

# insuJet™

## Inject Needle-Free

### FAQs on insulin compatibility

#### InsuJet™ compatibility

The InsuJet™ device is calibrated for U100 insulins, and compatible with all types available on the market. As there are many different insulins; regular, rapid acting, short acting, intermediates, long acting and premixed, we are often asked whether a specific insulin can be used with the device.

We support the compatibility of the device with all U100 insulins based on 3 different types of data (i) Efficacy data from clinical investigations, (ii) Integrity testing of various types of insulin propelled by the InsuJet™, and (iii) Literature from comparable devices.

Not only are there different types of insulin, there are also different types of insulin primary packaging, such as insulin cartridges (3ml), insulin vials (10ml) and disposable insulin pens. The InsuJet™ comes with Adaptors that ensures compatibility with all these packaging variations.

**Suitable for all U100 insulins and its primary packagings.**

#### InsuJet™ Adaptors

Primary packaging	Adaptor type
3ml insulin cartridge	InsuJet™ 3ml Adaptor
Disposable insulin pen	InsuJet™ 3ml Adaptor
10ml insulin vial	InsuJet™ 10ml Adaptor

#### An InsuJet™ adaptor for every primary packaging

The InsuJet does not come with insulin. Any patient's prescribed insulin can be used in combination with the InsuJet™ device. To allow the device's compatibility with different insulin primary packagings on the market, different adaptors can be purchased. The adaptor allows insulin to be transferred from an insulin reservoir to the InsuJet™ Nozzle, prior to injection.

Key to the InsuJet™ adaptor range is its suitability for all U100 insulin cartridges, or vials standard available on the current market worldwide.



With the possibility to future-proof itself by only having to add possible additions in the InsuJet™ Adaptor range, the flexibility of the system has the potential to become a worldwide needle-free solution for insulin therapy.

Overview of Insulin and Non-Insulin Delivery Devices in the Treatment of Diabetes

Insulin, Generic Name (Brand, Manufacturer)	Onset	Peak	Effective Duration
<b>Rapid-acting</b>			
Insulin aspart injection (Novolog, Novo Nordisk)	5–15 minutes	30–90 minutes	< 5 hours
Insulin lispro injection (Humalog, Lilly)	5–15 minutes	30–90 minutes	< 5 hours
Insulin glulisine injection (Apidra, Sanofi-Aventis)	5–15 minutes	30–90 minutes	< 5 hours
<b>Short-acting</b>			
Regular	30–60 minutes	2–3 hours	5–8 hours
<b>Intermediate, basal</b>			
Neutral protamine Hagedorn insulin	2–4 hours	4–10 hours	10–16 hours
<b>Long-acting, basal</b>			
Insulin glargine injection (Lantus, Sanofi-Aventis)	2–4 hours	No peak	20–24 hours
Insulin detemir injection (Levemir, Novo Nordisk)	3–8 hours	No peak	6–23 hours
<b>Premixed</b>			
75% insulin lispro protamine suspension/25% insulin lispro injection (Humalog Mix 75/25)	5–15 minutes	Dual	10–16 hours
50% insulin lispro protamine suspension/50% insulin lispro injection (Humalog Mix 50/50)	5–15 minutes	Dual	10–16 hours
70% insulin aspart protamine suspension/30% insulin aspart injection (Novolog Mix 70/30)	5–15 minutes	Dual	10–16 hours
70% neutral protamine Hagedorn insulin/30% regular	30–60 minutes	Dual	10–16 hours

#### Insulin compatibility data

##### (i) Efficacy data from clinical investigations

Multiple clinical investigations have been conducted with the InsuJet™ as is documented in the Clinical investigations chapter. In the clinical investigations, the InsuJet™ was used with:

- Insulin Aspart (NovoRapid, Novo Nordisk)
- regular human Insulin (Humalin R, Eli Lilly)

and was shown to be both safe and effective. Refer to the clinical investigation deck for detailed information.

