Activity Outline
FDA Drug Topics: Safety Labeling Changes for Leukotriene Receptor Antagonists and Decisions Behind a Boxed Warning
May 18, 2021
FDA

Activity Coordinator:
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Description
This presentation will review the existing data pertaining to neuropsychiatric adverse events with montelukast use and will provide an overview of the decision-making framework underlying the recent labeling changes. The FDA has been aware of post-marketing reports of neuropsychiatric adverse events associated with montelukast use for over a decade. In response to continued concerns from the public, FDA recently conducted another comprehensive review and observational study using claims data in the Sentinel Distributed Database, the results of which were presented at an Advisory Committee meeting in September of 2019. After careful consideration of the available data and feedback received during the FDA Advisory Committee meeting, the FDA required a boxed warning and a revision specifically for the allergic rhinitis indication to reserve use of montelukast for patients who have an inadequate response or intolerance to alternative therapies.

References

- U.S. Food and Drug Administration. FDA Briefing Materials for the September 27, 2019 Joint Meeting of the Pediatric and Drug Safety and Risk Management Advisory Committees. https://www.fda.gov/media/131035/download.
- U.S. Food and Drug Administration. Transcript of the September 27, 2019 Joint Meeting of the Pediatric and Drug Safety and Risk Management Advisory Committees. https://www.fda.gov/media/132560/download.
- U.S. Food and Drug Administration. "FDA requires Boxed Warning about serious mental health side effects fr asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis." FDA Drug Safety Communication. March 4, 2020. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-boxed-warning-about-serious-mental-health-side-effects-asthma-and-allergy-drug.
- Sansing-Foster V, Haug N, Mosholder A, Cocoros NM, Bradley M, Ma Y, et al. Risk of Psychiatric Adverse Events Among Montelukast Users. J Allergy Clin Immunol Pract. 2021;9(1):385-93.e12.
- Chin S, Clarridge K, Eworuke E, Seymour S. A Boxed Warning for Montelukast: The FDA Perspective The Journal of Allergy and Clinical Immunology: In Practice. 2021. In Press.

Learning Objectives

- Identify the spectrum of neuropsychiatric adverse events, including serious neuropsychiatric events associated with montelukast use.
- List the different sources of safety data that contributed to the understanding of the risk of neuropsychiatric events with montelukast.
- Describe the revised labeling recommendations for use of montelukast in patients with allergic rhinitis.

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, Certified Public Health Professionals (CPH), and physician assistants.

Agenda
Day 1 May 18, 2021

Time	Topic	Speaker
1:00 - 2:00 PM	FDA Drug Topics: Safety Labeling Changes for Leukotriene Receptor Antagonists and Decisions Behind a Boxed Warning	KATHERINE CLARRIDGE, MD Stacy Chin, MD Efe Eworuke, PhD

Continuing Education Accreditation

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-21-053-L01-P, and ACPE Universal Activity Number JA0002895-0000-21-053-L01-T for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

AAPA

This activity is designated for 1.00 AAPA Category 1 CME credits. FDA Center for Drug Evaluation and Research has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. PAs should only claim credit commensurate with the extent of their participation.

CPH

Up to 1.00 CPH Recertification Credits may be earned at this event.

Requirements for Receiving CE Credit

Physicians, physician assistants, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME:participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians, physician assistants, and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- CLARRIDGE, KATHERINE, MD, Medical Officer, FDA *nothing to disclose May reference off-label use.*
- Chin, Stacy, MD, Medical Officer, CDER *nothing to disclose*
- Eworuke, Efe, PhD, Lead Epidemiologist, FDA *nothing to disclose*

Planning Committee

- Burke, Kara, PharmD, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI *nothing to disclose*
- Cao, Christian, MPAS, PA-C, Safety Evaluator Team Leader, FDA/CDER/OSE/DPV *nothing to disclose*
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI *nothing to disclose*
- Kapoor, Rama, MD, Medical Officer, FDA *nothing to disclose*
- Navin, Lesley, RN, MSN, Consumer Safety Officer, FDA/CDER/DDI *nothing to disclose*
- Nguyen-Chu, Thanh Tam, PharmD, Pharmacist, FDA/CDER/OCOMM/DDI *nothing to disclose*
- Paraoan, Dianne, MPH, RN, Associate Director for Regulatory Affairs, FDA/ CDER/ OMP *nothing to disclose*

CE Consultation and Accreditation Team

- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 100% of the activity.