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PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
ursodiol (ursodeoxycholic acid, UDCA, ursodiol C, URSO®, URSO DS®)

Dominion Pharmacal

01/12/2011

Subject: **Association of high-dose ursodiol (ursodeoxycholic acid, UDCA) [URSO®, URSO DS® , Dom-URSODIOL C®, phl-URSODIOL C®, pms-URSODIOL C®, TEVA-URSODIOL®] with serious hepatic adverse events**

The manufacturers of ursodiol (Aptalis Pharma Canada Inc., Dominion Pharmacal, Pharmascience Inc., Pharmel Inc., and Teva Canada Ltd.), in consultation with Health Canada, would like to inform you of important new information regarding ursodiol.

Ursodiol is a medication used to treat some types of liver disease. Ursodiol is also called ursodeoxycholic acid, UDCA, URSO®, URSO DS®, Dom-URSODIOL C, phl-URSODIOL C, pms-URSODIOL C, or TEVA-URSODIOL.

Healthcare professionals, patients and their caregivers should be aware of the following information:

- In light of study findings in patients suffering from a liver disease known as primary sclerosing cholangitis, patients should discuss their ursodiol treatment with their healthcare provider at their next visit.
- Patients should not stop or modify their treatment without medical advice.
- Improved liver test results do not always mean that the liver disease has improved.

In a clinical study*, patients given **twice** the recommended dose of ursodiol had improved serum liver test results, but overall had more serious adverse events (including swollen veins of the digestive tube, replacement of a diseased liver or death) compared to patients given placebo (sugar pills). The patients in this trial had the liver disease known as primary sclerosing cholangitis which may be associated with these serious events during the disease progression.

The Canadian Product Monographs (PMs) for ursodiol have been revised, in October 2011, to describe the clinical trial, and advise that improved liver test results (e.g. ALP, AST) do not always indicate an improvement of liver disease.

It is still recommended that patients are monitored using blood liver tests every month for three months after starting ursodiol treatment, and every six months after that. Treatment should be stopped if the blood liver test results worsen.

* The results of the clinical trial are summarized in greater detail in a related communication to healthcare professionals. This information can be accessed at [http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2011/index-eng.php].

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Any case of serious hepatic adverse events or other serious or unexpected adverse reactions in patients receiving ursodiol should be reported to the manufacturer (Aptalis Pharma Canada Inc., Dominion Pharmacal, Pharmascience Inc., Pharmel Inc., Teva Canada Ltd.) or Health Canada.

Aptalis Pharma Canada Inc.,
Dominion Pharmacal,
Pharmascience Inc.,
Pharmel Inc.,
Teva Canada Ltd.

You can report any suspected adverse reactions associated with the use of health products to the Canadian Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

For other health product inquiries related to this communication, please contact Health Canada at:
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E-mail: mhpd_dpsc@hc-sc.gc.ca
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Fax: 613-952-7738

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