The **first biosimilar** of a rapid acting insulin

Available in the **SoloSTAR® pen**, cartridges and vials[3]

sanofi

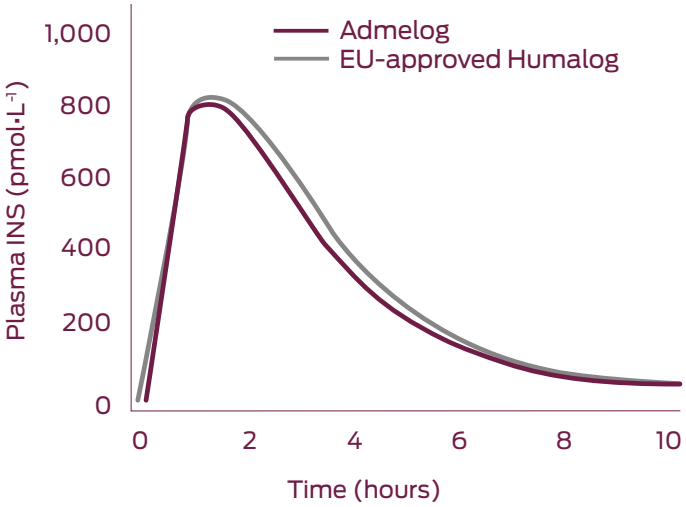
For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis and for the initial stabilisation of diabetes mellitus.[3]

Admelog®
insulin lispro
injection 100 Units/mL

Admelog is the first **rapid acting insulin biosimilar** of Humalog approved in the UK, **now available with a 25% lower NHS list price vs. Humalog cartridges and pre-filled pens.***[1,2]

Similarity for your patients

Plasma insulin mean concentration and GIR vs. time profile[5]



A double-blind, randomised, euglycaemic clamp crossover study in 30 adults with Type 1 diabetes to compare the PK/PD profile of Admelog, US-approved Humalog and EU-approved Humalog. Primary endpoints for PK analyses were INS-C_{max} and INS-AUC. Primary endpoints for PD analyses were GIRmax and GIR-AUC0-12h. All insulin lispro products demonstrated similar mean concentration and GIR vs. time profiles, with no relevant differences in the safety and tolerability profiles.[5]

Graph adapted from Kapitza *et al*. 2017.

Results from euglycaemic clamp studies do not necessarily relate to clinical outcomes.

Head-to-head studies in Type 1 and Type 2 diabetes demonstrated:[6,7]

Similar mean HbA_{1c} reduction

Similar long-term safety and tolerability profiles

Admelog offers similar efficacy, safety and tolerability profiles,[5–7] with no initial dose conversion required.*[3]

*Changes in strength, brand, type, species and/or method of manufacture may result in the need for a change in dosage. Transferring to a different insulin should be done under strict medical supervision.[3]

Freedom of choice for a range of patient needs

With the same indications as Humalog, Admelog can be used in:[3]

*Admelog should only be used in children in preference to soluble insulin when a fast action of insulin might be beneficial.[8]

1:1 unit dosing, no initial dose conversion required†[3]

†Changes in strength, brand, type, species and/or method of manufacture may result in the need for a change in dosage. Transferring to a different insulin should be done under strict medical supervision.[3]

Available in the SoloSTAR® pen, cartridges and vials[3]

The SoloSTAR® you know and trust[3]

UNIT 1:1

A treatment option with demonstrated similarity and initial 1:1 unit dosing – available in the SoloSTAR® pen, cartridges and vials.[3]

Admelog vs. Humalog

Available with a 25% lower NHS list price vs. Humalog cartridges and pre-filled pens*[1]

