Didanosine: Risk of non-cirrhotic portal hypertension

USA. The US FDA has alerted health-care professionals and patients about cirrhotic portal hypertension in patients using didanosine. Didanosine is used to treat human immunodeficiency virus (HIV) infection. The US FDA has received 42 post-marketing cases of non-cirrhotic portal hypertension in patients using didanosine with 4 deaths in those reported cases. The Agency explains that the cause of death in the four patients was due to:

- Haemorrhage from esophageal varices in two patients
- Progressive liver failure in one patient and
- A combination of multi-organ failure, cerebral haemorrhage, sepsis and lactic acidosis in one patient.

Based on the number of well-documented cases and exclusion of other causes of portal hypertension such as alcohol-related cirrhosis or hepatitis C., the US FDA has concluded that there is an association between use of didanosine and development of non-cirrhotic portal hypertension. Because of the potential severity of portal hypertension, the Agency has revised the warning and precautions section of the didanosine label to include information about non-cirrhotic portal hypertension. Didanosine already has a boxed warning for lactic acidosis and hepatomegaly with steatosis.

The US FDA states that the clinical benefits of didanosine for certain patients with HIV continue to outweigh its potential risks. The decision to use this medicine, however, must be made on an individual basis between the treating physician and the patient.

Reports in the WHO Global ICSR database, Vigibase:

Didanosine

Number of reports with cardiovascular disorders, general: 134

Most reported reactions (number of events):

- *Hypertension portal: 25*
- *Cardiac failure: 26*
- *Hypertension: 23*
- *Hypotension: 34*

Reference:

1. WHO Pharmaceuticals Newsletter No. 2, 2010 Page 3
2. Safety information, US FDA 29 January 2010 (www.fda.gov)

Any such reports in your practice? Have you noted the same or similar Adverse Drug Reactions? If yes, please report to:

The Pharmacovigilance Department, Pharmacy and Poisons Board.

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Remember…

"You need not be certain…

Just be suspicious"

Report all suspected cases of ADRs and Poor Quality Medicines