

# Humulin Packaging Changes

Human Insulin (prb)

**Safety Concerns - Please note the following to avoid confusion:**

**OLD Humulin® Lente will have a similar colour to the NEW Humulin® M3 (see below)**

**OLD Humulin® Zn will have a similar colour to the NEW Humulin® Lente (see below)**

**OLD PACKAGING**



**NEW Humulin M3**



**NOTE:** Symbol is identical

**NOTE:** The 3ml Humaject and 10ml Vial that are in this range will also have NEW packaging.

**OLD PACKAGING**



**NEW Humulin Lente**



**NOTE:** Symbol is identical

**NOTE:** There are no other packages in this range

**OLD PACKAGING**



**NEW Humulin S**



**NOTE:** Symbol is identical

**NOTE:** The 3ml Cartridge and 10ml Vial that are in this range will also have NEW packaging.

**OLD PACKAGING**



**NEW Humulin I**



**NOTE:** Symbol is identical

**NOTE:** The 3ml Cartridge and 10ml Vial that are in this range will also have NEW packaging.

**OLD PACKAGING**



**NEW Humulin M2**



**NOTE:** Symbol is identical

**NOTE:** There are no other packages in this range

**OLD PACKAGING**




**NEW Humulin Zn**




**NOTE:** Symbol is identical

**NOTE:** There are no other packages in this range

**OLD PACKAGING**



**NEW Humulin M5**



**NOTE:** Symbol is identical

**NOTE:** There are no other packages in this range

**NOTE:** Please ensure that your patients are aware that the packaging has changed and are comfortable that they have received the correct insulin. It is also important to note that particular attention should be paid to dispensing the Humulin insulins to avoid confusion between formulations.



**HUMULIN\* VIALS, CARTRIDGES AND 'PEN'. HUMAJECT\* PENS. HUMULIN IS HUMAN INSULIN (PRB). HUMAJECT IS A HUMULIN PREFILLED, DISPOSABLE PEN INJECTOR. THE 'PEN' IS A HUMULIN I PREFILLED, DISPOSABLE PEN INJECTOR OF DIFFERENT DESIGN FROM HUMAJECT PEN. VIALS, CARTRIDGES (3.0ML) AND HUMAJECT PENS (3.0ML). HUMULIN S. HUMULIN I (VIALS AND 3.0ML CARTRIDGE ONLY). HUMULIN M2 (3.0ML CARTRIDGE ONLY). HUMULIN M3. THE 'PEN' (3.0 ML). HUMULIN I. VIALS ONLY. HUMULIN LENTE. HUMULIN ZN. HUMULIN M5. Presentations: Humulin and HumaJect: Humulin S and HumaJect S: A sterile, aqueous solution of human insulin (prb). Humulin I: A sterile suspension of isophane human insulin (prb). Humulin Lente: A sterile suspension of 30% amorphous and 70% crystalline human insulin (prb) zinc suspension (vials only). Humulin Zn: A sterile suspension of crystalline human insulin (prb) zinc suspension (vials only). Humulin M2: A sterile suspension of human insulin (prb) in the proportion of 20% soluble insulin and 80% isophane insulin (3.0ml cartridge only). Humulin M3 and HumaJect M3: A sterile suspension of human insulin (prb) in the proportion of 30% soluble insulin and 70% isophane insulin. Humulin M5: A sterile suspension of human insulin (prb) in the proportion of 50% soluble insulin and 50% isophane insulin (vials only). Each presentation contains 100U/ml. **Uses:** For the treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Humulin is also indicated for the initial stabilisation of diabetes mellitus. Humulin is also indicated for diabetes mellitus in pregnancy. Humulin S in vials may also be of value during preparation of a diabetic patient for surgery, or in hyperglycaemic coma, trauma or severe infection. **Dosage and Administration:** All Humulin and HumaJect preparations should be given by subcutaneous injection. Only Humulin S in vials may be given intravenously but the HumaJect S pen should not be used for this administration route. HumaJect pens and Humulin I Pens are packed with instructions on how to use the prefilled insulin pens. These directions should be followed carefully for preparing a dose, priming the pens and caring for the pens. Patients should be advised to always keep either a spare HumaJect pen/Humulin I Pen or syringe and vial of Humulin. Humulin S may be administered in combination with Humulin I, Humulin Lente or Humulin Zn, as required. HumaJect pens and Humulin I Pen are not designed to allow any other insulin to be mixed in them. They are not designed to be refilled. Humulin cartridges are only to be used in CE marked pens, as recommended in the information provided by the device manufacturer. Patients should be advised to always keep a spare syringe and vial, or a spare pen and cartridge, of Humulin. **Resuspension: Vials of Humulin I, Lente, Zn and M5:** Rotate vial in palms of hands immediately before use to resuspend. Do not shake vigorously. **Cartridges, HumaJects and Humulin I Pen:** Please see Summaries of Product Characteristics or Patient Information Leaflets. **Mixing of insulins (vials only):** The shorter-acting insulin should be drawn into the syringe first, to prevent contamination of the vial by the longer-acting preparation. It is advisable to inject immediately after mixing. **Contra-indications:** Hypoglycaemia. **Humulin, HumaJect and Humulin I Pen:** Hypersensitivity to Humulin or to the formulation excipients, unless used as part of a desensitisation programme. Under no circumstances should any Humulin preparation, except Humulin S in vials, be given intravenously. **Side-effects:** Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Lipodystrophy, insulin resistance and hypersensitivity have rarely been reported. **Prices (Humulin and HumaJect):** Humulin S Vial: £13.75. Humulin I Vial: £13.75. Humulin Lente Vial: £13.75. Humulin Zn Vial: £13.75. Humulin M3 Vial: £13.75. Humulin M5 Vial: £13.75. Humulin S 3.0ml cartridge x 5: £23.43. Humulin I 3.0ml cartridge x 5: £24.95. Humulin M2 3.0ml cartridge x 5: £23.43. Humulin M3 3.0ml cartridge x 5: £23.43. Humulin I Pen x 5: £24.95. Humaject S x 5: £24.95. Humaject M3 x 5: £24.95. **Product Licence Numbers:** Humulin S: 0006/0216 and 0242. Humulin I: 0006/0228 and 0257. Humulin Lente: 0006/0224. Humulin Zn: 0006/0226. Humulin M2: 0006/0259. Humulin M3: 0006/0233 and 0260. Humulin M5: 0006/0270. HumaJect: 0006/0305 and 0309. Pen (Humulin I): 0006/0338. \*HUMULIN (human insulin [prb]) and HUMAJECT are trademarks 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 and adjusted only under medical supervision, according to the requirements of the patient. 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. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. **Special Warnings and Special Precautions for Use (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 change in the presence of renal impairment, hepatic impairment, illness or emotional disturbances. Patients with chronic hepatic impairment may have increased insulin requirements. Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand (manufacturer), type (soluble, isophane, lente, etc.), species (animal, human, human insulin analogue), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage. 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. A few patients who experienced hypoglycaemic reactions after transfer to human insulin have reported that the early warning symptoms were less pronounced or different from those experienced with their previous insulin. Patients whose blood glucose control is greatly improved, eg, by intensified insulin therapy, may lose some or all of the warning symptoms of hypoglycaemia and should be advised accordingly. Uncorrected hypoglycaemic and hyperglycaemic reactions, following incorrect dosage or discontinuation of treatment, can cause loss of consciousness, coma or death. 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. **Legal Category:** POM. **Date of Preparation or Last Review:** October 2001 (internal review September 2003). **Full Prescribing Information is Available From:** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL. Telephone: Basingstoke (01256) 315 999.