

Pediatric Use

Safety and efficacy of HUMIRA in pediatric patients for uses other than juvenile idiopathic arthritis have not been established.

Juvenile Idiopathic Arthritis

In the juvenile idiopathic arthritis study, HUMIRA was shown to reduce signs and symptoms of active polyarticular juvenile idiopathic arthritis in patients 4 to 17 years of age. HUMIRA has not been studied in children less than 4 years of age, and there are limited data on HUMIRA treatment in children with weight <15 kg.

Safety of HUMIRA in pediatric patients was generally similar to that observed in adults with certain exceptions [see *Adverse Reactions*].

Geriatric Use

A total of 519 rheumatoid arthritis patients 65 years of age and older, including 107 patients 75 years of age and older, received HUMIRA in clinical studies RA-I through IV. No overall difference in effectiveness was observed between these subjects and younger subjects. The frequency of serious infection and malignancy among HUMIRA treated subjects over 65 years of age was higher than for those under 65 years of age. Because there is a higher incidence of infections and malignancies in the elderly population in general, caution should be used when treating the elderly.

OVERDOSAGE

Doses up to 10 mg/kg have been administered to patients in clinical trials without evidence of dose-limiting toxicities. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

PATIENT COUNSELING INFORMATION

Patient Counseling

Patients should be advised of the potential benefits and risks of HUMIRA. Physicians should instruct their patients to read the Medication Guide before starting HUMIRA therapy and to reread each time the prescription is renewed.

• **Immunosuppression**

Inform patients that HUMIRA may lower the ability of their immune system to fight infections. Instruct the patient of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis and reactivation of hepatitis B virus infections.

• **Allergic Reactions**

Patients should be advised to seek immediate medical attention if they experience any symptoms of severe allergic reactions. Advise latex-sensitive patients that the needle cap of the prefilled syringe contains latex.

• **Other Medical Conditions**

Advise patients to report any signs of new or worsening medical conditions such as heart disease, neurological disease, or autoimmune disorders. Advise patients to report any symptoms suggestive of a cytopenia such as bruising, bleeding, or persistent fever.

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Ethmoid Carcinoma Link to Wood Dust Exposure Found

BY ROBERT FINN
San Francisco Bureau

SAN FRANCISCO — Intestinal-type adenocarcinoma of the ethmoid sinus appears to be strongly related to long-term occupational exposure to wood dust or leather dust, Dr. Stefano Riccio reported at the Seventh International Conference on Head and Neck Cancer.

In a case series involving 706 patients with malignant tumors of the paranasal sinuses, 92.2% of the patients with histologically confirmed adenocarcinoma of the ethmoid sinus acknowledged substantial exposure to one of these dusts, said Dr. Riccio of the National Cancer Institute of Milan.

Most patients had been exposed to organic dusts for 25-58 years in their jobs as woodworkers or shoemakers. But 17 patients reported only early and relatively limited exposure to organic dusts: from 4 to 18 years followed by 28-46 years before the appearance of disease.

In patients with nasal obstruction or small or occasional epistaxis, physicians should determine whether the patient had been exposed to any oncogenic agents in the past, Dr. Riccio recommended at the conference, which was sponsored by the American Head and Neck Society. If such exposure can be confirmed, adenocarcinoma of the ethmoid sinus should be part of the differential diagnosis.

Dr. Riccio pointed out that epidemiologists first noticed an association between wood dust and nasal cancer in 1965. But epidemiological studies rarely make anatomical distinctions among the paranasal sinuses.

On the other hand, physicians are aware that intestinal-type adenocarcinoma is peculiar to the ethmoid sinus. For the most part, however, they are unaware of the epi-

demiological connection with occupational exposure.

All patients in the case series were treated between 1987 and 2007 at the National Cancer Institute of Milan. The cancer originated in the ethmoid sinus 57% of the time and in the maxillary sinus 43% of the time.

Forty-five percent of the patients in the ethmoid group reported occupational exposure to wood or leather dust, compared with just 1.3% of the maxillary group, a significant difference.

Intestinal-type adenocarcinoma was the predominant histologic type in the ethmoid group, and was seen in 44% of those patients.

In comparison, squamous cell carcinoma was the most common histologic type in the maxillary group, and was seen in 35% of those patients.

In his review of the literature, Dr. Riccio found that the rate of adenocarcinoma among patients with malignant ethmoid tumors appears to be much higher in Europe than in North America. In five European case series, the rate ranged from 27% to 74%, with the lowest rate in the United Kingdom. In five North American case series, the rate ranged from 6% to 17%.

Dr. Riccio suggested the three possible explanations for this discrepancy. First, while the commonly accepted danger threshold for wood dust in Europe is 5 mg/m³, that level is routinely exceeded in European furniture factories. The American Conference of Governmental Industrial Hygienists recommends a limit of 1 mg/m³. Second, hardwoods are more dangerous than soft woods, and hardwoods are more widespread in Europe. Finally, Dr. Riccio hypothesized that safety measures such as masks and aspiration devices are more common in North America.

Dr. Riccio stated that he had no conflicts of interest related to his presentation. ■

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DATA WATCH

Top Recommended Sunscreen Brands



Notes: 1,045 surveys were completed at the 2008 AAD annual meeting. The figures represent the number of appearances among respondents' top three recommendations. Source: Coolibar