04 April 2023

PROFESSIONAL INFORMATION FOR TRUVELOG

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

TRUVELOG, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One mL solution contains 100 units (equivalent to 3,5 mg) insulin aspart.*

Sugar free.

TRUVELOG solution for injection in cartridge:

Each cartridge contains 3 mL equivalent to 300 units insulin aspart.

TRUVELOG solution for injection in pre-filled pen:

Each pre-filled pen contains 3 mL equivalent to 300 units insulin aspart.

Each pre-filled pen delivers 1-80 units in steps of 1 unit.

* produced in *Escherichia coli* by recombinant DNA technology.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (injection).

Clear, colourless, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TRUVELOG is indicated for the treatment of diabetes mellitus in adults, adolescents and children

aged 1 year and above.

4.2 Posology and method of administration

Posology

The potency of insulin analogues, including insulin aspart, is expressed in units, whereas the potency of human insulin is expressed in international units.

TRUVELOG dosing is individual and determined in accordance with the needs of the patient. It should normally be used in combination with intermediate-acting or long-acting insulin.

Blood glucose monitoring and insulin dose adjustments are recommended to achieve optimal glycaemic control.

The individual insulin requirement in adults and children is usually between 0,5 and 1 units/kg/day. In a basal-bolus treatment regimen 50-70 % of this requirement may be provided by TRUVELOG and the remainder by intermediate-acting or long-acting insulin.

Adjustment of dose may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness.

Transfer from other insulin medicines

When transferring from other insulin medicines, adjustment of the TRUVELOG dose and the dose of the basal insulin may be necessary. TRUVELOG has a faster onset and a shorter duration of action than soluble human insulin. When injected subcutaneously into the abdominal wall, the onset of action will occur within 10-20 minutes of injection. The maximum effect is exerted between 1 and 3 hours after the injection. The duration of action is 3 to 5 hours.

Close glucose monitoring is recommended during the transfer and in the initial weeks thereafter (see section 4.4).

Special populations

Elderly

TRUVELOG can be used in elderly patients.

In elderly patients, glucose monitoring should be intensified and the TRUVELOG dose adjusted on an individual basis.

Renal impairment

Renal impairment may reduce the patient's insulin requirements.

In patients with renal impairment, glucose monitoring should be intensified and the insulin aspart dose adjusted on an individual basis.

Hepatic impairment

Hepatic impairment may reduce the patient's insulin requirements.

In patients with hepatic impairment, glucose monitoring should be intensified and the TRUVELOG dose adjusted on an individual basis.

Paediatric population

TRUVELOG can be used in adolescents and children aged 1 year and above in preference to soluble human insulin when a rapid onset of action might be beneficial, for example, in the timing of the injections in relation to meals (see sections 5.1 and 5.2).

The safety and efficacy of TRUVELOG in children below 1 year of age have not been established. No data are available.

Method of administration

TRUVELOG is for subcutaneous use.

Insulin aspart is a rapid-acting insulin analogue.

TRUVELOG is administered subcutaneously by injection 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. Subcutaneous injection in the abdominal wall ensures a faster absorption than other injection sites. Compared to soluble human insulin the faster onset of action of insulin aspart is maintained regardless of the injection site. The duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity.

Due to the faster onset of action, insulin aspart should generally be given immediately before a meal. When necessary insulin aspart can be given soon after a meal.

Injecting a dose

1. Wash your hands.
2. Choose a site for injection.
3. Clean the skin as instructed.
4. Remove outer needle cap.
5. Stabilise the skin by spreading it or pinching up a large area. Insert the needle as instructed.
6. Press the knob.
7. Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.
8. Using the outer needle cap, unscrew the needle and dispose of it safely.
9. Use of injection sites should be rotated so that the same site is not used more than approximately once a month.

TRUVELOG solution for injection in cartridge

TRUVELOG in cartridges is only suitable for subcutaneous injections from a reusable pen. If administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used. Other insulin aspart medicines offering such an option should be used. TRUVELOG in cartridges is designated to be used in the following pens (see section 6.6).

- JuniorSTAR which delivers 1-30 units of insulin aspart in 0,5 unit dose increments.

