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MEDSAFE

NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
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Dear Healthcare Professional

Insulin glargine (Lantus)- possible link to cancer.

As you may be aware, four epidemiological studies were published in *Diabetologia* (on line) in July. These studies suggested a possible association between insulin glargine use and an increased risk of cancer.

Medsafe and the Medicines Adverse Reactions Committee (MARC) have closely reviewed the epidemiological studies and data provided by the sponsor.

The MARC noted that some preclinical studies suggested that insulin glargine may have greater potential to stimulate cell division than human insulin *in vitro*. However, studies in rats and mice did not confirm this finding. Data from controlled clinical trials and spontaneous reports were reviewed; this data did not provide evidence for an increased risk of cancer with insulin glargine.

The results from the epidemiology studies are summarised in the table:

Study	Any malignancy, hazard ratio (95% CI)	Breast cancer hazard ratio (95% CI)
Hemkens et al ¹	1.18 (1.08-1.28)¶	Not assessed
Currie et al ²	0.81 (0.59-1.11)⌘	0.86 (0.42-1.75)¥
Jonasson et al ³	1.06 (0.90-1.25)§	1.97 (1.30-3.00)§
Colhoun et al (incident cohort) ⁴	0.87 (0.63-1.21)§	1.47 (0.59-3.64)§

Comparators: ¶ Human insulin alone. ⌘ Long acting insulin- derived data published in drug safety update. ¥ All insulins. § Non glargine insulin.

Results where the confidence intervals include 1.0 are not significant.

The MARC considered that there were many methodological problems in these studies which included: potential exposure misclassification, selection bias, differing comparator groups, adjustment for confounding factors, short duration of the studies and incomplete information on risk factors.

These problems and the inconsistency in the results between studies meant that the MARC **could not determine** if there was an increased risk of cancer with insulin glargine.

The MARC advises that until more information is available, prescribers should inform their patients that there is less safety information available for newer insulins such as insulin glargine. The newer insulins should only be used when there is a potential benefit, such as management of nocturnal hypoglycaemia.

In addition, we would like to remind you that diabetic patients are at increased risk of cancer compared with non-diabetic patients⁵. Patients with diabetes should be carefully monitored for cancer development and assisted to make life style changes to reduce their cancer risk.

¹ Hemkens LG et al *Diabetologia* 2009 52(9): 1732-44 (DOI:10,1007/s00125-009-1418-4)

² Currie CJ et al *Diabetologia* 2009 52(9): 1766-77 (DOI:10,1007/s00125-009-1441-6)

³ Jonasson JM et al *Diabetologia* 2009 52(9): 1745-54 (DOI:10,1007/s00125-009-1444-2)

⁴ Colhoun HM et al *Diabetologia* 2009 52(9): 1755-65 (DOI:10,1007/s00125-009-1453-1)

⁵ Coughlin SS et al *Am J Epidemiol* 2004; 159: 1160-7

Medsafe will continue to closely monitor this issue and will work with the MARC to review new information when it becomes available.

As with any medicine please continue to report all suspected adverse reactions to the Centre for Adverse Reactions Monitoring (<http://carm.otago.ac.nz/reporting.asp>).

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Stewart Jessamine', with a large, stylized flourish at the end.

Stewart Jessamine
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Medsafe

Marius Rademaker
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Medicines Adverse Reactions Committee