SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE MEDICINAL PRODUCT

GLIFERIN A 100 units/ml solution for injection in pre-filled pen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml solution contains 100 units (equivalent to 3.5 mg) insulin aspart*.

GLIFERIN A 100 units/ml solution for injection in pre-filled pen
Each pre-filled pen contains 3 ml equivalent to 300 units.

*produced in *Pichia pastoris* by recombinant DNA technology. For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (injection).
The solution is clear, colourless and aqueous.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of diabetes mellitus

4.2 Posology and method of administration

Posology

Gliferin A is a rapid-acting insulin analogue.

The dosage is individual and is determined based on the physician's advice in accordance with the needs of the patient. It should normally be used in combination with intermediate-acting or long-acting insulin given at least once a day. Blood glucose monitoring and insulin dose adjustment are recommended to achieve optimal glycaemic control.

The individual insulin requirement in adult and children is usually between 0.5 and 1.0 U/kg/day. In a basal-bolus treatment regimen, 50-70% of this requirement may be provided by Insulin Aspart Injection and the remainder by intermediate-acting or long-acting insulin. Adjustment of dosage may be necessary, if patients undertake increased physical activity, change their usual diet or during concomitant illness.

Gliferin A has a faster onset and shorter duration of action than soluble human insulin. Due to the faster onset of action, Insulin Aspart Injection should generally be given immediately before a meal. When necessary, Insulin Aspart Injection can be given soon after meal.

Due to shorter duration, Insulin Aspart Injection has a lower risk of causing nocturnal hypoglycaemic episodes. No studies have been performed in Children under the age of 2 years.

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Special populations
As with all insulin products, in elderly patients and patients with renal or hepatic impairment, glucose monitoring should be intensified and Insulin Aspart Injection dosage adjusted on an individual basis.

Paediatric population
Insulin Aspart Injection can be used in children 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.

Transfer from other insulin products
When transferring from other insulin products, adjustment of the Insulin Aspart Injection dose and the dose of the basal insulin may be necessary.

Method of administration
Gliferin A is administered subcutaneously by injection in the abdominal wall, the thigh, the upper arm, the deltoid region, or the gluteal region. Injection sites should always be rotated within the same region to reduce the risk of lipodystrophy and cutaneous amyloidosis (see special warnings and precautions for use and Undesirable effects). As with all insulin products, subcutaneous injection in the abdominal wall ensures a faster absorption than other injection sites. The duration of action will vary according to the dose, injection site, blood flow, temperature, and level of physical activity. However, faster onset of action compared to soluble human insulin is maintained regardless of injection site.

Continuous Subcutaneous Insulin Infusion (CSII)
Insulin Aspart Injection may be used for CSII in pump systems suitable for insulin infusion. CSII should be administered in the abdominal wall. Infusion sites should be rotated. When used with an insulin infusion pump, Insulin Aspart Injection should not be mixed with any other insulin products.
Patients using CSII should be comprehensively instructed in the use of the pump system and use the correct reservoir and tubing 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. Patients administering Insulin Aspart Injection by CSII must have an alternative insulin delivery method available in case of pump system failure.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

ON MEDICAL PRESCRIPTION ONLY

Traceability

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

Travel

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

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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 **GLIFERIN A** 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 **GLIFERIN A** 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 medicinal products, the early warning symptoms of hypoglycaemia may change or become less pronounced than those experienced with their previous insulin.

Transfer from other insulin medicinal products

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 insulin aspart product 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 medicinal products. If an adjustment is needed, it may occur with the first dose or during the first few weeks or months.

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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 **GLIFERIN A.**

Skin and subcutaneous tissue disorders

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 from an affected to an unaffected area, and dose adjustment of antidiabetic medications may be considered.

Combination of insulin aspart 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 insulin aspart 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 insulin aspart 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.

Sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicinal products and other forms of interaction

A number of medicinal products are known to interact with the glucose metabolism. The following

substances may reduce the patient's insulin requirements:
Oral antidiabetic medicinal products, 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.

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Beta-blockers may mask the symptoms of hypoglycaemia. Octreotide/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

GLIFERIN A 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.

Breast-feeding

There are no restrictions on treatment with **GLIFERIN A** during breast-feeding. Insulin treatment of the nursing mother presents no risk to the baby. However, the **GLIFERIN A** dose may need to be adjusted.

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 operating machinery).

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 insulin aspart 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 in 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.

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Tabulated list of adverse reactions

Adverse reactions listed below are based on clinical trial data and classified according to MedDRA frequency and 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 class	**very common**	**uncommon**	**rare**	**very rare**	**Not known**
Immune system disorders		Urticaria, rash, eruptions		Anaphylactic reactions*	
Metabolism and nutritions disorders	Hypoglycaemia*				
Nervous system disorders			Peripheral neuropathy (painful neuropathy)		
Eye disorders		Refraction disorders, diabetic retinopathy			
Skin and subcutaneous tissue disorders		Lipodystrophy *			Cutaneous amyloidosis* †
General disorders and administration site conditions		Injection site reactions, oedema			

*see section 4.8, Description of selected adverse reactions.
† adverse drug reaction (ADR) from postmarketing sources.