- Tactipen which delivers 1-60 units of insulin aspart in 1 unit dose increments.
- AllStar and AllStar PRO which all deliver 1-80 units of insulin aspart in 1 unit dose increments.

TRUVELOG solution for injection in pre-filled pen

TRUVELOG in pre-filled pen is only suitable for subcutaneous injections. If administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used. Other insulin aspart medicines offering such an option should be used. TRUVELOG in pre-filled pen delivers 1-80 units in increments of 1 unit.

Patients must visually verify the dialled units on the dose counter of the pen. Therefore, the requirement for patients with self-inject is that they can read the dose counter on 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.

For detailed user instructions, please refer to the patient information leaflet.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicines, the name and the batch number of the administered product should be clearly recorded.

Hyperglycaemia

Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis. Usually the first symptoms of hyperglycaemia develop gradually over a period of hours or days. They include thirst, increased frequency of urination,

nausea, vomiting, drowsiness, flushed dry skin, dry mouth, loss of appetite as well as acetone odour of breath. In type 1 diabetes, untreated hyperglycaemic events eventually lead to diabetic ketoacidosis, which is potentially lethal.

Hypoglycaemia

Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycaemia. Especially in children, care should be taken to match insulin doses (especially in basal-bolus regimens) with food intake, physical activities and current blood glucose level in order to minimise the risk of hypoglycaemia.

Hypoglycaemia may occur if the insulin dose is too high in relation to the insulin requirement. In case of hypoglycaemia or if hypoglycaemia is suspected TRUVELOG must not be injected. After stabilisation of patient's blood glucose adjustment of the dose should be considered (see sections 4.8 and 4.9).

Patients whose blood glucose control is greatly improved, e.g. by intensified insulin therapy, may experience a change in their usual warning symptoms of hypoglycaemia, and should be advised accordingly. Usual warning symptoms may disappear in patients with longstanding diabetes.

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.

Since TRUVELOG should be administered in immediate relation to a meal, the rapid onset of action should be considered in patients with concomitant diseases or treatment where a delayed absorption of food might be expected.

Concomitant illness, especially infections and feverish conditions, usually increases the patient's insulin requirements. Concomitant diseases in the kidney, liver or affecting the adrenal, pituitary or

thyroid gland can require changes in the insulin dose.

When patients are transferred between different types of insulin medicines, the early warning symptoms of hypoglycaemia may change or become less pronounced than those experienced with their previous insulin.

Transfer from other insulin medicines

Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand (manufacturer), type, origin (animal, human insulin or human insulin analogue) and/or method of manufacture (recombinant DNA versus animal source insulin) may result in the need for a change in dose. Patients transferred to TRUVELOG from another type of insulin may require an increased number of daily injections or a change in dose from that used with their usual insulin medicines. If an adjustment is needed, it may occur with the first dose or during the first few weeks or months.

Injection site reactions

As with any insulin therapy, injection site reactions may occur and include pain, redness, hives, inflammation, bruising, swelling and itching. Continuous rotation of the injection site within a given area reduces the risk of developing these reactions. Reactions usually resolve in a few days to a few weeks. On rare occasions, injection site reactions may require discontinuation of insulin aspart.

Combination of TRUVELOG with pioglitazone

Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. This should be kept in mind if treatment with the combination of pioglitazone and TRUVELOG is considered. If the combination is used, patients 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.

Avoidance of accidental mix-ups/medication errors

Patients must be instructed to always check the insulin label before each injection to avoid accidental mix-ups between TRUVELOG and other insulin products.

Insulin antibodies

Insulin administration may cause insulin antibodies to form. In rare cases, the presence of such insulin antibodies may necessitate adjustment of the insulin dose in order to correct a tendency to hyper- or hypoglycaemia.

Travel

Before travelling between different time zones, the patient should seek the doctor's advice since this may mean that the patient has to take the insulin and meals at different times.

Sodium

This medicine product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free".

4.5 Interaction with other medicinal products and other forms of interaction

A number of medicines are known to interact with the glucose metabolism.

The following substances may reduce the patient's insulin requirements:
Oral antidiabetic medicines, monoamine oxidase inhibitors (MAOI), beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulphonamides.

The following substances may increase the patient's insulin requirements:
Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.

Beta-blockers may mask the symptoms of hypoglycaemia.

Octreatide/lanreotide may either increase or decrease the insulin requirement.

Alcohol may intensify or reduce the hypoglycaemic effect of insulin.

4.6 Fertility, pregnancy and lactation

Pregnancy

TRUVELOG (insulin aspart) can be used in pregnancy. Data from two randomised controlled clinical trials (322 and 27 exposed pregnancies) do not indicate any adverse effect of insulin aspart on pregnancy or on the health of the foetus/newborn when compared to human insulin (see section 5.1).

Intensified blood glucose control and monitoring of pregnant women with diabetes (type 1 diabetes, type 2 diabetes or gestational diabetes) are recommended throughout pregnancy and when contemplating pregnancy. Insulin requirements usually fall in the first trimester and increase subsequently during the second and third trimester. After delivery, insulin requirements normally return rapidly to pre-pregnancy values.

Breastfeeding

There are no restrictions on treatment with TRUVELOG during breastfeeding. Insulin treatment of the nursing mother presents no risk to the baby. However, the TRUVELOG dose may need to be adjusted.

Fertility

Animal reproduction studies have not revealed any difference between insulin aspart and human insulin regarding fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

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 (e.g. driving a car or using machines).

Patients should be advised to take precautions to avoid hypoglycaemia while driving, this is particularly important in those who have reduced or absent awareness of the warning signs of hypoglycaemia or have frequent episodes of hypoglycaemia. The advisability of driving should be considered in these circumstances.

4.8 Undesirable effects

Summary of the safety profile

Adverse reactions observed in patients using TRUVELOG are mainly due to the pharmacologic effect of insulin.

The most frequently reported adverse reaction during treatment is hypoglycaemia. The frequencies of hypoglycaemia vary with patient population, dose regimens and level of glycaemic control (see section 4.8 Description of selected adverse reactions).

At the beginning of the insulin treatment, refraction anomalies, oedema and injection site reactions (pain, redness, hives, inflammation, bruising, swelling and itching at the injection site) may occur. These reactions are usually of transitory nature. Fast improvement in blood glucose control may be associated with acute painful neuropathy, which is usually reversible. Intensification of insulin therapy with abrupt improvement of glycaemic control may be associated with temporary worsening of diabetic retinopathy, while long-term improved glycaemic control decreases the risk of progression of diabetic retinopathy.

Tabulated list of adverse reactions

Adverse reactions listed below are based on clinical trial data and classified according to System Organ Class. Frequency categories are defined according to the following convention: Very common (> 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000

to < 1/1 000); very rare (< 1/10 000); not known (cannot be estimated from the available data).

MedDRA system organ classes	**Very common**	**Uncommon**	**Rare**	**Very rare**
Immune system disorders		Urticaria, rash, eruptions		Anaphylactic reactions*
Metabolism and nutrition disorders	Hypoglycaemia*			
Nervous system disorders			Peripheral neuropathy (painful neuropathy)	
Eye disorders		Refraction disorders, diabetic retinopathy		
Skin and subcutaneous tissue disorders		Lipodystrophy*		
General disorders and administration site conditions		Injection site reactions, oedema		

* See section 4.8 Description of selected adverse reactions.

Description of selected adverse reactions

Anaphylactic reactions

The occurrence of generalised hypersensitivity reactions (including generalised skin rash, itching, sweating, gastrointestinal upset, angioneurotic oedema, difficulties in breathing, palpitation and reduction in blood pressure) is very rare but can potentially be life threatening.

Hypoglycaemia

The most frequently reported adverse reaction is hypoglycaemia. It may occur if the insulin dose is too high in relation to the insulin requirement. Severe hypoglycaemia may lead to unconsciousness and/or convulsions and may result in temporary or permanent impairment of brain function or even death. The symptoms of hypoglycaemia usually occur suddenly. They may include cold sweats, cool pale skin, fatigue, nervousness or tremor, anxiousness, unusual tiredness or weakness, confusion, difficulty in concentration, drowsiness, excessive hunger, vision changes, headache, nausea and palpitation.

