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Health Canada



July 22, 2008 17:06 ET

Warning: Health Canada Warns Consumers Not to Use Jin Bu Huan Anodyne Tablets Due to Potential Health Risk

OTTAWA, ONTARIO--(Marketwire - July 22, 2008) - Health Canada is warning consumers not to use the unauthorized product Jin Bu Huan Anodyne because it contains the undeclared ingredient tetrahydropalmatine, which has been associated with serious adverse health effects.

The amount of tetrahydropalmatine in a daily dose of Jin Bu Huan Anodyne tablets has been associated with reports of liver injury in adults, and reports of neurotoxicity (brain and nervous system injury) in children and adults. Tetrahydropalmatine has also been associated with adverse reactions such as fever, nausea, vomiting, abdominal pain, and diarrhoea.

In addition to containing an undeclared ingredient, Jin Bu Huan Anodyne's product label promotes an unauthorized use in the treatment of ulcer pain, and abdominal pain after childbirth. Use of this unauthorized product to treat these conditions may result in patients delaying effective treatments required for their conditions.

Jin Bu Huan Anodyne tablets are not authorized for sale in Canada. Authorized health products will bear an eight-digit Drug Identification Number (DIN), a Natural Product Number (NPN), or a Homeopathic Drug Number (DIN-HM). This authorization indicates that the products have been assessed by Health Canada for safety, effectiveness and quality.

Wing Quon Enterprises Ltd., the Canadian importer of Jin Bu Huan Anodyne tablets, has initiated a recall of the product. Health Canada will continue to monitor the effectiveness of this recall.

Consumers who have taken Jin Bu Huan Anodyne tablets should discontinue use immediately and consult a health care professional for advice on effective treatments for their conditions. Canadian retailers are advised to remove this product from their shelves.

Consumers requiring more information about this advisory can contact Health Canada's public enquiries line at (613) 957-2991, or toll free at 1-866-225-0709.

To date, there have been two cases of adverse reactions linked to the use of this product reported in Canada. To report a suspected adverse reaction to this product, please contact the Canada Vigilance Program of Health Canada by one of the following methods:

Telephone: 1-866-234-2345
Facsimile: 1-866-678-6789

Canada Vigilance Program
Marketed Health Products Directorate
Ottawa, Ontario, A1 0701C
K1A 0K9

E-mail: CanadaVigilance@hc-sc.gc.ca

The Canada Vigilance adverse reaction reporting form, including a version that can be completed and submitted online, is located in the MedEffect Canada (www.healthcanada.gc.ca/medeffect) area of the Health Canada Web site.

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