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) and cutaneous amyloidosis may occur at the

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injection site and delay local insulin absorption. Continuous rotation of the injection site within the given injection area may help to reduce or prevent these reactions (see section 4.4).
Reporting of suspected adverse reactions

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

Pusat Farmakovigilans
c.q. Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor, dan Zat Adiktif
Badan Pengawas Obat dan Makanan Republik Indonesia Post: Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560 Email: pv-center@pom.go.id
Tel: +62-21-4244691 Ext. 1079
Website: http://e-meso.pom.go.id/

and/or

Corporate Pharmacovigilance Dexa Group
Post: Titan Center. Jalan Boulevard Bintaro, Blok B7/B1, No.5, Bintaro Jaya, Sektor 7, Tangerang Selatan 15424, Indonesia
Email: pv@dexagroup.com Website: www.dexagroup.com

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 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

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

GLIFERIN A is a biosimilar medicinal product.

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

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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.

In study with innovator's insulin aspart product, 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.

A pharmacokinetic/pharmacodynamic (PK/PD) euglycemic clamp study conducted in healthy volunteers comparing single doses of MYL-1601D (Gliferin A), NovoLog®, and NovoRapid® demonstrated that MYL-1601D was bioequivalent to both NovoRapid® and NovoLog®. For the primary PK endpoints, AUC0–12h and Cmax, as the 90% confidence intervals (CIs) of the respective geometric LS-mean ratios were within the acceptance range of 80.00% to 125.00%. The secondary PK endpoints, AUC0–4h, AUC0–6h, and AUC0–?, also supported PK bioequivalence for all three pairwise comparisons. The 90% CIs for AUC6–12h exceeded the bioequivalence criteria; however, this parameter showed high variability, primarily due to the very slow response during the terminal time interval. Approximately half of the subjects had no measurable concentrations after 6 hours, which further reduced the statistical power for this parameter.

Based on the primary PD endpoints AUCGIR,0-last and GIRmax, MYL-1601D was equivalent to NovoRapid®, as the 95% CIs for the respective geometric LS-mean ratios were within the predefined acceptance interval of 80.00% to 125.00%. Similarly, based on the primary PD endpoints AUCGIR,0-last and GIRmax, MYL-1601D was equivalent to NovoLog®, as the 90% CIs for the respective geometric LS-mean ratios fell within the predefined acceptance interval of 80.00% to 125.00%. The secondary PD endpoints AUCGIR,0-4h, AUCGIR,0-6h, and AUCGIR,6h-last further supported PD equivalence and met the bioequivalence criteria for all three pairwise comparisons.

Clinical efficacy and safety from clinical trials of the innovator's insulin aspart product

Clinical trials in patients with type 1 diabetes have demonstrated a lower postprandial blood glucose with insulin aspart compared to soluble human insulin. 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.

Clinical efficacy and safety from clinical trials of the MYL-1601D insulin aspart product

A total of 528 subjects were randomized to receive MYL-1601D (n=263) or comparator insulin aspart (n=265). Baseline demographic and disease characteristics were comparable between treatment groups. The primary endpoint of immunogenicity, assessed by treatment-emergent antibody response (TEAR), demonstrated equivalence between MYL-1601D and comparator insulin aspart. TEAR responders were 24.9% and 27.8%, respectively, with a treatment difference of -2.86% (90% CI: -9.71, 3.99), within the predefined equivalence margin of -12% to 12%. Mean (SD) change from baseline in HbA1c at Week 12 and Week 24 was 0.04 (0.615) and 0.10 (0.735) in the MYL-1601D group and -0.01 (0.547) and 0.04 (0.723) in the comparator group, respectively. Treatment differences

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were 0.05% (95% CI: -0.05, 0.16) at Week 12 and 0.07% (95% CI: -0.06, 0.20) at Week 24, with no statistically significant differences observed.
No clinically meaningful differences were observed in secondary endpoints, including insulin dose, fasting plasma glucose, and 7-point self-monitored blood glucose (SMBG) profiles. Sensitivity analyses confirmed the robustness of the primary endpoint results.

