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## Pfizer Global Pharmaceuticals

25<sup>th</sup> May 2007

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***Direct Healthcare Professional Communication regarding important new advice to stop using certain Auxology Calculators for determination of body surface area and the dose of GENOTROPIN (somatropin)***

Pfizer Ltd  
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### Dear Healthcare Professional

#### Summary

In some circumstances, small electronic calculators (similar to those in the attached pictures) used for auxology measurement and dosing of growth hormone, may overestimate body surface area and result in patients receiving a higher dose than necessary.

These calculators were distributed by Pharmacia from 1996 onwards, and it is estimated that distribution was phased out around 2001.

The body of scientific evidence does not suggest that a dose of growth hormone higher than that recommended presents a clinically relevant risk. **However, any patient whose dose of growth hormone (or any other treatment) may have been calculated by the use of the calculator should have their dose verified at the next planned visit.**

With immediate effect, these calculators should not be used for dose determination on the basis of body surface area because of the potential for dose errors. We also request that if you have one of these calculators, you kindly return it in the prepaid envelope provided.



Registered in England: No 526209  
Registered Office: Ramsgate Road  
Sandwich, Kent CT13 9NJ, UK



**Further information on the calculators**

It has recently come to our attention that some auxology calculators resembling those in the attached pictures, which were distributed by Pharmacia from 1996 onwards and phased out around 2001, are still in use. A white label in the battery compartment of the calculator may include the following wording:

*Kabi Pharmacia  
Peptide Hormones  
Sweden  
FCC Part 15, Sup. B  
Class β, Type: GC-1*

In some circumstances these calculators are producing readings of body surface area (BSA) and dose that deviate from manual calculations based on several standard BSA formulae. Specifically, these deviations occur for heights shorter than about 100 cm and weights less than about 14 kg. Up to twice the correct dose of Growth Hormone (GH) can be derived with the BSA indicated by the calculator. See **Table 1**.

**Table 1:** Calculation of the BSA and GH dose (mg/day) from a standard BSA formula (BSA Boyd) and the calculators in question (BSA CALC). Dosage readings from BSA CALC that are higher than those from BSA Boyd formula are shown in bold in the right-hand column. Doses are calculated for deficiency of growth hormone in children.

Height (cm)	Weight (kg)	BSA Boyd	BSA CALC (m <sup>2</sup> )	Dose from Boyd (mg/day)	Dose from the CALC (mg/day)
67	10	<b>0.46</b>	<b>0.55</b>	0.32-0.46	<b>0.38-0.55</b>
67	15	<b>0.59</b>	<b>0.71</b>	0.41-0.59	<b>0.50-0.71</b>
67	14	<b>0.56</b>	<b>0.68</b>	0.39-0.56	<b>0.48-0.68</b>
67	16	<b>0.61</b>	<b>0.74</b>	0.42-0.61	<b>0.52-0.74</b>
77	14	<b>0.59</b>	<b>0.71</b>	0.41-0.59	<b>0.50-0.71</b>
77	16	<b>0.63</b>	<b>0.77</b>	0.44-0.63	<b>0.54-0.77</b>
80	14	<b>0.59</b>	<b>0.72</b>	0.41-0.59	<b>0.50-0.72</b>
80	16	<b>0.64</b>	<b>0.78</b>	0.44-0.64	<b>0.55-0.78</b>
84	13	<b>0.58</b>	<b>0.69</b>	0.41-0.58	<b>0.49-0.69</b>
84	16	<b>0.65</b>	<b>0.79</b>	0.45-0.65	<b>0.55-0.79</b>

The Boyd formula utilised to calculate the BSA for the above low end values of height and weight is the following:

$$BSA (m^2) = 0.0003207 \times \text{Height (cm)}^{0.3} \times \text{Weight(g)}^{(0.7285 - (0.0188 \times \text{LOG(g)}) )}$$

**Drug safety information**

The body of scientific evidence does not suggest that a dose higher than that recommended presents any clinically relevant risk. However, any patient whose dose of GH (or any other treatment) may have been calculated by the use of the calculator should have their dose verified at the next planned visit.

The Genotropin Summary of Product Characteristics states that acute overdosage could lead initially to hypoglycaemia and subsequently to hyperglycaemia. Long term overdosage could result in signs and symptoms consistent with the known effects of human growth hormone excess.

On the basis of an expedited review of preliminary data obtained from the Pfizer post-marketing adverse events database up to 31 March 2007, no specific concerns have been identified in EU countries in relation to events that suggest possible sequelae to somatotropin overdose.



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Please be advised that your regulatory authority for medicines has already been informed of this matter.

### Call for reporting

Please be reminded to report any cases of suspected adverse reactions in association with use of Genotropin to Medicine and Healthcare Products Regulatory Agency via the Yellow Card Scheme (<http://www.yellowcard.gov.uk>) or call 020 7084 3080 and the Pfizer Medical Information Department on 01304 616161.

### Action – calculators recall

With immediate effect, we request that you do not use these calculators because of the potential for dose errors, and that you kindly return the calculator in the prepaid envelope provided. Please confirm whether or not you have a calculator to return by completing the return slip below and returning it in the envelope provided, faxing the slip to 01737332511 or e-mailing it to [nurse.serviceuk@pfizer.com](mailto:nurse.serviceuk@pfizer.com).

If you require any further information, in particular if you use the calculator and are reluctant to return it, please contact the Pfizer Endocrine Care Freephone Helpline at: 0800521249. In addition, you can telephone 01304 616161 for medical information during normal working hours and out-of-hours medical emergencies.

Pfizer will investigate this matter further, and will contact you should additional information arise that you need to be aware of.

Yours sincerely

A handwritten signature in blue ink that reads "David Gillen".

Dr David Gillen  
Medical Director



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## **RETURN SLIP**

Please delete one of the following sentences as appropriate:

- 1. I confirm that I do not have the Calculator.
- 2. I confirm that I have the Calculator and I am returning it to Pfizer with this confirmation.

Name:

Address:

Telephone:

E-mail address:

Date: