

Pregnancy Registry: To monitor outcomes of pregnant women exposed to HUMIRA, a pregnancy registry has been established. Physicians are encouraged to register patients by calling 1-877-311-8972.

Nursing Mothers

It is not known whether adalimumab is excreted in human milk or absorbed systemically after ingestion. Because many drugs and immunoglobulins are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from HUMIRA, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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. Patients should be counseled about the risk of lymphoma and other malignancies while receiving HUMIRA.

• **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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Prednisone in RA: Low Dose Found Optimal

BY DIANA MAHONEY

COPENHAGEN — Prednisone in initial dosages lower than 5 mg/day is as effective as higher doses in rheumatoid arthritis patients, a study has shown.

Although the use of glucocorticoids in RA remains controversial, the drugs continue to play a major role in the treatment of the disease, Dr. Theodore Pincus said at the annual European Congress of Rheumatology. “Textbooks suggest that glucocorticoids should be used in rheumatoid arthritis only for patients with life-threatening complications, or as a bridge therapy until [disease modifying antirheumatic drug] treatment begins to work, yet estimates suggest that they are used by 20%-80% of patients in usual clinical practice.” Therefore, he noted, determining the lowest effective dosage is important.

Toward this end, Dr. Pincus, clinical professor of medicine at New York University and the Hospital for Joint Diseases, New York, and his colleagues retrospectively analyzed the efficacy of prednisone in the usual care of 308 RA patients treated over a 25-year period. Using a database of all patient visits to a weekly academic clinic during 1980-2004, the investigators analyzed all initial prednisone prescriptions and classified patients into those treated with an initial prednisone dosage of 5 mg/day or higher and those treated with an initial dose lower than 5 mg/day. The 5-mg threshold was used because the efficacy of prednisone at 5 mg daily in RA has been documented, according to Dr. Pincus.

Of the 308 patients, 195 were treated with an initial prednisone dose of 5 mg or higher and 113 were treated with an initial dose less than 5 mg. Nearly all of the patients taking prednisone also took DMARDs, primarily methotrexate.

All of the patients in the study completed the MDHAQ-FN (Multidimensional Health Assessment Questionnaire

including physical function measures), and a VAS (Visual Analog Scale) pain measure at each visit. The investigators compared the baseline, 12-month, and 24-month follow-up scores of patients in both dosage groups and used the change in scores from baseline to 12 and 24 months as outcome measures. They also analyzed the data based on 5-year subgroups to account for changes in prescribing practices over time. At baseline, patients in the higher-dose group had higher function and pain scores than did those in the lower-dose group, Dr. Pincus noted in a poster presentation.

The mean improvements in MDHAQ-FN scores were statistically similar between both groups, said Dr. Pincus. At 12 and 24 months, the mean MDHAQ-FN improvement from baseline was 40% and 31% in patients in the higher-dose group vs. 34% and 24% in patients in the lower-dose group. The mean improvements in pain scores were also similar between both groups. At 12 and 24 months, the mean improvement in pain from baseline was 37% and 42% in the higher-dose group, and 37% and 35% in the lower-dose group, he said.

When analyzed by 5-year periods, the initial prednisone dose fell from a mean of 10.3 mg in 1980-1984 to 6.5 mg (in 1985-89), 5.1 mg (in 1990-1994), 4.1 mg (in 1995-1999), and 3.6 mg (in 2000-2004). From 1980 to 2004, the median dosage fell from 5 mg/day to 3 mg/day. Before 1990, there were some differences in the pain and function scores between the lower- and higher-dose groups, but the differences were not maintained in the analysis of the 25-year period, he said.

“The findings suggest that many [RA] patients can be treated effectively with initial prednisone doses of less than 5 mg/day, achieving pain and function improvements comparable to those seen at higher doses,” said Dr. Pincus.

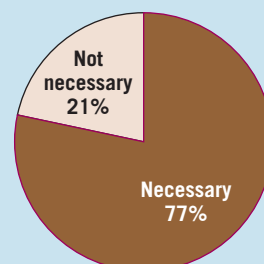
Dr. Pincus reported having no financial conflicts of interest to disclose. ■

DATA WATCH

Health Care Reform

The Spirit Seems Willing ...

Are structural changes needed to insure all Americans?

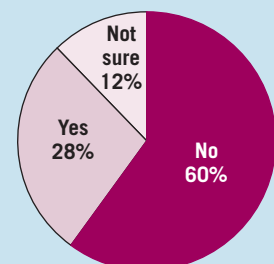


Note: Survey of 506 adults conducted July 31-Aug. 3; about 1% of respondents had no opinion.

Source: CNN/Opinion Research Corp.

But the Wallet May Be Weak

Are you willing to pay higher taxes to insure all Americans?



Note: Survey of 1,000 likely voters conducted Aug. 1-2.

Source: Rasmussen Reports