British Columbia Centre for Excellence in HIV/AIDS
Providence HEALTH CARE How you want to be treated.
Pharmacovigilance Program
SAFETY ALERT
No.3, June 2011

Darunavir (Prezista™) tablets: Possible "musty" odour

Sentinel event

On May 11, 2011, Janssen Inc. issued an advisory that some bottles of darunavir (Prezista™) 600 mg tablets in Lot # ALZ0J00 might have an uncharacteristic "musty" or "mouldy" odour. **Health Canada has advised the manufacturer that a product recall is NOT REQUIRED** because there is no known safety risk associated with the odour-causing agent.

Background

- Trace amounts of the chemical 2,4,6 tribromoanisole (TBA) have been detected in some bottles of darunavir 600 mg tablets Lot #ALZ0J00.
- TBA is a by-product of a wood preservative sometimes used to treat the wood pallets used for transporting food, drugs and other merchandise. TBA has a “musty” or “mouldy” odour that the human sense of smell can detect at extremely low levels – parts per billion or less.
- TBA is very volatile, and the odour can penetrate through sealed packages of food and drugs. Consumer complaints about unpleasant TBA odour and taste in food and beverages are well documented and industry is trying to eliminate this issue.
- There are **no known health risks** associated with the unpleasant smell or taste caused by trace amounts of TBA. Some consumers who have noted a foul odour in affected products have also experienced gastrointestinal symptoms. In Canada, to date, there have been two consumer complaints about darunavir tablets with unusual odour, with no complaints in British Columbia.
- In British Columbia, the potentially affected batch of darunavir 600 mg tablets **could have been dispensed between March 1st and May 12th, 2011**.

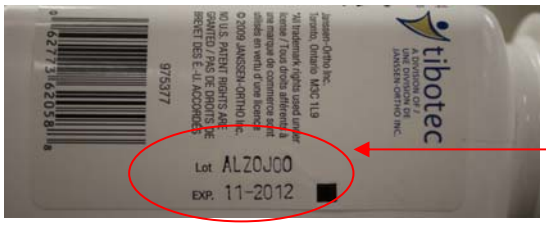
- As a precautionary measure, darunavir tablets from Lot # ALZ0J00, or any darunavir tablets with an uncharacteristic odour that were dispensed in BC **may be voluntarily returned to St Paul’s Hospital Ambulatory Pharmacy and exchanged for new product.**

Recommendations

- Based on available information, the affected batch of darunavir tablets is safe for consumption and **there is no requirement to return product** or recall patients for clinical assessment. Persons who take darunavir **should NOT stop taking their medication**.
- Consumers who have noted an unusual odour in their darunavir tablets, or who wish to receive further information about potential darunavir contamination or wish to request product exchange may telephone the St Paul’s Hospital Ambulatory Pharmacy at 604-806-8429 (in greater Vancouver) or 1-888-511-6222. Instructions for identifying potentially affected tablets are on the following page.
- Persons experiencing any unexpected symptoms or side effects they believe might be related to darunavir should seek medical attention and are encouraged to report the incident to the BC Centre for Excellence in HIV/AIDS Pharmacovigilance program, 604-806-8663.

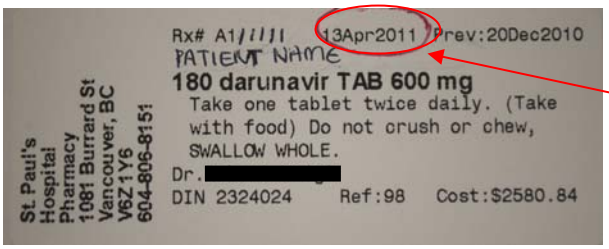
Recommendations continued…

- Clinicians who wish to identify and contact their patients who might have received the affected darunavir tablets may contact Ms Linda Akagi, Pharmacy Outreach Coordinator of the BC Centre for Excellence in HIV/AIDS Drug Treatment Program (telephone 604-806-9096) to receive a confidential list of their patients.
- The darunavir lot number appears on the manufacturer's product label as shown below. If this information is covered by the pharmacy dispensing label, contact your pharmacist for assistance. In Canada, only lot # ALZ0J00 is known to be potentially affected.



Lot number

- Pharmacy dispensing date is printed on the pharmacy label, as shown below. In British Columbia, only dispensing dates between March 1st and May 12th 2011 are potentially affected.



Dispensing date

Selected references

- Press release: Janssen identifies trace amounts of TBA in 5 lots of PREZISTA® in Canada and the EU. May 11, 2011. http://www.janssen.ca/JOI/en/about/media.asp
- Questions and answers on current good manufacturing practices, good guidance practices, level 2 guidance - buildings and facilities. US Food and drug administration. Web page last updated 25 Feb 2011. http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/ucm192869.htm#7
- Whitfield FB, Hill JL, Shaw KJ. 2,4,6-Tribromoanisole: A potential cause of mustiness in packaged food. J Agric Food Chem. 1997; 45:889-893.
- Letter to pharmacists: Important update regarding of PREZISTA® in Canada. Janssen Inc. May 31, 2011

Thank you for reporting suspected adverse reactions to antiretroviral drugs

The BC-CfE Pharmacovigilance Program conducts ongoing monitoring of adverse reactions to antiretroviral drugs in order to identify drug-related problems and alert health care providers and patients regarding safety concerns.

How to report: Complete the adverse reaction section on the HIV drug prescription request or therapy discontinuation form (available to HIV care providers) or download an adverse reaction report form at www.cfenet.ubc.ca (available to any health care provider, patient or caregiver).

Contact the BC-CfE Pharmacovigilance program:
Telephone: 604-806-8663 Fax: 604-806-8938 E-mail: ADR@cfenet.ubc.ca

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