

# Common Vaccinations Do Not Raise RA Risk

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ROME — Immunization with common vaccines is not associated with an increased risk for rheumatoid arthritis, nor does it trigger the autoimmune disease in individuals who have established risk factors, according to an analysis of data that was presented by Camilla Bengtsson.

Using data from the Swedish population-based EIRA (Epidemiological Investigation of Rheumatoid Arthritis) data set and 1,984 healthy matched controls, Ms. Bengtsson, a doctoral candidate at the Karolinska Institute in Stockholm, and her associates compared the 582 individuals in the EIRA data set who had been vaccinated in the 5 years prior to disease onset with the 1,269 RA patients who had not been vaccinated

within 5 years prior to disease onset. Among the control subjects, 617 had been vaccinated and 1,367 had not been vaccinated within the preceding 5 years.

Vaccine by vaccine, the odds ratio for developing RA after influenza vaccination was 1.1 (252 RA patients and 279 controls had received the flu vaccine during the period of interest). The OR for RA after tetanus vaccination was 1.0 (170 cases and 179 controls had received that vac-

nation). The OR was 1.0 for diphtheria vaccination (71 cases/71 controls). For tick-borne encephalitis, the OR was 0.8 (91 cases/122 controls). The OR for hepatitis A, B, and C was 0.9 (105 cases/124 controls). The OR for polio vaccination was 1.1 (29 cases/31 controls). The OR for pneumococcus was 1.0 (22 cases/22 controls). The RA OR for the unvaccinated was 1.0 (1,269 cases/1,367 controls). She reported having no conflicts. ■

## Zmax: the only extended-release azithromycin formulation<sup>1</sup>

For acute bacterial sinusitis in adults and community-acquired pneumonia in adults and children ≥6 months of age

- ✓ A complete course of therapy in one day, one dose\*
- ✓ Extended-release microspheres allow for single-dose tolerability<sup>2,3</sup>
- ✓ Front-loaded dosing means Zmax concentrations peak within 24 hours and remain high for a full 10 days of therapy<sup>4,5</sup>

\*Treatment is complete; however, Zmax continues working in their system for 10 days.

### Important Safety Information

Zmax is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin, or any macrolide or ketolide antibiotic. If an allergic reaction occurs, appropriate treatment should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

There have been rare reports of serious allergic reactions including angioedema, anaphylaxis, Stevens-Johnson syndrome, and toxic epidermal necrolysis in patients on other formulations of azithromycin therapy. Rarely, fatalities have been reported.

*Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including azithromycin, and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued, and appropriate management and treatment of *C. difficile* should be instituted as clinically indicated.

As with all macrolides, including Zmax, new onset or exacerbations of myasthenia gravis have been reported.

A higher incidence of gastrointestinal adverse events (8 of 19 subjects) was observed when Zmax was administered to a limited number of subjects with GFR <10 mL/min.

Overall, the most common treatment-related adverse reactions in:

- **Adult patients** receiving a single 2-g dose of Zmax were diarrhea/loose stools (12%), nausea (4%), abdominal pain (3%), headache (1%), and vomiting (1%).
- **Pediatric patients** receiving the recommended Zmax dose of 1 mL/lb were diarrhea (8%), loose stools (5.6%), vomiting (3.3%), abdominal pain (3%), rash (2.8%), nausea (1.7%), and anorexia (1.2%).

A more concentrated (60 mg/mL) formulation of Zmax was studied in investigational clinical trials and discontinued. Pediatric patients taking this more viscous formulation of Zmax experienced vomiting (11.9%).

**References:** 1. Zmax [prescribing information], New York, NY: Pfizer Inc; 2009. 2. Zithromax [prescribing information], New York, NY: Pfizer Inc; 2009. 3. Breen J, Herbig S, for the Zmax team. Zmax complete: a novel microsphere-based dosage form. Poster presented at: American Association of Pharmaceutical Scientists, November 6-10, 2005; Nashville, TN. 4. Liu P, Allaudeen H, Chandra R, et al. Comparative pharmacokinetics of azithromycin in serum and white blood cells of healthy subjects receiving a single-dose extended-release regimen versus a 3-day immediate-release regimen. *Antimicrob Agents Chemother.* 2007;51(1):103-109. 5. Data on file, Pfizer Inc.

 **Zmax**<sup>®</sup>  
(azithromycin extended release)  
for oral suspension

**1 Day. 1 Dose.**