Presentation	Humalog (insulin lispro) NHS indicative price (£)[1]	Admelog List price per pack (£)[2]	Admelog PIP codes
25% lower NHS list price vs. Humalog cartridges and pre-filled pens[1,2]			
5 x 3 mL 100 units/mL solution for injection in cartridge	28.31	21.23	4193801
5 x 3 mL 100 units/mL solution for injection in a pre-filled pen	29.46	22.10	4193769
15% lower NHS list price vs. Humalog vials[1,2]			
1 x 10 mL 100 units/mL solution for injection in vial	16.61	14.12	4193777

*This also includes a 15% lower NHS list price vs. Humalog vials.[1]

Prescribing Information

Admelog® (Insulin lispro 100 units/ml) Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentations: Admelog 100 units/ml solution for injection in a vial, each containing 10ml of solution for injection, equivalent to 1000 units. Admelog 100 units/ml solution for injection in a cartridge or in a pre-filled pen each containing 3 ml of solution for injection, equivalent to 300 units insulin lispro.

Indication: For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis and for the initial stabilisation of diabetes mellitus.

Dosage and Administrations: The dose should be determined by the physician, according to the requirement of the patient. Admelog may be given shortly before meals, when necessary can be given soon after meals. Insulin lispro takes effect rapidly and has a shorter duration of activity (2-5 hours) given subcutaneously as compared with regular insulin, regardless of injection site. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual and duration of action is dependent on dose, site of injection, blood supply, temperature, and physical activity. Admelog can be used in conjunction with longeracting insulin or oral sulphonylurea medicinal products, on the advice of a physician. Admelog in cartridges are only suitable for subcutaneous injections from a reusable pen. Admelog in pre-filled pen are only suitable for subcutaneous injections. Admelog solution for injection should be given by subcutaneous injection or by continuous subcutaneous infusion pump and may, although not recommended, also be given by intramuscular injection. If necessary, it may also be administered intravenously. If administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used. *Subcutaneous administration:* Should be in the upper arms, thighs, buttocks, or abdomen. Injection sites should always be rotated within the same region in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Care should be taken when injecting to ensure that a blood vessel has not been entered. After injection, the site of injection should not be massaged. Patients must be educated to use the proper injection techniques. *Administration via an insulin infusion pump (Admelog vials only):* Admelog should not be mixed with any other insulin. Continuous subcutaneous insulin infusion (CSII) may be given in pump systems suitable for insulin infusion; only certain CE-marked insulin infusion pumps may be used. Before infusing, the manufacturer's instructions should be studied to ascertain the suitability or otherwise for the particular pump. Use the correct reservoir and catheter for the pump. The infusion set (tubing and cannula) should be changed in accordance with the instructions in the product information supplied with the infusion set. A pump malfunction or obstruction of the infusion set can result in a rapid rise in glucose levels. If an interruption to insulin flow is suspected, follow the instructions in the product literature. *Intravenous administration (Admelog vials only):* Should be carried out following normal clinical practice for intravenous injections; frequent monitoring of the blood glucose levels is required. **Special Populations:** *Renal/Hepatic impairment:* Insulin requirements may be reduced. Patients with chronic hepatic impairment may have diminished insulin sensitivity and therefore require an increased dose. *Paediatric population:* Admelog can be used in adolescents and children.

Contraindications: Hypoglycaemia, hypersensitivity to insulin lispro or to any of the excipients.

