DEPARTMENT OF HEALTH
Republic of South Africa

SAHPRA
South African Health Products Regulatory Authority

Press Release

MEDICINES SAFETY COMMUNICATION

Recommendations about the urgent Recall of Valsartan in response to the Potential Risk of Cancer

TO ALL PATIENTS

From: The Acting CEO of SAHPRA

Date: 23 July 2018

The South African Health Products Regulatory Authority (SAHPRA), in collaboration with other regulatory agencies, are reviewing medicines containing the active substance, vasartan, supplied by Zhejiang Huahai Pharmaceuticals, located in Linhai, China. This review was triggered because of the detection of an impurity, N-nitrosodimethylamine (NDMA) in the valsartan active substance, which the company supplies to manufacturers producing some of the valsartan-containing medicines in South Africa. NDMA is classified as a probable human carcinogen (a substance capable of causing cancer) based on the results from laboratory tests. The presence of NDMA is unexpected and is thought to be related to changes in the way valsartan was manufactured. While the review is underway, medicines containing valsartan produced by Zhejiang Huahai Pharmaceuticals are being recalled by Pharma Dynamics in collaboration with SAHPRA. Recall letters have already been circulated to healthcare professionals.

The following valsartan-containing medicines are affected and therefore urgently recalled:

Name of product	Dosage Form	Registration Number
Dynaval Co 80/12,5 mg	Tablet	44/7.1.3/0018
Dynaval Co 160/12,5 mg	Tablet	44/7.1.3/0019
Dynaval Co 160/25 mg	Tablet	44/7.1.3/0020

Valsartan-containing medicines are commonly used to treat patients with high blood pressure in order to reduce complications such as heart attack and stroke. They are also used in patients who have had heart failure or a recent heart attack. Valsartan is available on its own or in combination with other medicines.

In light of the above, SAHPRA is issuing the following important advice:

- Not all valsartan-containing medicines are affected and being recalled.

Patients taking the affected medicines are advised of the following:

- Urgently consult your doctor or pharmacist and continue taking the medicine until you have a replacement medicine.
- The conditions the medication treats i.e. heart failure and high blood pressure, are serious, and you could be harmed if you suddenly stop taking it without a replacement medicine.
- You may be given a different valsartan medicine (or an alternative treatment) when you consult your doctor or pharmacist.
- Your blood pressure should be monitored closely during the process of switching.
- If you have any questions about your treatment and which medicines are affected, speak to your pharmacist who can tell you if your medicine is being recalled.
- If you are in a clinical trial with valsartan and have any questions, speak to the doctor treating you in the trial.
- SAHPRA will continue to investigate and assess whether the impurity may pose any risk to patients, and collect more data on the safety of valsartan-containing medicines as it becomes available. Any new information or recommendations will be communicated to the public.

Health professionals in South Africa are urged to report any adverse reactions, particularly associated with valsartan-containing medicines ,to SAHPRA Pharmacovigilance unit at (012) 395 9133 or to the National Adverse Drug Event Monitoring Centre at (021) 4471618 or using the reporting form which can be accessed at http://www.mccza.com/documents/14ed44a46.04_ARF1_Jul16_v4.pdf and e-mailed to adr@health.gov.za

For further enquiries / information contact:
Portia Nkambule
Acting CEO: SAHPRA
E-mail: portia.nkambule@health.gov.za
Tel: 012 395 8126

Or

Tohlang Sehloho
Acting Director: Clinical Evaluation and Trials
E-mail: tohlang.sehloho@health.gov.za
Tel: 012 395 8767

Or

Florah Matlala
Deputy Director: Pharmacovigilance Unit
E-mail: florah.matlala@health.gov.za
Tel: 012 395 9133

Website: http://www.mccza.com

Address:
Physical: South African Health Products Regulatory Authority, Department of Health, Civitas Building, 42 Thabo Sehume Street (formerly Andries), Pretoria, 0002
Postal: Private Bag x 828, Pretoria, 0001