HUMULIN* VIAL, CARTRIDGE, PEN, AND KWIKPEN
HUMULIN IS HUMAN INSULIN (PRB)

Presentation Humulin S is a sterile solution of 100IU/ml human insulin available as either 10ml vial or 3ml cartridge. Humulin I is a sterile suspension of 100IU/ml isophane human insulin available as either 10ml vial, 3ml cartridge, 3ml Pen, or 3ml KwikPen. Humulin M3 is a sterile suspension of 100IU/ml human insulin in the proportion of 30% soluble insulin and 70% isophane insulin available as either 10ml vial, 3ml cartridge, 3ml Pen, or 3ml KwikPen. **Uses** For the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis. **Dosage and Administration** All Humulin preparations should be given by subcutaneous injection. Only Humulin S may be given intravenously. *Resuspension* Humulin S does not require resuspension. Humulin I and Humulin M3 require resuspension immediately before use. Please see Summaries of Product Characteristics or Patient Information Leaflets for details on how to do this. *Mixing of insulins (vials only):* Humulin S may be administered in combination with Humulin I. The shorter-acting insulin (Humulin S) should be drawn into the syringe first, to prevent contamination of the vial by the longer-acting preparation (Humulin I). It is advisable to inject immediately after mixing.

Prices (Humulin)
£15.68 - 1 X 10ml vials Humulin S
£19.08 - 5 X 3ml cartridges Humulin S
£15.68 - 1 X 10ml vials Humulin I
£19.08 - 5 X 3ml cartridges Humulin I
£28.44 - 5 X 3ml Humulin I Pens
£21.70 - 5 X 3ml Humulin I KwikPens
£15.68 - 1 X 10ml vials Humulin M3
£19.08 - 5 X 3ml cartridges Humulin M3
£28.44 - 5 X 3ml Humulin M3 Pens
£21.70 - 5 X 3ml Humulin M3 KwikPens

Product Licence Numbers
Humulin S: 00006/0216 and 0242
Humulin I: 00006/0228 and 0257
Humulin M3: 00006/0233 and 0260
Humulin I Pen: 00006/0338
Humulin I KwikPen: 00006/0338
Humulin M3 Pen: 00006/0341
Humulin M3 KwikPen: 00006/0341

*HUMULIN (human insulin [prb]) is a trademark of Eli Lilly and Company.

LILLY INSULINS GENERAL INFORMATION
See Summaries of Product Characteristics for additional information, including time-action profiles of all formulations.
Dosage and Administration (general) The dosage or type of insulin should be determined according to the requirements of the patient. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. Vials are packed with instructions regarding dose preparation and administration, and these should be carefully followed. Lilly insulin cartridges are to be used with a CE marked pen according to the instructions provided by the device manufacturer. Patients should be advised to always keep a spare syringe and vial, or a spare pen and cartridge. Prefilled Pens are packed with instructions on how to use them. These directions should be followed carefully. Do not use if, after resuspension, the insulin remains at the bottom, if there are clumps in the insulin, or if solid white particles stick to the bottom or wall giving the container a frosted appearance. **Contra-indications** Hypersensitivity to the active ingredient or to any of the excipients. Hypoglycaemia. **Warnings and Special Precautions (general)** *Usage in pregnancy:* Insulin requirements usually fall during the first trimester and increase during the second and third trimesters. Patients should be advised to inform their doctors if they are pregnant or contemplating pregnancy. Insulin requirements may be reduced in the presence of renal impairment or hepatic impairment. However, in patients with chronic hepatic impairment, an increase in insulin resistance may lead to increased insulin requirements. Insulin requirements may be increased during illness or emotional disturbances. Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand, type, species, and/or method of manufacture may result in the need for a change in dosage. For fast-acting insulins, any patient also on basal insulin must optimise dosage of both insulins to obtain glucose control across the whole day, particularly nocturnal/fasting glucose control. Some patients taking human insulin may require a change in dosage from that used with animal-source insulins. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months. Changes in early warning symptoms of hypoglycaemia may occur on transfer between different types of insulin products. The patient's ability to concentrate and react may be impaired as a result of hypoglycaemia. This may constitute a risk in situations where these abilities are of special importance (eg, driving a car or operating machinery). Treatment with human insulin may cause formation of antibodies, but titres of antibodies are lower than those to purified animal insulin. **Undesirable Effects** Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Local allergy is common and usually resolves. Systemic allergy is rare but potentially more serious since severe cases may be life-threatening. Lipodystrophy is uncommon. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at http://emc.medicines.org.uk/.* **Legal Category** POM **Date of Preparation or Last Review** June 2010 **Full Prescribing Information is Available From** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL Telephone: Basingstoke (01256) 315 000 E-mail: ukmedinfo@lilly.com Website: www.lillypro.co.uk

Adverse events should be reported.Reporting forms and information can be found at www.yellowcard.gov.uk Adverse events should also be reported to Eli Lilly and Company Limited (Tel No 0870 240 1125).

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Lilly

Proving our point: the need for valid and reliable measures of diabetes education

As the global epidemic of diabetes continues to rise, the need for effective diabetes self-management education also continues to increase. Self-management education is a necessary component of diabetes prevention and care because outcomes are highly dependent on the daily efforts and decisions made by people with diabetes and those at risk.

There is a growing number of studies demonstrating both the effectiveness of education for improving outcomes[1–7] and its cost-effectiveness.[8] However, with the current emphasis on cost-efficiencies, the resources to provide diabetes education are threatened in many places around the world. We cannot assume that other health professionals, insurance providers and health ministries will continue to provide the necessary support for diabetes education unless we are able to document its effectiveness at a local and national level.

Standards for diabetes self-management education[9] are calling for better documentation about the effects of diabetes education on the knowledge, behavioural and psychosocial domains. A variety of valid and reliable instruments for measuring these outcomes are available,[10] particularly in European and other developed countries. Although it is tempting to create a programme-specific instrument or to simply translate standardised instruments, this approach will not provide the level of evidence needed to ensure financial and other support for education in many countries. Standardised instruments cannot be reliably used in different countries until they are validated among the target population. Validation is necessary to ensure consistency of understanding, language, culture and literacy.

In this issue of *Practical Diabetes International* (p 238), Al-Qazaz *et al.* report on the translation and validation of one standardised instrument, the Diabetes Knowledge Test (DKT).[11] Although the DKT evaluates only one of the domains that needs to be measured, this paper by Al-Qazaz *et al.* provides an excellent model for the translation and validation process that can be used for other instruments. This represents a significant effort; nevertheless, it is essential if we are going to be able to continue to make available and provide diabetes self-management education for the millions in need.

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