Recall of Epadoren Solution for Injection 50mg/2ml (with photo)

The Department of Health (DH) today (October 11) endorsed a licensed drug wholesaler, Hind Wing Co Ltd (Hind Wing), to recall a ranitidine-containing product, namely Epadoren Solution for Injection 50mg/2ml (Hong Kong registration number: HK-61752), from the market as a precautionary measure due to the potential presence of an impurity in the product.

The DH received notification from Hind Wing today that the manufacturer of the product suspected that the above product may contain an impurity, N-nitrosodimethylamine (NDMA), based on recent overseas announcements on the said impurity. NDMA is classified as a probable human carcinogen based on results from laboratory tests. As a precautionary measure, Hind Wing is voluntarily recalling the affected product from the market.

The DH noted that certain ranitidine-containing products were found to contain NDMA in other countries and has endorsed voluntary recalls of seven ranitidine-containing products since September 24. The DH has been collecting samples of ranitidine-containing products from the market for analysis. The DH also noted that overseas drug regulatory authorities have been reviewing the safety impact of the impurity found in the ranitidine-containing products. The DH will closely monitor the development of the issue and any safety updates of the drug issued by overseas drug regulatory authorities for consideration of any action deemed necessary. A letter was also sent to healthcare professionals on September 18 notifying them about the issue.

The above product is a prescription medicine used for the treatment of gastric diseases. According to Hind Wing, the product has been supplied to private hospitals, local doctors, veterinary surgeons and pharmacies.

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 product. The DH will closely monitor the recall," a spokesman for the DH said.

Patients who require use of the above product should seek advice from their healthcare professionals for appropriate arrangements.

5 ampoules of 2 ml
IM. IV.
EPADOREN
Ranitidine (as HCl)
50mg/2ml
Solution for Injection
Epadoren
Manufactured by:
DEMO S.A.
PHARMACEUTICAL INDUSTRY
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