# Valsartan Recall

*updated August 20, 2018*

Health Canada issued an advisory on July 9, 2018, detailing a manufacturers' recall of products containing valsartan, due to an impurity that could have health impacts for those taking the drug. An update was issued on August 18, 2018, adding more products to the recall list.

The recall affects up to 90% of single-molecule valsartan products. Except for some strengths of TEVA-Valsartan/HCTZ, most formulations of valsartan-hydrochlorothiazide are *not* affected by the recall.

## Pharmacy Recall Procedures

Pharmacies should use their standard corporate recall processes to identify and inform patients who currently have a supply of any of the affected lot numbers or DINs. Patients should be requested to replace their existing supply as soon as possible.

- If a patient filled their prescription recently and you need to override fill-too-soon controls, please use intervention code "UF–Patient gave adequate explanation. Rx filled as written." Ensure you document the rationale, as this intervention code is monitored and subject to audit.
- The UF intervention code is not necessary if you have confirmation from the manufacturer that the pharmacy will be reimbursed for returned product, and you are able to simply reverse the claim, and refill with new product.
- If the original claim is reversed, ensure the actual quantity used by the patient is re-billed and back-dated to the original fill date.

## Reference Drug Program

Valsartan and valsartan/HCTZ are RDP (Reference Drug Program) reference drugs, subject to LCA (low-cost alternative) pricing. Because the recall is highly likely to result in an actual shortage, PharmaCare is now reimbursing the brand name product, Diovan®, at list price.

Please note that the supply of Diovan is also limited. We are working closely with suppliers and distributors to locate and distribute all available stock.

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## Therapeutic Substitutions

As with any RDP drug, pharmacists may switch patients to another product within the RDP category if such a switch would be beneficial to the patient, allowable under the College of Pharmacists Professional Practice Policy 58, and result in a lower (or same) cost to PharmaCare. Due to the nature of the valsartan recall, pharmacists may encounter patients eager to switch their medication. Please refer to:

- PPP58 to determine if a patient can be switched to a different angiotensin receptor blocker; and
- current RDP and LCA data files for PharmaCare coverage information.

In some cases, patients may have a Special Authority in place for only the reference ARBs. In this situation, if a patient is switched to a non-reference ARB, only a partial Special Authority will apply.