

# Needle-free insulin devices (Insujet™ and Injex™)

## What is the Technology

Two needle-free devices to deliver insulin are available on the NHS- Insujet™ and Injex™. Both utilise jet injector technology to fire a jet of insulin at high velocity into the subcutaneous region. They are promoted as a possible option for patients with needle phobia.

## Device names and manufacturers

Insujet™ (European Pharma Group, distributed in the UK by Spirit Healthcare Ltd)

Injex™ (InjexUK)

## What is the evidence for effectiveness of the device?

Jet injectors were first developed more than 50 years ago to deliver vaccinations<sup>1</sup>. A variety of jet injectors have been designed over this period, with emphasis on nozzle diameter, velocity and jet power. However, their development and more widespread use has been hindered by their use being associated with pain and bruising. It has been suggested that pain and bruising is due to deep penetration of the jet and minimising the penetration depth may reduce the incidence of bruising<sup>2</sup>.

There are no controlled clinical trials of these products in patients with diabetes.

One pharmacokinetic study compared delivery of a specified dose of insulin aspart (0.2 units/kg), either by Insujet™ or conventional pen injection, to 18 healthy volunteers using a double-blind, double-dummy cross-over design<sup>3</sup>. After the insulin injection, plasma glucose was maintained at approximately 5mmol/L for 8 hours by a variable infusion of 20% dextrose. The time to peak insulin concentration was shorter (31+/-3 vs 64+/-6 minutes, P>0.0001) and the peak plasma insulin concentration was higher (108+/-13 vs 79 +/-7mU/L, P=0.012) with Insujet™ as compared with conventional pen injection. There were no statistically significant differences in maximal glucose-lowering effect or the total amount of glucose administered, however the duration of glucose lowering effect was approximately 40 minutes shorter with Insujet™. Thus patients would need to monitor blood glucose levels carefully if switching to this method.

The Injex™ website includes results of an unpublished pharmacokinetic study in 25 patients with diabetes (type 1 and 2)<sup>4</sup>. Patients were injected on two occasions with insulin lispro using either the Injex™ device or conventional needle and syringe on consecutive days. There was no attempt to conceal which device was used. There was no statistically significant difference in the mean free insulin level at baseline, 20, 40 or 60 minutes after the injection between the devices.

There is no information on incidences of bruising or pain with either device. The trial comparing Insujet™ with conventional pen injection reported that neither device resulted in haematomas or redness, although some participants reported that the firm pressure required for the Insujet™ device was unpleasant.

## How to use the devices

There are practical differences between the devices.

### Insujet™

Any 10ml vial or 3ml cartridge of 100units/ml insulin can be attached to the device using a disposable adapter. A nozzle is then attached and the dose of insulin (range 4-40 units) can be dialled up. The device is then placed against the skin and the dose is delivered by pressing a button. It is recommended that the nozzle is replaced every 1-2 weeks and every time a new vial or cartridge is used. A new adaptor is also required every time a new vial or cartridge is used. A different Insujet™ device is required for each type of insulin used.<sup>5</sup>

### Injex™

The appropriate dose of insulin (range 3-30 units) is drawn into what is described as an 'ampoule', although this looks similar to a syringe barrel; an appropriate adapter is purchased to transfer the insulin from the cartridge/ vial or pen device into the 'ampoule'. Note that only the 10ml vial adapter can be prescribed on the NHS. The 'ampoule' is then attached to the Injex device which is placed against the skin and the dose is delivered by pressing a trigger. A new 'ampoule' is required for each injection. A vial adapter is required for each new vial used.<sup>5</sup>

Costs (taken from the Drug Tariff April 2013). Note that these EXCLUDE the cost of insulin itself.

### **Insujet™**

Starter pack £143.60 (Set includes 1 InsuJet™ pen, 1 nozzle cap, 1 nozzle & piston, 1 vial (10ml) adaptor, 1 cartridge (3ml) adaptor, 1 cartridge cap removal key)

InsuJet™ Nozzle Pack (contains 15 pieces) £28.40

InsuJet™ 3ml Cartridge or 10ml vial Adaptor Pack (contains 15 pieces) £21.70

It is recommended that the nozzle is replaced every 1-2 weeks and every time a new vial or cartridge is used. A new adaptor is required every time a new vial or cartridge is used.

### **Injex™**

Starter set £149.36 (Set includes 1 needle-free delivery system, reset box, transporter, 9 disposable 10ml vial adaptors, 165 ampoules)

Injex™ 4 monthly Refill Pack £24.47 (Pack contains 6 disposable 10ml vial adaptors, 100 ampoules)

Injex™ Ampoule Pack (50 ampoules) £12.28

Injex™ 10ml Vial Adaptor Pack (20 vial adapters) £12.23

A new ampoule is required for each dose (NB the maximum dose that can be given with Injex™ is 30 units, thus more than one 'ampoule' will be required if a dose greater than this is prescribed). A vial adapter is required for each new vial used.

### **Annual costs**

Approximate annual costs of the devices and consumables are given below for a range of dosing regimens. Note these assume each device will last approximately 3 years. NB this does NOT include the cost of the insulin itself

| Device                                                                                                                                                                  | Cost per annum                                                                                                         |                                                                                                                         |                                                                                                                                      |                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
|                                                                                                                                                                         | One basal long-acting insulin 20units/ day and three short-acting doses of 7 units per day (total daily dose 41 units) | One basal long-acting insulin 20units/ day and three short-acting doses of 15 units per day (total daily dose 65 units) | Twice daily dosing- 40units of mixed insulin in the morning and 30 units of mixed insulin in the evening (total daily dose 70 units) | Once daily dosing- 40 units of long-acting insulin (total daily dose 40 units) |
| Insujet™ (using 3ml cartridges)                                                                                                                                         | £263                                                                                                                   | £363                                                                                                                    | £335                                                                                                                                 | £211                                                                           |
| Insujet™ (using 10ml vials)                                                                                                                                             | £162                                                                                                                   | £187                                                                                                                    | £142                                                                                                                                 | £126                                                                           |
| Injex™ (using 10ml vials)<br>NB costing based on new 'ampoule' for each administration.                                                                                 | £395                                                                                                                   | £395                                                                                                                    | £305                                                                                                                                 | £216                                                                           |
| Injectable insulin (including cost of pen device(s) for 3ml cartridges)<br>NB costing based on a new needle for each dose (range 7p – 12p per needle) plus sharps bins. | £126 - £204                                                                                                            | £126 - £204                                                                                                             | £69 - £108                                                                                                                           | £44 - £64                                                                      |

### **References**

1. Baxter J, Mitragotri S Needle-free liquid jet injectors: Mechanisms and applications Exp Review Med Devices 2006; 3: 565-574
2. Arora A, Hakim I, Baxter J et al Needle-free delivery of macromolecules across the skin by nanoliter-volume pulsed microjets Proc Nat Acad Sci USA 2007; 104: 4255-4260
3. Engwerda E, Tack C, Abbink E et al Improved pharmacokinetic and pharmacodynamic profile of rapid-acting insulin using needle free jet injection Diabetes Care 2011; 34: 1804-1808
4. Insujet™ website ([www.insujet.com](http://www.insujet.com)) Accessed 14<sup>th</sup> March 2013
5. Injex™ website ([www.injexuk.com](http://www.injexuk.com)). Accessed 14<sup>th</sup> March 2013