In clinical trials, the frequency of hypoglycaemia varied with patient population, dose regimens and level of glycaemic control. During clinical trials the overall rates of hypoglycaemia did not differ between patients treated with insulin aspart compared to human insulin.

Skin and subcutaneous tissue disorders

Lipodystrophy (including lipohypertrophy, lipoatrophy) may occur at the injection site. Continuous rotation of the injection site within the particular injection area reduces the risk of developing these reactions.

Paediatric population

Based on post-marketing sources and clinical trials with insulin aspart, the frequency, type and severity of adverse reactions observed in the paediatric population do not indicate any differences to the broader experience in the general population.

Other special populations

Based on post-marketing sources and clinical trials with insulin aspart, the frequency, type and severity of adverse reactions observed in the elderly patients and in patients with renal or hepatic impairment do not indicate any differences to the broader experience in the general population.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to:

The Pharmacovigilance Unit at Sanofi: za.safety@sanofi.com (email) or 011 256-3700 (tel), or SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

A specific overdose for insulin cannot be defined, however, hypoglycaemia may develop over sequential stages if too high doses relative to the patient's requirement are administered:

- Mild hypoglycaemic episodes can be treated by oral administration of glucose or sugary products. It is therefore recommended that the diabetic patient always carries sugar-containing products.
- Severe hypoglycaemic episodes, where the patient has become unconscious, can be treated with glucagon (0,5 to 1,0 mg) given intramuscularly or subcutaneously by a trained person, or with glucose given intravenously by physicians or other healthcare staff. Glucose must be given intravenously, if the patient does not respond to glucagon within 10 to 15 minutes. Upon regaining consciousness, administration of oral carbohydrates is recommended for the patient in order to prevent a relapse.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 21.1 Insulin preparations

Pharmacotherapeutic group: Drugs used in diabetes. Insulins and analogues for injection, fast-acting. ATC code: A10AB05

TRUVELOG is a biosimilar medicine.

Mechanism of action and pharmacodynamic effects

The blood glucose lowering effect of insulin aspart is due to the facilitated uptake of glucose following binding of insulin to receptors on muscle and fat cells and to the simultaneous inhibition of glucose output from the liver.

Insulin aspart produces a more rapid onset of action compared to soluble human insulin, together with a lower glucose concentration, as assessed within the first four hours after a meal. Insulin aspart has a shorter duration of action compared to soluble human insulin after subcutaneous injection.

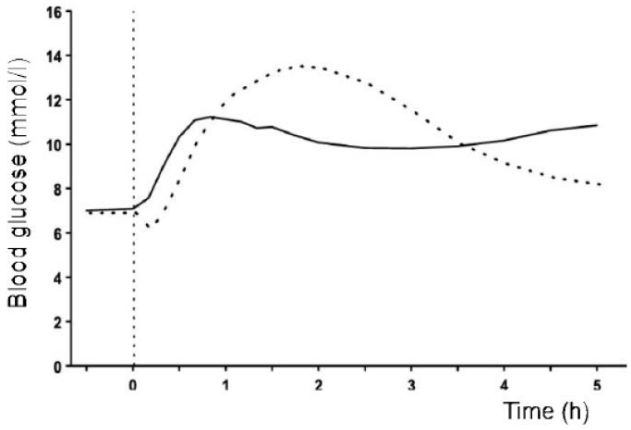

Fig. I. Blood glucose concentrations following a single pre-meal dose of insulin aspart injected immediately before a meal (solid curve) or soluble human insulin administered 30 minutes before a meal (hatched curve) in patients with type 1 diabetes mellitus.

When insulin aspart is injected subcutaneously, the onset of action will occur within 10 to 20 minutes of injection. The maximum effect is exerted between 1 and 3 hours after injection. The duration of action is 3 to 5 hours.

Clinical efficacy

Clinical trials in patients with type 1 diabetes have demonstrated a lower postprandial blood glucose with insulin aspart compared to soluble human insulin (Fig. I). In two long-term open label trials in patients with type 1 diabetes comprising 1070 and 884 patients, respectively, insulin aspart reduced glycated haemoglobin by 0,12 [95 % C.I. 0,03; 0,22] percentage points and by 0,15 [95 %

C.I. 0,05; 0,26] percentage points compared to human insulin; a difference of limited clinical significance.

