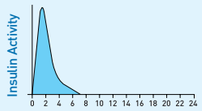
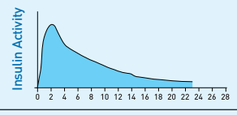
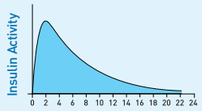
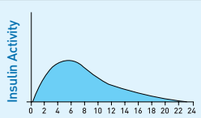
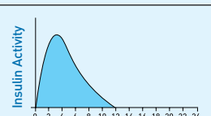
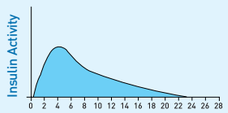
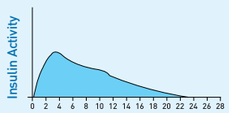
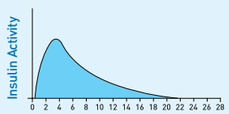
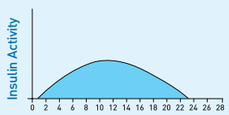
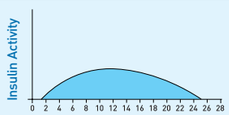
Lilly Partnership in Diabetes

Insulin	Type	Time action characteristics Exact time action profile may vary with patient and injection site	Presentation	3ml pre-filled pen (100iu/ml)		PIP code	EAN code
Humalog® insulin lispro	Rapid acting		10ml 3ml	 Humalog Pen	3ml Cartridge 10ml Vial Humalog Pen	248-7486 231-0498 271-0507	5014602101046 5014602100957 5014602101145
Humalog Mix25™ 25% insulin lispro solution 75% insulin lispro protamine suspension	Intermediate acting		3ml	 Humalog Mix25 Pen	3ml Cartridge Humalog Mix25 Pen	258-9604 258-9596	5014602101176 5014602101169
Humalog Mix50 50% insulin lispro solution 50% insulin lispro protamine suspension	Intermediate acting			 Humalog Mix50 Pen	Humalog Mix50 Pen	271-0499	5014602101152
Humulin® I Human Insulin (prb)	Isophane		10ml 3ml	 Humulin I Pen	3ml Cartridge 10ml Vial Humulin I Pen	221-0896 039-0567 271-0515	5014602100759 5014602100094 5014602101138
Humulin® S	Soluble		10ml 3ml	 HumaJect® S	3ml Cartridge 10ml Vial 3ml Humaject	221-0888 039-0724 218-9033	5014602100742 5014602100087 5014602100810
Humulin® M2	20/80 mixture		3ml		3ml Cartridge	221-0912	5014602100773
Humulin® M3	30/70 mixture		10ml 3ml	 HumaJect® M3	3ml Cartridge 10ml Vial 3ml Humaject	221-0904 040-1216 218-9066	5014602100780 5014602100131 5014602100858
Humulin® M5	50/50 mixture		10ml		10ml Vial	210-9171	5014602100735
Humulin® Lente	Lente		10ml		10ml Vial	040-1257	5014602100155
Humulin® Zn	Ultra-lente		10ml		10ml Vial	014-3420	5014602100100
HumaPen® Ergo	For all Lilly 3ml Cartridges				Burgundy Teal	290-3466 290-3474	5014602500306 5014602500290

Lilly

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.

