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Advisory: Precautionary voluntary recall at the pharmacy level of specific batches of Vivasartan and Vivasartan Plus batches

October 19, 2021, Makati City, Philippines - Sandoz Philippines has issued a precautionary voluntary recall at the pharmacy level of the following batches of Vivasartan (Losartan) and Vivasartan Plus (Losartan+HCTZ):

Generic Name and dosage strength	Brand Name	Registration number	Lot/ Batch Number	Manufacturing Date	Expiry Date
Losartan Potassium 50mg Film Coated Tablet	Vivasartan	DRP-2183	KJ4685	19 February 2020	31 January 2024
	Vivasartan	DRP-2183	JB0407	26 April 2018	01 April 2022
	Vivasartan	DRP-2183	JB0412	24 May 2018	01 May 2022
	Vivasartan	DRP-2183	LD4572	11 February 2021	31 January 2025
	Vivasartan	DRP-2183	JT8301	10 April 2019	01 April 2023
	Vivasartan	DRP-2183	JT8302	10 April 2019	1 April 2023
Losartan Potassium 100mg Film Coated Tablet	Vivasartan	DRP-2184	LD4574	11 February 2021	31 January 2024
	Vivasartan	DRP-2184	JP5951	19 February 2019	01 February 2022
	Vivasartan	DRP-2184	JP5950	19 February 2019	01 February 2022
Losartan Potassium + Hydrochlorothiazide 50mg +12.5mg Film Coated Tablet	Vivasartan Plus	DRP-2185	KJ6421	26 November 2019	31 October 2021

Losartan and Losartan HCTZ are prescription medicines indicated to lower blood pressure in patients diagnosed with hypertension.

The abovementioned batches were found to have impurity levels that exceed acceptable limits. The batches identified are those that fall within remaining shelf life but which, may or may no longer be available in the market.

Although safety assessment tests show that the impurities present a negligible risk, Sandoz Philippines is initiating the voluntary recall as a precautionary measure in line with the company's commitment to patient safety.

Distributors, hospitals, clinics, pharmacies, and retailers carrying the aforementioned batches should immediately stop the distribution, sale, and use of said batches.

Additionally, as there is no immediate risk to patients that are currently taking the product, there is no need to discontinue their medication. Patients are advised to consult with their doctors for any inquiries regarding their treatment regimen.

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Meanwhile, the Global company has secured an optimized manufacturing process to ramp up resupply of Vivasartan and Vivasartan Plus at the soonest possible time.

For more information about the voluntary recall, email sandoz_ph.communications@sandoz.com or call (02) 7-368-7777.

For suspected adverse drug reaction, report to the Food and Drug Administration: www.fda.gov.ph or through https://primaryreporting.who-umc.org/PH