

Judith Cope, MD, MPH

Safety Team Lead, Office of Pediatric Therapeutics

Office of the Commissioner, FDA

PEDIATRIC ADVISORY COMMITTEE UPDATES

*Pediatric Advisory Committee Meeting
September 20, 2018*



Montelukast

- Approved for
 - Prophylaxis and chronic treatment of asthma (12 months and older)
 - Seasonal allergic rhinitis (2 years and older)
 - Perennial allergic rhinitis (6 months and older)
 - Prevention of exercise-induced bronchoconstriction (6 years and older)
- Neuropsychiatric Events
 - Current label dated 12/2016 includes information in Warnings and Precautions, Adverse Reactions, and Patient Counseling Information sections
 - Safety issue reopened and under evaluation including FDA Adverse Event Reporting System (FAERS) reports, published literature, clinical trials, and Sentinel database
- FDA will update the PAC when full analysis and review are completed. It is anticipated that this will be in 2019.

Noxafil® (posaconazole) Labeling Changes



- April 12, 2016 PAC meeting Noxafil had an initial pediatric safety review and the Committee was informed that FDA was evaluating a safety signal of posaconazole – vincristine drug interaction and would report back about any modified labeling.
 - Labeling changes
 - 9/9/2016 (1) WARNINGS AND PRECAUTIONS section (5); a new subsection Vincristine Toxicity (5.6) to describe adverse reactions associated with concomitant administration of vinca alkaloids, including vincristine, with Noxafil. (2) DRUG INTERACTIONS section (7); update the Vinca Alkaloids subsection (7.10)
 - 1/4/2018 Also an additional labeling change 1/4/2018: ‘Pancreatitis’ has been added to the ADVERSE REACTIONS (6) section, Clinical Trials Experience (6.2) subsection, list of Less Common Adverse Reactions.
- Noxafil (posaconazole) underwent another pediatric safety review in 2018 which is webposted for this September PAC. There were no new safety issues or concerns.