Clinical trials in patients with type 1 diabetes have demonstrated a reduced risk of nocturnal hypoglycaemia with insulin aspart compared with soluble human insulin. The risk of daytime hypoglycaemia was not significantly increased.

Insulin aspart is equipotent to soluble human insulin on a molar basis.

Special populations

Elderly

A randomised, double-blind cross-over PK/PD trial comparing insulin aspart with soluble human insulin was performed in elderly patients with type 2 diabetes (19 patients aged 65 – 83 years, mean age 70 years). The relative differences in the pharmacodynamic properties (GIR_{max}, $AUC_{GIR, 0\text{-}120\ min}$) between insulin aspart and human insulin in the elderly were similar to those seen in healthy subjects and in younger patients with diabetes.

Paediatric population

A clinical trial comparing preprandial soluble human insulin with postprandial insulin aspart was performed in small children (20 patients aged 2 to less than 6 years, studied for 12 weeks, among those four were younger than 4 years old) and a single dose PK/PD trial was performed in children (6-12 years) and adolescents (13-17 years). The pharmacodynamic profile of insulin aspart in children was similar to that seen in adults.

The efficacy and safety of insulin aspart given as bolus insulin in combination with either insulin detemir or insulin degludec as basal insulin has been studied for up to 12 months, in two randomised controlled clinical trials in adolescents and children aged 1 to less than 18 years (n=712). The trials included 167 children aged 1-5 years, 260 6-11 and 285 aged 12-17. The observed improvements in HbA1c and the safety profiles were comparable between all age

groups.

Pregnancy

A clinical trial comparing safety and efficacy of insulin aspart vs. human insulin in the treatment of pregnant women with type 1 diabetes [322 exposed pregnancies (insulin aspart: 157; human insulin: 165)] did not indicate any adverse effect of insulin aspart on pregnancy or on the health of the foetus/newborn.

In addition, the data from a clinical trial including 27 women with gestational diabetes randomised to treatment with insulin aspart vs. human insulin (insulin aspart: 14; human insulin: 13) showed similar safety profiles between treatments.

5.2 Pharmacokinetic properties

Absorption, distribution and elimination

In insulin aspart substitution of amino acid proline with aspartic acid at position B28 reduces the tendency to form hexamers as observed with soluble human insulin. Insulin aspart is therefore more rapidly absorbed from the subcutaneous layer compared to soluble human insulin.

The time to maximum concentration is, on average, half of that for soluble human insulin. A mean maximum plasma concentration of 492 ± 256 pmol/L was reached 40 (interquartile range: 30-40) minutes after a subcutaneous dose of 0,15 unit/kg bodyweight in type 1 diabetic patients. The insulin concentrations returned to baseline about 4 to 6 hours after dose. The absorption rate was somewhat slower in type 2 diabetic patients, resulting in a lower C_{max} (352 ± 240 pmol/L) and later t_{max} (60 (interquartile range: 50-90) minutes). The intra-individual variability in time to maximum concentration is significantly less for insulin aspart than for soluble human insulin, whereas the intra-individual variability in C_{max} for insulin aspart is larger.

Special populations

Elderly

The relative differences in pharmacokinetic properties between insulin aspart and soluble human insulin in elderly patients (65-83 years, mean age 70 years) with type 2 diabetes were similar to those observed in healthy subjects and in younger patients with diabetes. A decreased absorption rate was observed in elderly patients, resulting in a later t_{max} (82 (interquartile range: 60-120) minutes), whereas C_{max} was similar to that observed in younger patients with type 2 diabetes and slightly lower than in patients with type 1 diabetes.

Hepatic impairment

A single dose pharmacokinetic study of insulin aspart was performed in 24 subjects with hepatic function ranging from normal to severely impaired. In patients with hepatic impairment, absorption rate was decreased and more variable, resulting in delayed t_{max} from about 50 min in subjects with normal hepatic function to about 85 min in patients with moderate and severe hepatic impairment. AUC, C_{max} and CL/F were similar in patients with reduced hepatic function compared with subjects with normal hepatic function.

