Long-Acting Beta-Agonists (LABAs): New Safe Use Requirements

U.S. Food & Drug Administration

[UPDATED 06/03/2010] Drug labels now contain updated recommendations.

FDA notified healthcare professionals and consumers that, due to safety concerns, FDA is requiring a risk management strategy (REMS) and class-labeling changes for all LABAs. The REMS will require a revised Medication Guide written specifically for patients, and a plan to educate healthcare professionals about the appropriate use of LABAs. These changes are based on FDA's analyses of studies showing an increased risk of severe exacerbation of asthma symptoms, leading to hospitalizations in pediatric and adult patients as well as death in some patients using LABAs for the treatment of asthma.

Healthcare professionals are reminded that to ensure the safe use of these products:

- Single-ingredient LABAs should only be used in combination with an asthma controller medication; they should not be used alone.
- LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications.
- LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. Patients should then be maintained on an asthma controller medication.
- Pediatric and adolescent patients who require the addition of a LABA to an inhaled corticosteroid should use a combination product containing both an inhaled corticosteroid and a LABA, to ensure compliance with both medications.

FDA has determined that the benefits of LABAs in improving asthma symptoms outweigh the potential risks when used appropriately with an asthma controller medication in patients who need the addition of LABAs. FDA believes the safety measures recommended will improve the safe use of these drugs.

[06/03/2010 - Drug Safety Communication [1] - FDA] [1]
[02/18/2010 - Drug Safety Communication [2] - FDA]
[02/18/2010 - Questions and Answers: Long-Acting Beta Agonists [3] - FDA]
[02/18/2010 - Press Release [4] - FDA]

SOURCE [5]

Source URL (retrieved on *03/14/2014 - 12:35am*):
http://www.mdtmag.com/news/2010/06/long-acting-beta-agonists-labas-new-safe-use-requirements

Links:
[1] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm213836.htm
[2] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm200776.htm
[3] http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm200719.htm
[4] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm200931.htm
[5] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm201003.htm