

Recent Safety Concerns For Singulair



Singulair (montelukast) is Leukotriene-Receptor Blocker indicated for the treatment of Seasonal Allergic Rhinitis (SAR) in adults and children two years and older, Perennial Allergic Rhinitis (PAR) in adults and children six months and older, and in the prevention and chronic treatment of asthma in adults and children 12 months of age and older.

On March 27, 2008, Merck & Co., Inc., who manufactures and markets Singulair, issued a statement in response to the FDA's Early Communication on an Ongoing Safety Review of Singulair.

The statement included the fact that Merck & Co., Inc. voluntarily updated the worldwide product information for Singulair in October 2007 to include "suicidal thinking and behavior" and included a similar statement in the patient package insert. This decision by Merck came from a limited amount of post-marketing observational studies that demonstrated the potential for an increased risk of suicidal behavior.

Data from post-marketing studies, which begin soon after the drug is introduced onto the market and continue for many years, are not always conclusive enough to derive an exact "cause-and-effect" relationship. In general, a post-marketing adverse event that is reported could be caused by an underlying condition, genetic predisposition, the medication, concomitant medications, or circumstantial events that are ongoing.

The recent information being introduced on Singulair, though limited in depth, still needs to be addressed. If you have the slightest concern about your child and this potential risk, address it immediately with your healthcare provider.

What Should I Do?

- Watch for unusual changes in mood, eating habits, sleeping habits, and concentration
- Talk to your Pharmacist or Physician for more information
- Do not stop taking Singulair without first talking to your healthcare provider
- Visit Merck's website at www.merck.com to read a statement by Merck & Co.