Recall of Ulticer Tab 150mg (with photo)

The Department of Health (DH) today (November 12) endorsed a registration certificate holder, Medreich Far East Limited, to recall a ranitidine-containing product, namely Ulticer Tab 150mg (Hong Kong registration number: HK-53488), from the market due to the potential presence of an impurity in the product.

The DH received notification from Medreich today that the manufacturer suspected that the product might contain the impurity N-nitrosodimethylamine (NDMA). NDMA is classified as a probable human carcinogen based on results from laboratory tests. Therefore, as a precautionary measure, Medreich is voluntarily recalling the above product from the market.

The DH noted that certain ranitidine-containing products were found to contain NDMA in other countries and therefore sent a letter to healthcare professionals on September 18 notifying them about the issue. The DH has endorsed the recalls of a total of 22 ranitidine-containing products since September 24. 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 action deemed necessary.

The above product is an over-the-counter medicine used for the treatment of gastric diseases. According to Medreich, the product has been supplied to local private doctors and pharmacies.

Medreich has set up a hotline (2572 6348) to answer related enquiries.

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

"Patients who are taking the above product should seek advice from their healthcare professionals for appropriate arrangements. There are alternative medicines available on the market with similar indications," the spokesman added.


100 comprimés
150
mg
Ulticer®
ranitidine
MEDREICH