Australian Government

Department of Health
Therapeutic Goods Administration

URGENT MEDICINE RECALL*

LEVEL: Consumer

CLASS: Class II

REFERENCE: RC-2018-RN-01525-1

DATE AGREED: 17/12/2018

PRODUCT: **APO-Valsartan 40/80/160/320mg products**

APO-VALSARTAN valsartan 40 mg tablet blister pack
All batches
ARTG 185806

APO-VALSARTAN valsartan 80 mg tablet blister pack
All batches
ARTG 185814

APO-VALSARTAN valsartan 160 mg tablet blister pack
All batches
ARTG 185821

APO-VALSARTAN valsartan 320 mg tablet blister pack
All batches
ARTG 185826

SPONSOR: Apotex Pty Ltd

PHONE: 1800 276 839 - Apotex Customer Service

REASON: Following an internal investigation by Apotex, trace amounts of an impurity called N-nitrosodiisopropylamine (NDIPA) have been detected in the two active pharmaceutical ingredient (API) batches used to manufacture APO-Valsartan tablets currently in the Australian market. NDIPA belongs to the N-nitroso chemical class, known to contain mutagens and carcinogens (substances that could cause cancer). Based on the information available to date, Apotex expects the health risk from use of these tablets is very low.

As with previous findings of N-Nitrosodiethylamine (NDEA) and N-Nitrosodimethylamine (NDMA), there is no immediate risk to patients. It is riskier for patients to suddenly stop taking high blood pressure medication due to clinical sequelae surrounding rebound hypertension, especially in complex patients and those using maximal doses of antihypertensive.

Patients should therefore not stop any treatments without consulting their doctor or pharmacist.

This action does not impact any other Apotex products.

PROPOSED CUSTOMER ACTIONS:

Apotex is advising pharmacists:
1. Inspect all relevant stock on hand and return any APO-Valsartan to your primary wholesaler;
2. Existing return processes with your primary wholesaler should be used to return stock; and
3. Complete the Facsimile Reply Form (provided with the Customer Letter) and return it to Apotex.

Patients are requested to:
1. Consult your doctor or pharmacist before stopping or changing medication; and
2. Where possible, return unused packs to the pharmacy where your APO-Valsartan was dispensed, in order to obtain a refund and arrange an alternate supply.

Patients should not stop any treatments without consulting their doctor or pharmacist.

Further information is available on the TGA Website:
https://www.tga.gov.au/alert/apo-valsartan-valsartan-tablets

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 1547 retail pharmacies, hospitals and wholesalers nationally

Product export status: Unknown

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm