APhA DrugInfoLine®

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Focus on Immunizations

Advising on this article: John D. Grabenstein

August 6, 2018

DTaP vaccines are safe, but take care to prevent vaccination-related errors

Key Point

An in-depth review of data from the Vaccine Adverse Event Reporting System (VAERS) on DTaP-based vaccines over a 19-year period showed no new or unexpected safety signals, with the most common adverse events being injection-site reactions and fever. Nonserious vaccination errors were also identified as an issue.

Source URL:

http://www.aphadruginfoline.com/focus-immunizations/dtap-vaccines-are-safe-take-care-prevent-vaccination-related-errors

Endocrinology

Advising on this article: Frank Pucino

August 6, 2018

Denosumab is a good option for patients receiving glucocorticoids

Key Point

Use of denosumab (Prolia—Amgen) for 12 months was shown to be both noninferior and superior to risedronate on select bone mineral density endpoints for patients newly initiating glucocorticoids or those continuing therapy, according to results of a trial published in The Lancet Diabetes and Endocrinology.

Source URL:

http://www.aphadruginfoline.com/endocrinology/denosumab-good-option-patients-receiving-glucocorticoids

New Drug Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
August 1, 2018	
Lusutrombopag ***(Mulpleta—Shionogi)*** **New drug targets thrombocytopenia in adults with chronic liver disease**	FDA approved lusutrombopag, a once-daily, orally administered, small molecule thrombopoietin receptor agonist, for treatment of thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure. Approval was based on two randomized, double-blind, placebo-controlled trials involving 312 patients with chronic liver disease and severe thrombocytopenia who were undergoing an invasive procedure and had a platelet count of less than 50 x 109/L. Patients were randomized 1:1 to receive 3 mg of lusutrombopag or placebo once daily for up to 7 days. In one trial, 78% of patients (38/49) receiving lusutrombopag required no platelet transfusion prior to the primary invasive procedure, compared with 13% (6/48) who received placebo. In the second trial, 65% (70/108) of patients who received lusutrombopag required no platelet transfusion prior to the primary invasive procedure or rescue therapy for bleeding from randomization through 7 days after the procedure, compared with 29% (31/107) receiving placebo. The most common adverse reaction (?3% of patients) was headache. The recommended lusutrombopag dosage is 3 mg orally once daily with or without food for 7 days.

Source URL:

http://www.aphadruginfoline.com/new-drug-approvals/new-drug-targets-thrombocytopenia-adults-chronic-liver-disease

Alerts and Recalls

Generic Name (Trade Name—Company)	**Uses**/Notes
August 3, 2018	
Azithromycin ***(Zithromax, Zmax—Pfizer, others)*** **Increased risk of cancer relapse with long-term use of azithromycin after donor stem cell transplant**	FDA is warning that the antibiotic azithromycin should not be given long term to prevent an inflammatory lung condition known as bronchiolitis obliterans syndrome in patients with cancers of the blood or lymph nodes who undergo a donor stem cell transplant. Results of a clinical trial found an increased rate of relapse in cancers affecting the blood and lymph nodes, including death, in these patients. Bronchiolitis obliterans syndrome is caused by inflammation and scarring in the airways of the lungs, resulting in severe shortness of breath and dry cough. Patients with cancer who undergo stem cell transplants from donors are at risk for bronchiolitis obliterans syndrome.There are no known effective antibiotic treatments that prevent the syndrome, and azithromycin is not approved for this use. It is an FDA-approved antibiotic used to treat many types of infections affecting the lungs, sinuses, skin, and other parts of the body. The drug, which has been used for more than 26 years, is sold under the brand names Zithromax and Zmax and as generics by many different drug companies. Pfizer, the manufacturer of brand name azithromycin, is providing a Dear Healthcare Provider letter on this safety issue to health professionals who care for patients undergoing donor stem cell transplants. FDA is reviewing additional data and will communicate its conclusions and recommendations when the review is complete. Patients who have had a stem cell transplant should not stop taking azithromycin without first consulting with their health care provider.

Source URL:

http://www.aphadruginfoline.com/alerts-and-recalls/increased-risk-cancer-relapse-long-term-use-azithromycin-after-donor-stem-cell