DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

792/NDA/DPS/07/2018

26 July 2018

CIRCULAR NO. 18

To: Health Workers

Detection of Impurity in the Active Pharmaceutical Ingredient (API) valsartan manufactured by Zhejiang Huahai Pharmaceuticals, Linhai, China

This is to notify you of an impurity, N-nitrosodimethylamine (NDMA), which is classified as a probable human carcinogen (a substance that could cause cancer) that was discovered in valsartan API produced by Zhejiang Huahai Pharmaceuticals, Linhai, China.

Consequently, all medicines containing valsartan API supplied by the above named company as well as any company with an API with NDMA as a possible process impurity or contaminant in the dug substance Valsartan have been recalled in Uganda as a precautionary measure. Similar recalls have also been instituted in other countries including EU Member States, USA.

Below are the affected products registered by National Drug Authority:

Distributor Company	Name of Drug Affected	Manufacturer
Benle Consults Limited	Valsar-Denk 80	DENK PHARMA GMBH & CO. KG - GOLLSTR. 1 84529 TITTMONING
	Valsar-Denk 160	
	Valsar-Denk 320	
	CoValsar-Denk 80/12.5	
	CoValsar-Denk 160/12.5	
	CoValsar-Denk 320/12.5	
Abacus Pharma (Africa) Limited	VALSAR 160	HETERO LABS LTD. UNIT (V)-439, 440,441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA
	VALSAR 80	

Please kindly note that there is no immediate risk and patients taking the above listed valsartan brands are advised to switch to alternative available brands. NDA will continue to investigate presence of NMDA in all Valsartan products on the market and will update this communication accordingly.

Thank you for your continued cooperation.

Victoria Nambasa
FOR: DIRECTOR PRODUCT SAFETY

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OUR MISSION
Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

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