**Needle-Free Jet Injection Technology improves Pharmacokinetic and Pharmacodynamic Profile of Rapid-Acting Insulin\***

*\*Improved Pharmacokinetic and Pharmacodynamic Profile of Rapid-Acting Insulin Using Needle-Free Jet Injection Technology Diabetes Care, August 2011*

**Jet injection advances the pharmacodynamics of regular insulin to that of an analogue\*\***

*\*\*A comparison of the pharmacodynamic profiles of jet-injected regular human insulin versus conventionally administered insulin aspart in healthy volunteers. Diabetes Research and Clinical Practice, September 2016*

##### (ii) Integrity testing of various types of insulin propelled by the InsuJet™

The research by BasicPharma laboratory shows that different types of insulin remain molecularly structurally intact after being propelled (injected) by the InsuJet™.

**The molecular structure of insulin injected with InsuJet™ remains intact and functional.**

The research included the following insulin brands:

- Insulin Lantus, Sanofi Aventis
- Insulin Levimir, Novo Nordisk
- Insulin Mumuline NHP, Eli Lilly
- Insulin Aspart, EDQM

The tests replicated extreme conditions and proved the stability and capability of the InsuJet™ medical device and its suitability for its purpose.

No degradants were measured. The limit of detection was set at approximately 0.0001% relative to the respective insulin used with testing. The full report is available upon request.

##### (iii) Literature from comparable devices

The use of needle-free injection for administration of various types of insulins is well supported by clinical investigations with similar devices. Below is a literature overview of various investigations.

**Many clinical investigations support liquid jet injection of insulins as an effective and safe method**

Future developments will include further research into adding all U100 and other insulin therapy options to the compatibility library or InsuJet™.

