief of symptoms, improvement in lung function, decrease asthma flare-ups and less use of oral prednisone.

I have read and reviewed additionally printed and electronic information for Dupixent.

Patient Signature:

Date:

Witness Signature:

Date:

Physician Signature:

Date: