Dupixent

(dupilumab)

New Product Slideshow

MPR

Introduction

- **Brand name:** Dupixent
- **Generic name:** Dupilumab
- **Pharmacological class:** Interleukin-4 receptor alpha antagonist
- **Strength and Formulation:** 300mg/2mL; solution for SC injection; preservative-free
- **Manufacturer:** Sanofi and Regeneron
- **How supplied:** Single-dose prefilled syringes—2 (with or without needle shield)
- **Legal Classification:** Rx

DUPIXENT


NDC 0024-5914-01
DUPIXENT®
(dupilumab)
Injection
Rx Only
300 mg/2 mL (150 mg/mL)
For Subcutaneous Injection Only
2 Single-dose Pre-filled Syringes with Needle Shield
Keep out of reach of children. Do not use after expiration. Do not use if seal is broken or damaged.
Store refrigerated at 36° to 46°F (2° to 8°C) in the original carton.
Dosage and Administration: See package insert for dosage information and directions for use.
SANOFI GENZYME
REGENERON
300mg/2mL
DUPIXENT

Indications

- Moderate-to-severe **atopic dermatitis** in adults who are not adequately controlled with topical prescription therapies or when they are not advisable

Dosage & Administration

- Give by SC inj into thigh, abdomen (except around navel), or upper arm; rotate inj sites
- **≥18yrs:** Initially 600mg (two 300mg inj at different sites) followed by 300mg every other week
- May use with or without topical corticosteroids
- Topical calcineurin inhibitors may also be used, but should be reserved only for problem areas (eg, face, neck, intertriginous and genital areas)

Considerations for Special Populations

- **Pregnancy:** No available data of use in pregnant women to inform any drug associated risk
- **Nursing mothers:** Consider health benefits of breastfeeding with potential adverse effects
- **Pediatric:** <18yrs: not established
- **Elderly:** No differences in safety or efficacy were observed

Warnings/Precautions

- Discontinue if significant hypersensitivity reaction occurs; treat appropriately
- Advise patients to report new onset or worsening eye symptoms
- Comorbid asthma
- Helminth infections
- Do not inject into tender, damaged, bruised or scarred skin

Interactions

- Avoid concomitant **live vaccines**
- Concomitant CYP450 substrates with **narrow therapeutic index** (eg, warfarin, cyclosporine); monitor and consider dose adjustment

Adverse Reactions

- Injection site reactions
- Conjunctivitis
- Blepharitis
- Oral herpes
- Keratitis
- Eye pruritus
- Other herpes simplex virus infection
- Dry eye
- Hypersensitivity

Mechanism of Action

- Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by specifically binding to the IL-4Rα subunit shared by the IL-4 and IL-13 receptor complexes
- This inhibits the release of proinflammatory cytokines, chemokines, and IgE

Clinical Trials

- **Trials 1, 2, and 3** (N=2,119) evaluated subjects with moderate-to-severe atopic dermatitis (AD) not adequately controlled by topical medication(s)
- At baseline, 52% of subjects had an IGA score of 3 (moderate AD) and 48% of subjects had an IGA of 4 (severe AD)
- The baseline mean EASI score was 33 and the baseline weekly averaged peak pruritus Numeric Rating Scale (NRS) was 7 on a scale of 0−10

Clinical Trials

- All subjects were given Dupixent 600mg at Week 0, followed by 300mg every other week in all 3 trials
- In **Trials 1 and 2**, subjects received Dupixent or placebo for 16 weeks
- In **Trial 3**, subjects received Dupixent or placebo with concomitant topical corticosteroids (TCS) and as-needed topical calcineurin inhibitors for problem areas only for 52 weeks

Clinical Trials

- All trials assessed the primary endpoint, which was the change from baseline to Week 16 in the proportion of subjects with an IGA 0 or 1 and at least a 2-point improvement
- Other endpoints included the proportion of subjects with EASI-75 and reduction in itch (defined by ≥4 point improvement in peak pruritus NRS) from baseline to Week 16

Clinical Trials

- In **Trial 1**, 38% of subjects in the Dupixent group achieved IGA 0 or 1 vs. 10% in the placebo group
  - EASI-75 was achieved in 51% of subjects in the Dupixent group vs. 15% in the placebo group
  - Peak pruritus NRS was seen in 41% of subjects in the Dupixent group vs. 12% in the placebo group
- In **Trial 2**, 36% of subjects in the Dupixent group achieved IGA 0 or 1 vs. 9% in the placebo group
  - EASI-75 was achieved in 44% of subjects in the Dupixent group vs. 12% in the placebo group
  - Peak pruritus NRS was seen in 36% of subjects in the Dupixent vs. 10% in the placebo group

Clinical Trials

- In **Trial 3**, 39% of subjects in the Dupixent + TCS group achieved IGA 0 or 1 vs. 12% in the placebo + TCS group
  - EASI-75 was achieved in 69% of subjects in the Dupixent + TCS group vs. 23% in the placebo + TCS group
  - Peak pruritus NRS was seen in 59% of subjects in the Dupixent + TCS group vs. 20% in the placebo + TCS group

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/dupixent/drug/34658/