AMERICAN HEALTH CARE
DRUG PRODUCTS & SAFETY NEWS

FDA Approves Cinqair

March 23, 2016

The U.S. Food and Drug Administration (FDA) approved Cinqair (reslizumab) for use with other asthma medicines for the maintenance treatment of severe asthma in patients aged 18 years and older. Cinqair is approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines.

Asthma is a chronic disease that causes inflammation in the airways of the lungs. During an asthma attack, airways become narrow making it hard to breathe. Severe asthma attacks can lead to hospitalizations because these attacks can be serious and even life-threatening. According to the Centers for Disease Control and Prevention, as of 2013, more than 22 million people in the U.S. have asthma, and there are more than 400,000 asthma-related hospitalizations each year.

Cinqair is administered once every four weeks via intravenous infusion by a health care professional in a clinical setting prepared to manage anaphylaxis.

Cinqair is made by Teva Pharmaceuticals in Frazer, Pennsylvania.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

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