FAQ document Admelog® (insulin lispro 100 units/mL)

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This document is designed to provide factual information about Admelog

SUMMARY

Product Type	Biosimilar Rapid Acting Insulin
Brand Name	Admelog
Generic Name	Insulin lispro
Strength and Form	100 units/ml in vial, cartridge and pre-filled pen
Manufacturer	Sanofi
Other Information	Biosimilar to Humalog

PACKAGING & LABELLING

Does the product have a UK marketing authorisation?	Yes
Is the medicine's generic name clearly identifiable in English on the packaging	Yes
Is other critical information also clearly identifiable in English on the packaging?	Yes
Is the critical information above clear on all sides of the packaging as well as on both primary (e.g. the pen) and secondary (e.g. the carton) packaging?	Yes
Is the generic name also suitably prominent?	Yes
Is pharmaceutical information such as the batch number, expiry date, and storage conditions clear and unambiguous on the packaging?	Yes
Are all generic constituents clearly stated on the packaging?	Yes
Is the expression of strength stated on the packaging consistent with prescribing practice?	Yes
Does the packaging encourage (or at the least not hinder) differentiation between a range of products from a single supplier, or between different products from different suppliers?	Yes. Admelog pre-filled pens are in yellow and purple Sanofi Insulins have distinct colour packaging for each insulin

INFORMATION WITH PRODUCT

Is an English language patient information leaflet available with the product?	Yes
Is English language prescribing information available for the product?	Yes
Is appropriate technical information available in English at the point of care to guide calculations, preparation, and administration?	Yes -Sanofi provide a patient booklet and insulin passport.
Does the product information only contain positive statements about use?	Appropriate special warnings and precautions for use are included in the patient information leaflet in the pack.

PRESCRIBING RISKS

Is the product an additional treatment option, or is it replacing another product or drug?	Admelog is a biosimilar to Humalog (Insulin Lispro)
Are there particular issues associated with non-familiarity or confusion with existing treatments?	No additional issues other than those already associated with insulin use and biosimilar medicines
Is the dosing and prescribing of the medicine complex?	Dosing and prescribing is the same as any other rapid acting insulins
Who will prescribe the item? And is the prescribing of the medicine likely to be within the normal scope of practice for expected prescribers?	All healthcare professionals who currently prescribe bolus insulins within the normal scope of practice.
Is the process of prescribing likely to be familiar to the prescriber?	Yes
Is the prescribed dose consistent with the way the strength, form, and (where applicable) base salt are presented?	In line with originator insulin (Humalog)

RISK MANAGEMENT

Has the medicinal product (or any similar product) been the subject of any previous medicines safety alerts (such as an NPSA report, description as a never event, or inclusion on an MHRA drug safety bulletin)?	All insulins remain a focus for patient safety and have been subject to medicines safety alerts.
Is the medicine under intensive regulatory surveillance?	No
Are new or amended clinical or laboratory monitoring requirements associated with the introduction of the medicinal product?	No
Does the medicine have the potential to cause significant harm in deliberate or inadvertent overdose? And if it does, are suitable reversibility and antidote strategies available? Or alternatively are clinical management strategies in such circumstances defined?	As with all insulin, there is potential for harm and overdose. Existing strategies for rapid acting insulin would be appropriate for Admelog
Where necessary, is tailored patient facing information available to support safe use of the medicine? For example, are steroid or lithium cards present if necessary?	Patient information leaflets/booklet and insulin passport cards are provided by the manufacturer

PREPARATION CALCULATION & LABELLING

Are there current known operator safety issues with the drug?	Admelog is provided in a vial for withdrawal and administration in a hospital setting
Is the medicine of a class where operator safety issues might be a concern? Is the medicine subject to COSHH regulations, for example?	No further concerns other than those associated with insulin use

ADMINISTRATION

Is administration of the product in any way complex?	Same as originator insulin (Humalog)
Is the route of administration of the product intrinsically high risk (such as intrathecal)?	Same as originator insulin (Humalog)
Does administration require the use of a device and/or disposables?	Patients will either self-administer (if appropriate) or a healthcare professional using an insulin syringe can withdraw and administer to a patient from a vial
Where the product requires the use of a device and/or disposables are there any issues related to their use?	Same as originator insulin (Humalog)
For injectable medicines, how safety critical is the rate of administration? And what mechanisms are in place to ensure it is correct?	Same as originator insulin (Humalog)
For injectable medicines, is any specific monitoring required during administration?	Same as originator insulin (Humalog)
If specific monitoring is required, is it practicable and achievable?	Same as originator insulin (Humalog)

SUPPLY CHAIN

Is the product readily and reliably available from a recognised supplier?	Sanofi manufacturer and supply a range of insulins to the NHS
Are expiry dates (both for the product in its original form, and in-use as necessary) available and clear?	Yes
Are there any specific storage requirements for the product?	Cold chain storage, as per all insulins
Are there any other issues in relation to storage? For example, is bulk and the space necessary to store the product an issue?	Same as originator insulin (Humalog)
Are there any issues in relation to security of storage? For example, is there a likelihood of misappropriation?	Same as originator insulin (Humalog)
Overall, consider whether the storage requirements can likely be met?	Same as originator insulin (Humalog)
DISPOSAL	
Does the product pose any special risks during disposal to either the user or staff?	Same as originator insulin (Humalog)
Are there any specific disposal requirements of the product?	Same as originator insulin (Humalog)

SETTING TO BE USED IN

Is the product for use in a highly specialist environment? For example, in neonates, fluid restricted patients, or those in critical care scenarios?	Same as originator insulin (Humalog)
Where the product is highly specialist, is there the potential that it will be used outside such an environment? And if so have issues associated with such use been identified and addressed?	Same as originator insulin (Humalog)
Is the medicine one which is likely to be used across other boundaries of care?	Same as originator insulin (Humalog)
If the medicine is used across care boundaries, have issues associated with such use been identified and addressed?	Same as originator insulin (Humalog)
Is the medicine one for which self-administration by patients is a possibility? Have any issues associated with such use been identified and addressed?	Same as originator insulin (Humalog)
Where the manipulation of the product is complex, is the environment in which it is to be prepared conducive to its safe use? That is, will it be as free as possible from distractions and is it an otherwise suitable environment for complex manipulation?	Same as originator insulin (Humalog)

Admelog® is manufactured in Germany and quality checked & released at Sanofi-Aventis Deutschland GmbH in Frankfurt, Germany. Admelog® is readily available from mainline wholesalers including AAH and Phoenix. Sanofi have sufficient stock in the UK and a robust supply plan in place to ensure continued supply of Admelog®. These supply plans are constantly reviewed and updated.

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 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: S*hould 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