Tumor Necrosis Factor (TNF) blockers, Azathioprine and/or Mercaptopurine: Update on Reports of Hepatosplenic T-Cell Lymphoma in Adolescents and Young Adults

U.S. Food & Drug Administration

AUDIENCE: Rheumatology, Gastroenterology, Oncology, Dermatology

ISSUE: FDA continues to receive reports of a rare cancer of white blood cells (known as Hepatosplenic T-Cell Lymphoma or HSTCL, primarily in adolescents and young adults being treated for Crohn’s disease and ulcerative colitis with medicines known as tumor necrosis factors (TNF) blockers, as well as with azathioprine, and/or mercaptopurine. TNF blockers include Remicade (infliximab), Enbrel (etancercept), Humira (adalimumab), Cimzia (certolizumab pegol) and Simponi (golimumab).

BACKGROUND: HSTCL is an aggressive (fast-growing) cancer and is usually fatal. The majority of cases reported were in patients being treated for Crohn’s disease or ulcerative colitis, but also included a patient being treated for psoriasis and two patients being treated for rheumatoid arthritis. FDA is now updating the number of reported cases of HSTCL.

Although most reported cases of HSTCL occurred in patients treated with a combination of medicines known to suppress the immune system, including the TNF blockers, azathioprine, and/or mercaptopurine, there have been cases reported in patients receiving azathioprine or mercaptopurine alone.

RECOMMENDATIONS:

- Educate patients and caregivers about the signs and symptoms of malignancies such as HSTCL so that they are aware of and can seek evaluation and treatment of any signs or symptoms. These may include splenomegaly, hepatomegaly, abdominal pain, persistent fever, night sweats, and weight loss.
- Monitor for the emergence of malignancies when a patient has been treated with TNF blockers, azathioprine, and/or mercaptopurine.
- Know that people with rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis may be more likely to develop lymphoma than the general U.S. population. Therefore, it may be difficult to measure the added risk of TNF blockers, azathioprine, and/or meracaptopurine.

Read the Drug Safety Communications for other specific recommendations for Healthcare Professionals and Patients and the Data Summary for additional

information.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[04/14/2011 - Drug Safety Communication [3] - FDA]

Previous MedWatch Alert:

[08/04/2009 [4]]

SOURCE [5]

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http://www.mdtmag.com/news/2011/04/tumor-necrosis-factor-tnf-blockers-azathioprine-and/or-mercaptopurine-update-reports-hepatosplenic-t-cell-lymphoma-adolescents-and-young-adults

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/ucm250913.htm
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