

Recall of three Apo-Acyclovir products and Apo-Amitriptyline tablets due to presence of impurity (with photos)

The Department of Health (DH) today (August 14) endorsed a licensed drug wholesaler, Hind Wing Co Ltd (Hind Wing), to recall a total of four batches of the following four products from the market as a precautionary measure due to the presence of impurity in the products.

Name of product	Hong Kong registration number	Batch number
Apo-Acyclovir Tablets 200mg	HK-43427	TK5832
Apo-Acyclovir Tablets 400mg	HK-58229	TH6096
Apo-Acyclovir Tablets 800mg	HK-58228	TK1734
Apo-Amitriptyline Tablets 10mg	HK-09273	RM0518

The DH received notification from Hind Wing that the overseas manufacturer of the products is recalling the above batches due to the presence of a higher than accepted level of an impurity, N-nitrosodimethylamine (NDMA), in the above Apo-Acyclovir products, and an impurity, N-Nitrosoamitriptyline (NNORT), in the above Apo-amitriptyline tablets. Both NDMA and NNORT are classified as a probable human carcinogen based on results from laboratory tests. As a precautionary measure, Hind Wing is voluntarily recalling the affected batches of products from the market.

The above products are all prescription medicines. The Apo-Acyclovir products containing aciclovir are used for the treatment of infections due to herpes simplex virus or varicella-zoster virus whereas the Apo-Amitriptyline tablets containing amitriptyline are used for the treatment of depression. According to Hind Wing, the above batches of products had been imported into Hong Kong. The affected Apo-Acyclovir products had been supplied to DH clinics, private doctors and pharmacies, while the affected Apo-amitriptyline tablets had been supplied to the Hospital Authority, private hospitals and re-exported to Macao.

Hind Wing has set up a hotline (2541 5731) to answer 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 the medicine, but should seek advice from their healthcare professionals as soon as possible for appropriate arrangements," the spokesman added.