Renal impairment

A single dose pharmacokinetic study of insulin aspart in 18 subjects with renal function ranging from normal to severely impaired was performed. No apparent effect of creatinine clearance values on AUC, C_{max}, CL/F and t_{max} of insulin aspart was found. Data were limited in patients with moderate and severe renal impairment. Patients with renal failure necessitating dialysis treatment were not investigated.

Paediatric population

The pharmacokinetic and pharmacodynamic properties of insulin aspart were investigated in children (6-12 years) and adolescents (13-17 years) with type 1 diabetes. Insulin aspart was rapidly absorbed in both age groups, with similar t_{max} as in adults. However, C_{max} differed between the age groups, stressing the importance of the individual titration of insulin aspart.

5.3 Preclinical safety data

Non-clinical data reveal no specific hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

In *in vitro* tests, including binding of insulin and IGF-1 receptor sites and effects on cell growth, insulin aspart behaved in a manner that closely resembled human insulin. Studies also demonstrate that the dissociation of binding to the insulin receptor of insulin aspart is equivalent to human insulin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol

Metacresol

Zinc chloride

Polysorbate 20

Sodium chloride

Hydrochloric acid (for pH adjustment)

Sodium hydroxide (for pH adjustment)

Water for injections

6.2 Incompatibilities

This medicine must not be diluted or mixed with other medicines.

6.3 Shelf life

Before first use

30 months

After first use

4 weeks

6.4 Special precautions for storage

TRUVELOG solution for injection in cartridge

Before first use

Store in refrigerator (2 °C – 8 °C). Do not freeze.

Keep the cartridge in the outer carton in order to protect from light.

After first use

Store below 30 °C. Do not refrigerate. Do not freeze.

Keep the pen cap on the pen in order to protect from light.

TRUVELOG solution for injection in pre-filled pen

Before first use

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Keep the pre-filled pen in the outer carton in order to protect from light.

After first use

Store below 30 °C. Do not refrigerate. Do not freeze.

Keep the pen cap on the pen in order to protect from light.

6.5 Nature and contents of container

TRUVELOG solution for injection in cartridge

Type 1 colourless glass cartridge with a grey plunger (bromobutyl rubber) and a flanged cap (aluminium) with a sealing disk (laminate of isoprene and bromobutyl rubber). Each cartridge contains 3 mL of solution.

Pack sizes: 5 or 10 cartridges.

Not all pack sizes may be marketed.

TRUVELOG solution for injection in pre-filled pen

Type 1 colourless glass cartridge with a grey plunger (bromobutyl rubber) and a flanged cap (aluminium) with a sealing disk (laminate of isoprene and bromobutyl rubber) sealed in a

disposable pen injector (SoloStar).

Each pre-filled pen contains 3 mL of solution.

Pack sizes: 1, 5 or 10 pre-filled pens.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The TRUVELOG solution should be inspected before use. This medicine should not be used if you notice that the solution is not clear, colourless and aqueous.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

TRUVELOG solution for injection in cartridge

To prevent the possible transmission of disease, each cartridge must be used by one patient only, even if the needle on the delivery device is changed.

TRUVELOG in cartridges are to be used with JuniorSTAR, Tactipen, AllStar or AllStar PRO pens as recommended (see section 4.2 and 4.4).

The pen with the inserted cartridge should not be stored with the needle attached.

A new needle should always be used for each injection.

The manufacturer’s instructions with each individual pen must be followed for loading the cartridge, attaching the needle and administering the insulin injection.

TRUVELOG solution for injection in pre-filled pen

To prevent the possible transmission of disease, each pen must be used by one patient only, even if the needle is changed.

The pre-filled pen should not be stored with the needle attached.

A new needle should always be used for each injection.

Needles are not included in the pack.

7. HOLDER OF CERTIFICATE OF REGISTRATION

sanofi-aventis south africa (pty) ltd

Hertford Office Park, Building I, 5th floor

90 Bekker Road, Vorna Valley, Midrand, 2196

(011) 256-3700

8. REGISTRATION NUMBER

55/21.1/0513

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

04 April 2023

10. DATE OF REVISION OF TEXT