Recall of Glucofit Film Coated Tablets 500mg (with photo)

The Department of Health (DH) today (August 24) endorsed a licensed drug wholesaler, Suntol Medical Ltd (Suntol), to recall a metformin-containing product, Glucofit Film Coated Tablets 500mg (Hong Kong Registration Number: HK-64639), from the market as a precautionary measure due to the possible presence of an impurity in the product.

The DH received notification from Suntol this afternoon that following the recall of Glucofit Extended-Release Tablets 500mg (Hong Kong Registration Number: HK-64640) on July 22 this year, the Taiwan manufacturer of the product decided to extend the recall to Glucofit Film Coated Tablets 500mg as a precautionary measure, as the product might contain an impurity of N-nitrosodimethylamine (NDMA).

NDMA is classified as a probable human carcinogen based on results from laboratory tests and overseas drug regulatory authorities, which have been reviewing the safety impact of NDMA found in some medicinal products including metformin. 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 action deemed necessary.

The above product, containing metformin, is a prescription medicine used for the treatment of diabetes mellitus. According to Suntol, the product has been supplied to local private doctors and pharmacies.

Suntol has set up a hotline (2546 5699) 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 are taking the above product should not stop taking the medicine, and should seek advice from their healthcare professionals as soon as possible for appropriate arrangements," the spokesman added.


1000'S
POISON 中毒
固糖平 膜衣錠 500 毫克
Glucofit Film Coated Tablets 500 mg