HU3224 SEPTEMBER 2003

HUMALOG* VIALS, CARTRIDGES AND PENS. HUMALOG IS INSULIN LISPRO (HUMAN INSULIN ANALOGUE). Presentation: Humalog is a sterile, clear, colourless, aqueous solution of insulin lispro ([Lys (B28), Pro (B29)] human insulin analogue of recombinant DNA origin). The Humalog Pen is a prefilled/disposable pen injector containing a 3.0ml cartridge. Each presentation contains 100U/ml. **Uses:** For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Humalog or Humalog Pen are also indicated for the initial stabilisation of diabetes mellitus. **Dosage and Administration:** Humalog may be given shortly before meals. When necessary, Humalog can be given soon after meals. Humalog can be given in conjunction with a longer acting human insulin. Humalog preparations should be given by subcutaneous injection or by continuous subcutaneous infusion pump, and may, although not recommended, also be given by intramuscular injection. Humalog cartridges are to be used with a CE marked pen, as recommended in the information provided by the device manufacturer. Follow pen manufacturer's directions for loading the pen and priming it. Patients should be advised to always keep a spare syringe and vial, or a spare pen and cartridge, of Humalog. Humalog should be clear and colourless. Do not use it if appears cloudy, thickened or slightly coloured or if solid particles are visible. Humalog or Humalog Pen take effect rapidly (approximately 15 minutes) and has a shorter duration of activity (2 to 5 hours) as compared with soluble insulin. This rapid onset of activity allows Humalog to be given very close to mealtime. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. As with all insulin preparations, the duration of action of Humalog or Humalog Pen is dependent on dose, site of injection, blood supply, temperature and physical activity. Humalog may be administered in conjunction with a longer acting human insulin (Humulin I or Humulin Zn), on the advice of a physician. **Contra-indications:** Hypoglycaemia. Hypersensitivity to insulin lispro or one of its excipients. **Special Warnings and Special Precautions for Use:** *Usage in pregnancy:* There is no significant experience of Humalog during pregnancy or lactation. A consequence of the pharmacodynamics of rapid acting insulin analogues is that if hypoglycaemia occurs, it may occur earlier after an injection when compared with soluble human insulin. Patients taking Humalog may require a change in dosage from that used with their usual insulins. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months. **Side-effects:** Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Lipodystrophy and hypersensitivity have rarely been reported. **Prices (Humalog):** Humalog Vial: £17.28. Humalog 3.0ml cartridges x 5: £29.46. Humalog Pen x 5: £29.46. **Marketing Authorisation Numbers:** EU/1/96/007/002. EU/1/96/007/004. EU/1/96/007/015. *HUMALOG (insulin lispro) is a trademark of Eli Lilly and Company.

HUMALOG MIX25*. 100U/ML SUSPENSION FOR INJECTION IN CARTRIDGE (3.0ML). 100U/ML PEN, SUSPENSION FOR INJECTION. HUMALOG MIX50*. 100U/ML PEN, SUSPENSION FOR INJECTION. HUMALOG* IS INSULIN LISPRO (HUMAN INSULIN ANALOGUE). Presentations: Humalog Mix25 cartridge (3.0ml). Humalog Mix25 Pen - prefilled/disposable pen injector containing a 3.0ml cartridge. Humalog Mix50 Pen - prefilled/disposable pen injector containing a 3.0ml cartridge. Humalog Mix25 is a white, sterile suspension of 25% insulin lispro ([Lys (B28), Pro (B29)] human insulin analogue, rDNA origin) and 75% insulin lispro protamine suspension adjusted to pH 7.0-7.8. Humalog Mix50 is a white, sterile suspension of 50% insulin lispro ([Lys (B28), Pro (B29)] human insulin analogue, rDNA origin) and 50% insulin lispro protamine suspension adjusted to pH 7.0-7.8. Each presentation contains 100U/ml. **Uses:** For the treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. **Dosage and Administration:** Humalog Mix25 or Humalog Mix50 may be given shortly before meals. When necessary, Humalog Mix25 or Humalog Mix50 can be given soon after meals. Humalog Mix25 or Humalog Mix50 should only be given by subcutaneous injection. Under no circumstances should Humalog Mix25 or Humalog Mix50 be given intravenously. Humalog Mix25 cartridges are to be used with a CE marked pen, as recommended in the information provided by the device manufacturer. Follow the pen manufacturer's directions for loading the pen and priming it. Patients should be advised to always keep a spare pen and cartridge of Humalog Mix25 or a spare Humalog Mix25 Pen (prefilled). The rapid onset and early peak of activity of Humalog itself is observed following the subcutaneous administration of Humalog Mix25 or Humalog Mix50. This allows Humalog Mix25 or Humalog Mix50 to be given very close to mealtime. The duration of action of the insulin lispro protamine suspension (NPL) component of Humalog Mix25 or Humalog Mix50 is similar to that of a basal insulin (NPH). **Contra-indications:** Hypoglycaemia. Hypersensitivity to insulin lispro or to any of the excipients. **Special Warnings and Special Precautions for Use:** *Usage in pregnancy:* There is no significant experience with insulin lispro in pregnancy. Administration of insulin lispro to children below 12 years of age should be considered only in case of an expected benefit when compared to regular insulin. Patients taking Humalog Mix25 or Humalog Mix50 may require a change in dosage from that used with their usual insulins. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months. **Side-effects:** Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Lipodystrophy and hypersensitivity have been reported rarely. **Prices (Mix25/Mix50):** Humalog Mix 25 3.0ml cartridges x 5: £29.46. Humalog Mix 25 Pen x 5: £30.98. Humalog Mix 50 Pen x 5: £30.98. **Marketing Authorisation Numbers:** EU/1/96/007/008. EU/1/96/007/016. EU/1/96/007/017. *HUMALOG (insulin lispro), HUMALOG MIX25 and HUMALOG MIX50 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.