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PRESS RELEASE

Public Advisory on the Voluntary Recall of Losartan Medication

Belmopan, October 6, 2021. 2:40 p.m.

The Ministry of Health & Wellness advises the public of a voluntary recall of Losar-Denk (Losartan) and CoLosar-Denk (Losartan/Hydrochlorothiazide) from the Belize market.

In a letter dated October 4, 2021, Denk Pharma GMBH & Co. KG informed the Ministry of Health & Wellness of an update to perform a voluntary recall of Losar-Denk and CoLosar-Denk from the German market. The recall comes after the European health authorities announced the detection of an impurity called "4-Chlor-Azidomethyltetrazole" in the active Losartan potassium.

The most recent information from European authorities indicates that the impurity can only be formed during the production of the active ingredient Losartan and it has been found in the active ingredient of at least three manufacturers. The presence of the impurity is also above the Threshold of Toxicological Concern (TTC) limit according to the guidelines used to identify potential genotoxic impurities to limit potential carcinogenic risk.

These medications are used to treat high blood pressure and heart failure.

This ministry strongly encourages the public to immediately discontinue the use of this medication, discard any unused medication or return it to their nearest pharmacy. James Brodie & Co. Ltd. is the only importer that is Denk manufacturer registered for importation in Belize. James Brodie & Co. Ltd. has put out a call to customers on their Facebook page to return this medication to their pharmacies.

Denk Pharma GMBH & Co. KG has stated that there is no clinical data available on the impact this impurity can have on humans.

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