Precautions and Warnings: *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. *Transferring to another type/ brand of insulin:* Should be done under strict medical supervision and may result in the need for change in dose. For fast-acting insulins, any patient also on basal insulin must optimise dose of both insulins to obtain glucose control across the whole day, particularly nocturnal/ fasting glucose control. *Injection technique:* Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered. *Hypoglycaemia or hyperglycaemia:* Conditions which may make the early warning symptoms of hypoglycaemia different or less pronounced include long duration of diabetes, intensified insulin therapy, diabetic nerve disease or medications such as beta-blockers. Uncorrected hypoglycaemic or hyperglycaemic reactions can cause loss of consciousness, coma, or death. Inadequate dose or discontinuation of treatment, especially in insulin dependent diabetics, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal. *Dose adjustment:* Insulin requirements may be increased during illness or emotional disturbances. Adjustment of dose may also be necessary if patients undertake increased physical activity or change their usual diet. *In combination with pioglitazone:* Cases of cardiac failure have been reported, especially in patients with risk factors for development of heart failure. Patients using this combination should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. *Medication errors:* Patients must be instructed to always check the insulin label before each injection to avoid mix-ups between Admelog and other insulin products. Patients must visually verify the dialled units on the dose counter of the pen. Patients who are blind or have poor vision must be instructed to always get help/assistance from another person who has good vision and is trained in using the insulin device. *Excipients:* This medicine is essentially "sodium-free". *Pregnancy:* It is essential to maintain good control of the insulin-treated (insulin-dependent or gestational diabetes) patient throughout pregnancy. Patients with diabetes should be advised to inform their doctor if they are pregnant or are contemplating pregnancy. Careful monitoring of glucose control, as well as general health, is essential in pregnant patients with diabetes. *Breastfeeding:* Patient may require adjustments in insulin dose, diet or both.

Interactions: The physician should be consulted when using other medicinal products in addition to Admelog. Insulin requirements may be increased by medicinal products with hyperglycaemic activity and reduced in the presence of medicinal products with hypoglycaemic activity.

Adverse Reactions: Hypoglycaemia is the most frequent adverse reaction. Oedema has been reported, particularly if previous poor metabolic control is improved by intensified insulin therapy. *Common (≥1/100 to <1/10):* Local allergy. *Uncommon (≥1/1,000 to <1/100):* Lipodystrophy. *Rare (≥1/10,000 to <1/1,000):* Systemic allergy. *Not known (cannot be estimated from the available data):* Cutaneous amyloidosis. *Prescribers should consult the SmPC in relation to other adverse reactions.*

Legal Category: POM.

Marketing Authorisation (MA) Holder: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK

UK List price and MA Numbers: *Admelog 100 units/ml solution for injection in vial 1 x 10ml:* £14.12 – PLGB 04425/0822. *Admelog 100 units/ml solution for injection in cartridge 5x 3ml:* £21.23 – PLGB 04425/0823. *Admelog 100 units/ml solution for injection in pre-filled pen 5 x 3ml:* £22.10 – PLGB 04425/0824.

Further information is available from: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. Uk-medicalinformation@sanofi.com.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Sanofi Tel: 0800 090 2314. Alternatively, send via email to UK-drugsafety@sanofi.com

EU, European Union; GIR, glucose infusion rate; GIR_{max}, maximum smoothed bodyweight-standardised glucose infusion rate; GIR-AUC0-12h, area under the bodyweight-standardised glucose infusion rate vs. time curve from 0–12 hours; HbA_{1c}, glycated haemoglobin;INS-AUC, area under the insulin concentration vs. time curve; $INS\text{-}C_{max}$, maximum observed plasma insulin lispro concentration; PD, pharmacodynamic; PK, pharmacokinetic; US, United States.

1. British National Formulary Insulin lispro: solution for injection. Available at: https://bnf.nice.org.uk/medicinal-forms/insulin-lispro.html. Date last accessed: October 2022. **2.** Data on file, REF 152020. October 2021. **3.** Admelog Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/13083/smpc. Date accessed: October 2022. **4.** European Commission. Community register of medicinal products for human use. Admelog. Available at: https://ec.europa.eu/health/documents/community-register/html/h1203.htm. Date last accessed: November 2021. **5.** Kapitza C, *et al. Diabetes Obes Metab.* 2017;19(5):622–7. **6.** Garg SK, *et al. Diabetes Technol Ther.* 2017;19(9):516–26. **7.** Derwahl K, *et al. Diabetes Technol Ther.* 2018;20(1):1–10. **8.** MIMS. Available at: https://www.mims.co.uk/drugs/diabetes/insulins/PrescribingNotes. Date last accessed: October 2022.

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