WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

DRS/MtH/IEA.66

10 November 1997

Information Exchange System

Alert No. 66

Troglitazone – revised prescribing information : liver injury

United states of America. The manufacturer of the diabetes drug, troglitazone (Riluzin®: Parke Davis), is changing the prescribing information for the product to include a new warning in the labelling in response to reports of liver injury associated with its use.

Troglitazone is used in combination with insulin or sulfonylurea in patients with type II diabetes (adult-onset diabetes mellitus) whose blood glucose levels are not adequately controlled by these therapies alone.

About 500,000 patients in the United States have been treated with troglitazone since it came on the market in January 1997; of those, approximately 85,000 have been taking the drug for six months or more.

As of 21 October 1997, 35 post-marketing reports of liver injury of various degrees have been received. These reports ranged from mildly elevated blood levels of the liver transaminase enzymes to liver failure leading to one liver transplant and one death.

Based on these reports, the Food and Drug Administration and the manufacturer are recommending that serum transaminase levels in patients be checked routinely within the first one to two months of troglitazone therapy, every three months thereafter during the first year of treatment, and periodically thereafter. In addition, liver function tests should be performed on any patient taking troglitazone who develops symptoms of liver dysfunction, such as nausea, vomiting, abdominal pain, fatigue, loss of appetite, or dark urine. Patients taking troglitazone who develop jaundice or whose laboratory results indicate liver injury should stop taking the drug.

References: FDA Talk Paper T97-55 dated 3 November 1997 [Internet: http://www.fda.gov]

❖

CH-1211 GENEVA 27-SWITZERLAND Telegr.: UNISANTE-GENEVA Telex: 415416 OMS Fax 791.07.46 CH-1211 GENEVE 27-SUISSE Télégr.: UNISANTE-GENEVE