Recall of Losacor Tablets and Losacor HCT Tablets (with photos)

The Department of Health (DH) today (September 16) endorsed a licensed drug wholesaler, Novartis Pharmaceuticals (HK) Limited (Novartis), to recall all batches of the following four products from the market as a precautionary measure due to the presence of an impurity in the products.

Name of product	Hong Kong registration number
Losacor Tablets 50mg	HK-60232
Loscaor Tablets 100mg	HK-60234
Losacor HCT 50mg-12.5mg Tablets	HK-59806
Losacor HCT 100mg-25mg Tablets	HK-59544

The DH today received notification from Novartis of the finding by the overseas manufacturers of the above products that the active pharmaceutical ingredient of the products contains a higher than accepted level of azido impurity. As a precautionary measure, Novartis is voluntarily recalling all batches of the products from the market.

Azido impurity is considered a mutagen that can cause a change in the DNA of a cell and may increase the risk of cancer, but the risk of causing cancer in humans is unknown. Overseas drug regulatory authorities have been reviewing the safety impact of azido impurity found in medicinal products. The DH will closely monitor the development of the issue and any safety updates regarding the drug issued by overseas drug regulatory authorities for consideration of any necessary action.

The above products are prescription medicines used to lower blood pressure. According to Novartis, the products have been imported to Hong Kong and supplied to private hospitals, private doctors and community pharmacies as well as re-exported to Macao.

Novartis has set up a hotline (8203 6077) to handle related enquiries.

"So far, the DH has not received any adverse reaction reports in connection with the products. The DH will closely monitor the recall," a spokesman for the DH said.

"Patients who are taking the above products should not stop taking them, but should seek advice from their healthcare professionals as soon as possible for appropriate arrangements," the spokesman added.

Losacor™ 50 mg

losartan potassium

30 film-coated tablets

⬡ **SANDOZ**

Losacor™ 100 mg

losartan potassium

30 film-coated tablets

⬡ **SANDOZ**

Losacor® HCT 50 mg - 12.5 mg

Losartan potassium/hydrochlorothiazide

30 film-coated tablets

⬡ **SANDOZ**

Losacor® HCT 100 mg - 25 mg

Losartan potassium/hydrochlorothiazide

30 film-coated tablets

⬡ **SANDOZ**