



AVARA[®]
(Leflunomide)

DRUG NEWSFLASH

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Aventis Pharma Inc. - Important safety information (liver injury) - PATIENTS TAKING ARAVA (LEFLUNOMIDE) FOR RHEUMATOID ARTHRITIS ASKED TO TAKE SPECIAL PRECAUTIONS -

LAVAL, Quebec, May 7 /CNW/ - Aventis Pharma Inc. announced today that it is issuing a letter to healthcare professionals regarding reports of liver injury in patients taking its drug leflunomide, sold under the brand name ARAVA[®]. ARAVA is used to treat patients with active rheumatoid arthritis. Patients with rheumatoid arthritis often have other serious medical conditions and receive several drugs in their treatment regimen which could be toxic to their liver. Therefore, it is difficult to identify definitively a specific cause for severe liver injury.

"Many other factors could be involved in these cases, but we cannot completely exclude a causal relationship to leflunomide at this time," says Dr. Jean Bourgoïn, Vice-President of Scientific Affairs at Aventis Pharma. "That's why we urge that patients experiencing symptoms such as nausea, vomiting, stomach pain or swelling, jaundice(*), dark urine or unusual tiredness report these to their doctor at once."

In view of this new information, Aventis has posted its product and patient monograph on its Web site at www.aventispharma.ca.

Blood tests may show an increase in some liver enzymes, which in very rare cases may develop into serious conditions such as hepatitis and liver failure. Isolated cases with fatal outcomes have been observed. ARAVA has been on the market in Canada since March 2000 and, when used according to product labeling and under physician supervision, is a safe and efficacious drug.

(*) Jaundice causes yellow discoloration of the eyes or skin.

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