



Health Enterprises

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02.06.11

<<NAME>>
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CUSTOMER COMMUNICATION
PRODUCTS: ACULIFE DOSAGE SPOON (AC210B) &
ACULIFE DOSAGE DROPPERS (AC250B & AC220B)

Dear Pharmacist,

We write to you with reference to a recent safety notice SN2011 (10) issued by the Irish Medicines Board (IMB) in relation to Aculife Dosage Spoons and Droppers. These products although they have a CE mark – it is not accompanied by a four digit Notified Body number which confirms the measuring aspect of the medical device has been certified by a Notified Body as required by medical devices legislation. There have been no incidents reported to the manufacturer, Health Enterprises or the IMB in relation to these devices however as a precautionary measure, Health Enterprises are asking consumers to stop using the Aculife Dosage Spoons and Aculife Dosage Droppers.

What to do:

Health Enterprises has distributed these products through Fleming Medical, Dock Road, Limerick to pharmacies in Ireland. Fleming Medical's records show that you have purchased some or all of these products. We ask you to check your stock and see if you have still these items - if so please cease sales and contact Fleming Medical by email to info@flemingmedical.ie or free phone 1800 307777 – detailing the quantity you have of each item and they will arrange collection of stock and also issue you with a credit for the value of goods.

Health Enterprises are in the process of submitting these products for appropriate CE mark certification in compliance with medical devices legislation.

Thank you for your assistance.

Yours Sincerely

Brooke Fishback
Health Enterprises Inc.

Dr. Natasha Forde
Atlantico Systems (European Authorised Representative)