

COM-2024-015

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PLEASE REVIEW Drug Information

PharmPix Clinical Department

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and disease prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 219.

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PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Dupixent™ (dupilumab): Possible Approval for COPD

The Food and Drug Administration (FDA) has accepted for priority review the supplemental biologics license application (sBLA) for Dupixent™ (dupilumab) as an add-on maintenance treatment in certain adult patients with uncontrolled chronic obstructive pulmonary disease (COPD). It is expected that the FDA will have a decision by mid-2024. If approved, this would be the sixth indication for Dupixent™ and the only biologic therapy for COPD.

Background:

First approved back in 2017 for atopic dermatitis, dupilumab is a biologic treatment for a range of other conditions, including eosinophilic esophagitis, moderate-to-severe atopic dermatitis, moderate-to-severe asthma, chronic rhinosinusitis with nasal polyposis and the rare skin disease prurigo nodularis.

Data from Clinical Trials:

Two phase 3 trials (NOTUS and BOREA) evaluated the efficacy and safety of Dupixent™ in adults who were current or former smokers with uncontrolled COPD with evidence of type 2 inflammation. The primary endpoint was met in both trials, showing Dupixent™ reduced annualized moderate or severe acute COPD exacerbations by 30% in one trial and 34% in the second trial, compared with placebo. In both trials, Dupixent™ improved lung function compared with placebo, with improvements sustained at 52 weeks.

In NOTUS, the most common adverse effects associated with dupilumab were COVID-19, nasopharyngitis, and headache. In BOREAS, the most common adverse effects associated with dupilumab were headache, diarrhea, and back pain.



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