#### Overview of insulin administration using Needle-free administration devices as reported in clinical literature.

#	Reference	Device	Insulin	Remarks
1	Comparison of jet injector and insulin pen in controlling plasma glucose and insulin concentrations in type 2 diabetic patients Guo, Lixin MD; Xiao, Xinhua MD; Sun, Xue MD; Qi, Cuijuan MD Comparison of jet injector and insulin pen in controlling plasma glucose and insulin concentrations in type 2 diabetic patients. Medicine: January 2017 - Volume 96 - Issue 1 - p 45482 doi: 10.1097/MD.0000000000005482	OS-M, OS Medical Technology; Beijing, China) and an insulin pen (NovoPen S, Novo Nordisk, Copenhagen, Denmark	Insulin, regular and insulin analog	Sixty patients with type 2 diabetes were treated with rapid-acting insulin (regular insulin) and insulin analog (insulin aspart) using the jet injector. Regular insulin and insulin aspart administration by the jet injector showed significant decreases in plasma glucose levels as compared to the pen injection (P<0.05). Postprandial plasma insulin levels were markedly higher in the jet-treated patients than the pen-treated ones (P<0.05).
2	Xing Y, Xie X, Xu J, et al. Efficacy and safety of a needle-free injector in Chinese patients with type 2 diabetes mellitus treated with basal insulin: a multicentre, prospective, randomised, crossover study. Expert Opin Drug Deliv. 2019;16(9):995-1002. doi:10.1080/17425247.2019.1649251 PMID 31358813	OS-M, OS Medical Technology; Beijing, China) and an insulin pen (NovoPen S, Novo Nordisk, Copenhagen, Denmark	Glargine insulin	The use of a needle-free injector can lower the dosage of insulin required to achieve good glycaemic control in patients with type 2 diabetes. The results of this study indicate that the benefits of a needle-free injector in the treatment of the type 2 diabetes may be superior to those of glargine pen injections, not only by reducing the adverse effects associated with high insulin dosages, but also by reducing topical adverse reactions and the fear of injections, which should help to improve patient compliance with insulin treatment.
3	Comparison of Blood Sugar and Insulin Kinetics following Needle-free and Pen Injection of Insulin; M. Ehren, O. Lieder, S. Engelbert, H. Schatzl, M. Pföhl, (abstract) Diabetes and Metabolism 10:suppl. May 2001, 19-09.	Injec™	NPH insulin regular insulin	[...] compares well to the insulin pen and provides an attractive alternative to the conventional pen injection for most patients.
4	Delivery of insulin by jet injection: recent observations; D. J. Brenneise, Diabetes Technol Ther., (2001 Summer) 3(2): 225-32	Medi-Jector Vision	rapid-, regular-, intermediate and long-acting	Well accepted by people with diabetes and offers a reliable alternative to the use of needles.
5	Jet-injected insulin is Associated With Decreased Antibody Production and Postprandial Glucose Variability When Compared With Needle-Injected Insulin in Gestational Diabetic Women; Diabetes Care, vol 16, 11 (November 1993)	Tender Touch	Human NPH and human regular	Jet injected insulin is acceptable to GDM Women and produces less hypo- and hyperglycemia after meals. In addition, less of an immune response to insulin injected with the jet injector than with a syringe and needle has been observed.
6	Risks of jet injection of insulin in children; G.E. Theitz, P.C. Sizonenko, abstract Eur J Pediatr (1991) 150:556-556	Preci-jet-20 Preci-jet-50	rapid/intermediate-acting and long-acting	May be an alternative to syringe and needle for older children and adolescents, provided repeated detailed information and tight medical supervision is available.
7	Efficacy of a new needleless insulin delivery system monitoring of blood glucose fluctuations and free insulin levels; E.C. Katoulis, E.K. Drosinos, G.K. Dimitriadis, D.J. Hadjidakis, P.G. Mavrokelafos, S.A. Raptis, Int J Artif Organs (1989) 12: 333-8	Vitajet™	intermediate acting; Humulin NPH & Regular 70/30, Ely Lilly	Blood glucose control attained is better than with conventional injection
8	A New Insulin Jet Injector: Short and Long Term Effects on Blood Glucose, Dosage Accuracy and Patient Acceptance; F.A. Arduno, D.B. Benchimol, ArquivosBrasileiros de Medicina, vol 58 1 (Jan/Feb 1984)	Vitajet	Actrapid	There appears to be a strong patient preference to the jet injector. Diabetic patients achieved significantly improved blood glucose levels with the jet injector compared to conventional syringe.
9	Comparison of Plasma Insulin Profiles After Subcutaneous Administration of Insulin by Jet Spray and Conventional Needle Injection in patients With Insulin-Dependent Diabetes Mellitus; G.B. Pehling, J.E. Gerich, Mayo Clin. Proc. November 1984, Vol 59	Medi-Jector	Actrapid	Administration of insulin with a jet injector may be considered as a useful alternative to subcutaneous needle injection of insulin or pump administration of insulin in patients who prefer not to use these modes of insulin delivery or in whom these methods do not produce satisfactory glycaemic control.
10	Painfulness of needle and jet injection in children with diabetes mellitus; U. Schneider, R. Brimbacher, E. Schober, Eur.J.Pediatr (1994) 153:409-410	Vitajet II U-40	N.A.	There seems to be no advantage in using this device in the treatment of diabetic children.
11	Plasma Free Insulin Profiles After Administration of Insulin by Jet and Conventional Syringe Injection; R. Taylor, P.H. Home, K.G.M.M. Albert, Diabetes Care 4: 377-379, (May-June, 1981)	Med-E-Jet	Actrapid	Jet administration results in more rapid absorption of insulin and could be useful in providing a more physiological postprandial insulin profile.
12	Jet injection of insulin: comparison with conventional injection by syringe and needle; R. Worth, J. Anderson, R. Taylor, K.G.M.M. Albert, Br. Med.J. 1980 v281 713-714	Med-E-Jet	short-acting and intermediate-acting	
13	Evaluation of the insulin jet injector as a potential source of infection.; Price JP, Kruger DF, Saravolatz LD, Whitehouse FW, Department of Internal Medicine, Henry Ford Hospital, Detroit, MI 48202, Oct 17, 1989	Medi-Jector-II jet injector	Insulin	This study demonstrates that in 14 days repeated administration of insulin by needle-free application, no study patient showed any clinical evidence of infection attributable to needle-free injections.