TEAEs were reported in 45.4% of subjects receiving MYL-1601D and 42.9% receiving NovoLog. The most common TEAEs were nasopharyngitis, hypoglycemia, and upper respiratory tract infection. Hypoglycemia was the most frequently reported treatment-related TEAE; overall, treatment-related TEAEs occurred in 7.6% of subjects in the MYL-1601D group and 4.2% in the NovoLog group. The incidence of severe (Grade ≥3) TEAEs (9.2% vs 5.8%) and SAEs (9.2% vs 6.3%) was comparable between treatment groups. Severe hypoglycemia was reported in 6.3% of subjects in both groups. The overall incidence of hypoglycemia was also similar (91.6% vs 92.5%). Discontinuations due to TEAEs were low (1.3% vs 0.4%). One death (0.4%) occurred in the NovoLog group and was not considered related to study treatment. No systemic allergic reactions were reported; local allergic reactions occurred in 1.7% of subjects in each group.
The incidence of anti-drug antibodies (ADA) was comparable between groups (10.1% vs 14.6%), including ≥4-fold increases (11.8% vs 9.2%), with no clinically meaningful impact on safety or efficacy.

Data on special populations from clinical trials of the innovator's insulin aspart product

Elderly (≥ 65 years old)

In a PK/PD trial the relative differences in the PD properties between insulin aspart and soluble human insulin in the elderly patients with type 2 diabetes were similar to those seen in healthy subjects and younger patients with diabetes

Paediatric population

When given to children, insulin aspart showed similar long-term glucose control compared to soluble human insulin. In clinical trials for children and adolescents aged 2 to 17 the pharmacodynamic profile of insulin aspart in children was similar to that seen in adults.

Pregnancy

A clinical trial comparing safety and efficacy of insulin aspart vs. soluble human insulin in the treatment of pregnant women with type 1 diabetes (322 exposed pregnancies) 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. soluble human insulin showed similar safety profiles between treatments as well as a significant improvement in postprandial glucose control in the insulin aspart treated group.

5.2 Pharmacokinetic properties

Data on absorption, distribution and elimination from clinical trials of the innovator's insulin aspart product

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.

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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 Cmax (352±240 pmol/l) and later tmax (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 Cmax for insulin aspart is larger.

Data on special populations from clinical trials of the innovator's insulin aspart product
Elderly (≥ 65 years old)
The relative differences in pharmacokinetic properties between insulin aspart and soluble human insulin in elderly patients 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 tmax (82 minutes), whereas Cmax was similar to that observed in younger patients with type 2 diabetes and slightly lower than in patients with type 1 diabetes.

Hepatic impairment
In patients with hepatic impairment tmax was delayed to about 85 min. (50 min. in subjects with normal hepatic function) while AUC, Cmax and CL/F were similar

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, Cmax, CL/F and tmax 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.

Children and adolescents
The pharmacokinetic and pharmacodynamic properties of insulin aspart were investigated in children and adolescents with type 1 diabetes. Insulin aspart was rapidly absorbed in both age groups, with similar tmax as in adults. However, Cmax 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 special 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 to 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

Glycerol
Phenol
Metacresol
Zinc chloride
Disodium phosphate dihydrate

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Sodium chloride
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Incompatibilities

This medicinal product must not be diluted or mixed with other medicinal products.

6.3 Shelf life

Before opening
30 months

After first opening
28 days

Chemical and physical in-use stability has been demonstrated for 31 days at 30°C and 5°C. From a microbiological point of view, once opened, the medicinal product may be stored for a maximum of 28 days at 30°C. Other in-use storage times are the responsibility of the user.

GLIFERIN A *100 units/ml solution for injection in pre-filled pen*
Store below 30°C. Can be stored in a refrigerator (2°C-8°C). Do not freeze. Keep the pen cap on the pen in order to protect from light.

6.4 Special precautions for storage

Store in a refrigerator (2°C-8°C). Do not freeze.
Keep the medicinal product in the outer carton in order to protect from light.

For storage conditions of the medicinal product after first opening, see section 6.3.

6.5 Nature and contents of container

GLIFERIN A 100 units/ml solution for injection in pre-filled pen

3 ml solution in cartridge (type 1 glass) with a plunger and stopper (bromobutyl) and aluminium seal contained in a multidose pre-filled pen.

5 pen in a carton

6.6 Special precautions for disposal and other handling

Do not use this medicinal product if you notice that the solution is not clear, colourless and aqueous.

GLIFERIN A which has been frozen must not be used.

The patient should be advised to discard the needle after each injection.

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

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Needles, syringes, and pre-filled pens must not be shared.

-GLIFERIN A 100 units/ml solution for injection in pre-filled pen

The needle sizes compatible with this pen are:
- 31G, 5 mm,
- 32G, 4-6 mm,
- 34G, 4 mm.

7. MARKETING AUTHORISATION NUMBER(S)

DKIxxxxxxxx

8. MARKETING AUTHORISATION HOLDER

PT. Fonko International Pharmaceuticals Bekasi – Indonesia

9. Manufactured by:

Biocon Sdn. Bhd.
No.1, Jalan Bioteknologi 1,
Kawasan Perindustrian SiLC,
79200 Iskandar Puteri
Johor, Malaysia.

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Refer to approval of the product

11. DATE OF REVISION OF THE TEXT

Not Applicable

12. DRUG CLASSIFICATION

Prescription Drug

13. SPECIAL PRECAUTION

HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY

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