



**Strategy and Sustainability Division
MINISTRY FOR SOCIAL POLICY**

DH CIRCULAR No. 5/2010

DH 277/2010

7th January 2010

Attention all Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Change-over from Insulin Glargine (Lantus®) vials to cartridges

Diabetics entitled to Insulin Glargine are now going to benefit from free pen cartridges. Insulin Glargine is a protocol-regulated drug (protocol 101) indicated for Type 1 Diabetes Mellitus.

Each ml contains 100 Units insulin Glargine (equivalent to 3.64 mg). Each cartridge contains 3 ml of solution for injection, equivalent to 300 Units. Insulin Glargine is an insulin analogue with a prolonged duration of action that should be administered subcutaneously once daily at any time but at the same time each day. The dosage and timing of dose should be individually adjusted.

Unopened cartridges should be stored in the outer carton in order to protect from light, in a refrigerator (2°C-8°C) and they should not be placed next to the freezer compartment or a freezer pack. After first use of the cartridge, the product may be stored for a maximum of 4 weeks not above 25°C away from direct heat or direct light. The pen containing a cartridge in use must not be stored in the refrigerator.

Before insertion into the pen, the cartridge must be stored at room temperature for 1 to 2 hours. It must only be used if the solution is clear, colourless, with no solid particles visible, and if it is of water-like consistency. Air bubbles must be removed from the cartridge before injection and empty cartridges must not be refilled.

For your attention please.

Dr. Natasha Azzopardi Muscat

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Insulin cartridges, pens and needles

Prescriber Criteria: Consultant Endocrinologist

Clinical Indications: Diabetes Mellitus

Conditions qualifying patients for drug:

Patients suffering from juvenile diabetes mellitus Type I, or patients with Type II DM and having visual disturbance.

Insulin Glargine

Prescriber Criteria: Consultant Endocrinologist.

Clinical Indications: Type 1 Diabetes Mellitus

Conditions qualifying patients for drug:

Patients with the above medical condition who are over six years of age and who:

- must have been for at least six months on a multi dose regimen of conventional insulins having up to 4 insulin injections daily
- must be testing their blood sugar on a four times a day basis for at least three months
- blood glucose monitoring reveals that the patient is suffering from frequent fluctuations in blood sugar having as a minimum an average of two nocturnal hypoglycaemic episodes per week.

Treatment Evaluation:

Blood sugar testing must continue on a four times a day basis for a further period of three months after the start of treatment with insulin glargine.

Treatment with insulin glargine is to be stopped if there is no significant improvement in overall glucose control.

Duration of treatment : Initially for 6 months, following which the prescribing consultant must submit a report regarding outcome of treatment, in terms of degree of control of the patient's condition.