

衛生署
醫療儀器管制辦公室

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DEPARTMENT OF HEALTH
MEDICAL DEVICE CONTROL OFFICE

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本署檔號 OUR REF. S/F(48) in DH/MDCO/20-5/8

來函檔號 YOUR REF.:

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24 May 2011

Dear healthcare professional,

Recall of Braunoderm Disinfectant Solution

We would like to bring to your attention that the Department of Health (DH) alerted the public on 23 May 2011 concerning a voluntary recall of three batches of "Braunoderm" iodine solution by its German manufacturer B. Braun Medical AG as less than the specified amount of the active ingredient, iodine was detected in the products through ongoing in-house monitoring.

DH is notified of the move by the product's local supplier, United Base (Hong Kong) Ltd. The latter reports that regular stability analysis by the product manufacturer reveals that the level of available iodine in some batches falls slightly under the shelf-life specification before the expiry date is reached.

The exact details of the three batches under global recall are -

- a) Braunoderm Ungef Variofl 'DE' 1000ml (Article No.: 3881156, Batch No.: 0253M14)
- b) Braunoderm Ungef Spruehfl 'DE' 250ml (Article No.: 3881105, Batch No.: 0253M14)
- c) Braunoderm Ungef Spruehfl 'DE' 1000ml (Article No.: 3881105, Batch No.: 0103M11)

In Hong Kong, only (b) has been imported by United Base for distribution to public and private hospitals, dialysis centres and nursing home.

DH understands that the product is also used by some hospitals and dialysis centres to

disinfect haemodialysis equipment besides for skin disinfection in Hong Kong. This may pose safety concern to renal patients who are often chronically ill and immune-compromised.

DH has not received any report of adverse event related to the affected product. If you happen to possess the affected disinfectant in hand, you are advised to stop using it immediately and to choose substitutes from alternatives available on the market.

United Base (Hong Kong) Ltd. has also set up hotlines 2959 6138 or 9859 0231 to answer related enquiries.

Thank you for your attention.

Yours faithfully,

A handwritten signature in dark ink, appearing to be 'Addi Chan', is centered on a light yellow rectangular background.

(Dr Addi Chan)

for Director of Health