

衛生署藥物辦公室
藥物註冊及進出口管制部

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6 December 2011

Dear Healthcare Professionals,

**Ursodiol (ursodeoxycholic acid, UDCA) - association of high-dose with
serious liver side effects**

Your attention is drawn to that the Health Canada alerted healthcare professionals of possible increase in serious liver adverse effects as a result of taking an unapproved dose of ursodeoxycholic acid equivalent to twice the maximum recommended dose.

In a 5-year randomized, double-blind, clinical trial, primary sclerosing cholangitis (PSC) patients were treated with placebo or twice the recommended dose of ursodeoxycholic acid and it was found that the risk was 2.1-fold greater for death, liver transplantation in the high-dose ursodeoxycholic acid group. Consequently, the Health Canada updated the Canadian Product Monographs (PMs) for ursodeoxycholic acid containing drugs to describe the clinical trial, and advise that improved serum liver tests (e.g. AST, ALP) do not always correlate with an improved liver disease status. The PMs continue to recommend monitoring of GGT, alkaline phosphatase, AST, ALT and bilirubin every month for three months after start of therapy, and every six months thereafter. Treatment should be discontinued if the levels of these parameters increase.

The approved indications of ursodeoxycholic acid containing-drugs are cholesterol gallstones and primary biliary cirrhosis.

Healthcare professionals are warned to be alerted of the above possible risk associated with the drugs. For details, please refer to the following link:
http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2011/ursodiol_hpc-cps-eng.php

In Hong Kong, there are 10 over-the-counter registered products containing ursodeoxycholic acid and 8 of them contain ursodeoxycholic acid as single ingredient. In view of Health Canada's recommendation, the issue will be discussed in the Registration Committee coming meeting of the Pharmacy and Poisons Board. Department of Health will also closely monitor related developments both locally and worldwide.

Please report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: <http://www.drugoffice.gov.hk> at Drug Office under "Reporting an Adverse Drug Reaction".

Yours sincerely,


(Ms Pamela LI)
for AD(D)

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