November 2021

Product Announcement
Insulin lispro Sanofi▼ (insulin lispro U100) permanent change of name to Admelog▼ (insulin lispro U100)

PRESCRIBING INFORMATION CAN BE FOUND ON THE LAST PAGE OF THIS LETTER

Sanofi would like to inform you of the name change for Insulin lispro Sanofi (insulin lispro U100) to Admelog (insulin lispro U100).

Summary

The new brand name Admelog (insulin lispro U100) was approved by the Medicines and Healthcare products Regulatory Agency (MHRA) on 5th August 2021 and will come in to use in England, Wales and Scotland from December 2021. This change is being made to reflect UK physician feedback that the name Insulin Lispro Sanofi, could be confusing, no safety issues have been identified in the UK, and the drug will continue to be supplied as Insulin Lispro Sanofi, within the European Union

Action Required

Prescribers

If your patient receives their prescription from you, it will need changing, from Insulin Lispro Sanofi to Admelog, It is planned for Insulin Lispro Sanofi to stop being supplied at the end of January 2022 – dependent on 3rd party systems updating

Non Prescribers

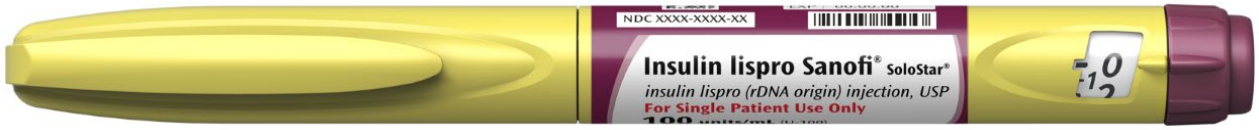
If you are involved in the supply of a patient's insulin but are not the person who prescribes, please can you ensure the prescriber is aware of the change in name and the need to change the prescription

Stock

The supply of insulin lispro U100 under the brand name of Insulin lispro Sanofi within England, Wales and Scotland will be transitioned over to the brand name Admelog following the staggered updates on third party prescribing systems. After this transition Insulin lispro Sanofi will not be supplied in England, Scotland and Wales. Sanofi will supply Admelog only from February 2022 providing all third party prescribing systems have updated.

Visual Changes

Insulin Lispro Sanofi Solostar



Admelog Solostar

Helpful Codes and Information

The presentations for Admelog remain the same as Insulin lispro Sanofi:

PRE-FILLED PEN:	5 x 3 mL 100 units/mL solution for injection
CARTRIDGES:	5 x 3 mL 100 units/mL solution for injection
VIALS:	1 x 10 mL 100 units/mL solution for injection

	Old PIP Code	New PIP Code	Old EAN Code	New EAN Code
Prefilled pens:	4079265	4193769	5000283660071	5000283662624
Cartridges:	4079273	4193801	5000283660064	5000283662617
Vials:	4079257	4193777	5000283660057	5000283662631

Other Support

More Information can be obtained from our HCP website

https://www.sanofidiabetes.co.uk/en

Call for reporting

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:

- Post: Sanofi, 410 Thames Valley Park Drive, Reading, RG6 1PT, UK
- Tel: 0800 0902314
- Email: uk-drugsafety@sanofi.com

Company contact points

Should you have any question or require additional information, please contact:

Sanofi Medical Information at Sanofi, 410 Thames Valley Park Drive, Reading, RG6 1PT, UK

- Tel : 08000 35 25 25
- Email: uk-medicalinformation@sanofi.com

For questions relating to the ordering of product please contact:

Sanofi Customer Services

- Tel: 01183 543000 (9am – 5 pm Monday-Thursday, 9am – 4pm Friday).

Yours faithfully,

Richard Kett

Brand Lead – Insulin Portfolio UK & Ireland

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 dosage 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. Admelog 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 longer-acting 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. Only certain CE-marked insulin infusion pumps may be used to infuse Admelog. 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 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. 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 dosage or discontinuation of treatment, especially in insulin dependent diabetics, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal. *Dosage adjustment*: Insulin requirements may be increased during illness or emotional disturbances. Adjustment of dosage 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 medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. 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. Please consult SmPC for full details of the 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.
Date of preparation: August 2021 (MAT-GB-2102774 V1.0)

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