Odactra

(house dust mite allergen extract)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Odactra
- **Generic name:** House dust mite allergen extract (*Dermatophagoides farinae, Dermatophagoides pteronyssinus)*
- **Pharmacological class:** Allergen extract
- **Strength and Formulation:** 12 SQ-HDM; sublingual tabs
- **Manufacturer:** Merck & Co., Inc.
- **How supplied:** Blisters—30
- **Legal Classification:** Rx

Indications

- House dust mite-induced **allergic rhinitis**, with or without conjunctivitis, confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
- **Not** for immediate relief of allergic symptoms

Dosage & Administration

- Give 1st dose under physician supervision; observe ≥30mins for any signs/symptoms of severe allergic reaction; if tolerated, subsequent doses may be taken at home
- **18–65yrs:** 1 tab daily

Dosage & Administration

- Allow complete dissolution under the tongue before swallowing
- Avoid food or beverage for 5 mins after dosing
- Wash hands after handling tab

Considerations for Special Populations

- **Pediatric:** <18yrs: not established
- **Pregnancy:** Insufficient human data to establish drug-associated risk
- **Nursing mothers:** Consider mother's need and potential adverse effects on child
- **Elderly:** >65yrs: not established

Contraindications

- Severe, unstable or uncontrolled asthma
- History of any severe systemic or local allergic reaction to sublingual allergen immunotherapy
- History of eosinophilic esophagitis

Warnings/Precautions

- Risk of severe **allergic reactions** (eg, anaphylaxis, laryngopharyngeal swelling); discontinue if occurs
- Prescribe auto-injectable epinephrine for emergency use
- Underlying conditions that may reduce survival of a serious allergic reaction after epinephrine use (eg, markedly compromised lung function, unstable angina, recent MI, significant arrhythmia, uncontrolled HTN)

Warnings/Precautions

- Upper airway compromise: consider discontinuing if persistent adverse reactions in the mouth or throat develops
- **Withhold** therapy in acute asthma exacerbation; consider discontinuing if recurrent. Interrupt therapy for oral inflammation or wounds to allow complete healing

Interactions

- Concomitant **other allergen immunotherapy**: not studied; may increase risk of local or systemic adverse reactions
- **Avoid** concomitant drugs that can potentiate or inhibit effects of epinephrine (eg, beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, TCAs, levothyroxine, MAOIs, chlorpheniramine, diphenhydramine, [cardiac glycosides, diuretics; monitor for arrhythmias])

Adverse Reactions

- Throat irritation/tickle
- Mouth or ear itching
- Swelling (uvula/back of mouth, lips, tongue, throat)
- Nausea
- Tongue pain
- Tongue or mouth ulcer/sore
- Stomach pain
- Taste alteration
- Eosinophilic esophagitis (discontinue if occurs)

Mechanism of Action

- The precise mechanisms of action of allergen immunotherapy have not been fully established

Clinical Studies

- The efficacy of Odactra for HDM-induced allergic rhinitis was evaluated in 2 double-blind, placebo-controlled, randomized clinical field efficacy studies (Studies 1 and 2) and one environmental exposure chamber (ECC) study (Study 3)

Clinical Studies

- **Study 1** (N=1,482) compared the efficacy of Odactra vs placebo in patients aged 12 to 85yrs that had a history of symptomatic allergic rhinitis and were sensitized to *D. farina* and/or *D. pteronyssinus*

Clinical Studies

- Efficacy was assessed through self-reporting of symptoms and medication use to calculate the Total Combined Rhinitis Score (TCRS), daily symptom scores (DSS) and daily medication scores (DMS) for rhinoconjunctivitis
- The **primary endpoint** was the difference between treatment vs placebo in the average TCRS during ~8 weeks of treatment

Clinical Studies

- The TCRS was **4.10** in the Odactra arm vs **4.95** in the placebo arm (treatment difference -0.8)
  - Difference relative to placebo (estimate -17.2%, 95% CI: -25.0%, -9.7%)

Clinical Studies

- **Study 2** (N=656) compared Odactra vs placebo for approximately 12 months in adults aged 18 to 66yrs with a history of symptomatic allergic rhinitis when exposed to house dust and were sensitized to *D. farina* and/or *D. pteronyssinus*

Clinical Studies

- The **primary efficacy endpoint** was the difference relative to placebo in the average TCRS during the last 8 weeks of treatment

Clinical Studies

- The TCRS was **5.71** in the Odactra arm vs **6.81** in the placebo group (treatment difference -1.09)
  - Difference relative to placebo (estimate -16.1%, 95% CI: -25.8, -5.7%)

Clinical Studies

- **Study 3** (N=83) evaluated adults aged 18 to 58yrs with a history of symptomatic allergic rhinitis and were sensitized to *D. farinae* and/or *D. pteronyssinus* who were given Odactra for approximately 24 weeks

Clinical Studies

- The **primary endpoint** was the difference relative to placebo in the average Total Nasal Symptom Score (TNSS) at Week 24

Clinical Studies

- At Week 24, the TNSS was **3.83** in the Odactra arm vs **7.45** in the placebo arm (treatment difference -3.62)
  - Difference relative to placebo (estimate -48.6%, 95% CI: -60.2%, -35.3%)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/odactra/drug/34762/