InsuJet™ Inject Needle-Free

Intended use and safety information

InsuJet™ Clarification of intended use

The InsuJet™ insulin-jet administration system is intended for the subcutaneous jet injection of insulin in adults and children with Diabetes Mellitus who require insulin therapy.

Insulin therapy may be used with the following patients:

• Patients with type I diabetes mellitus
• Patients with type II diabetes mellitus in whom control cannot be adequately achieved with oral hypoglycemic or diet.
• Patients with diabetes in pregnancy in whom control is inadequate with diet

The InsuJet™ insulin-jet administration system is for single patient use only.

The InsuJet™ insulin-jet administration system is suitable for U100 (100 IU/ml)

The InsuJet™ can be used to inject 4 to 50 Insulin Units per administration. Insulin is not provided with the system.

For practice purpose, saline solution and/or sterile water for injection may be injected with the device.

For the administration of other injectables, please refer to the NuGen MD device, which is approved by different regulatory agencies, including Health Canada.

InsuJet™ Intended patient populations

• Adults
• Under supervision as recommended by their physician" or diabetes specialist.
- School age children of the age 6-12 who can be injected by a caregiver
- Adolescents of the age 12-18 who can be trained to self-inject

The InsuJet™ may be used by healthcare providers who routinely administer injections.

The InsuJet may also be used by patients, at home, to self-inject, or have other individuals administer injections of prescribed medication.

⚠ Warnings

• Do not drop the InsuJet™ injector or the consumables.
• The InsuJet™ should only be used for the administration of (U-100) insulins.
• The InsuJet™ should only be used with InsuJet™ Nozzles and Adaptors.
• Check the expiration dates of your insulin. Do not use insulin past its expiration date.
• Check the expiration dates of the InsuJet™ and its consumables on the outer packaging. Do not use past its expiration date or past the indicated lifetime.
• Check the integrity of the InsuJet™ consumables packaging. Do not use if the package is breached.
• Never use the same Nozzle for different types of insulin.
• Never use the same cartridge- or vial Adaptor for different insulin cartridges or vials. Discard the Adaptor with the empty insulin cartridge or vial.
• Be careful not to touch the needle inside the Adaptor.
• Never discharge the InsuJet™ without a Nozzle attached, or air inside the Nozzle. This is called DRY-FIRING and may damage the device beyond repair.
• Do not store insulin inside the Nozzle. The Nozzle is only intended to be filled immediately before injection.
• Replace the Nozzle whenever the InsuJet™ has not been used for more than 3 days.
• Never use the same Nozzle or cartridge or vial Adaptor for different patients. Using the same device for multiple patients may result in the direct transfer of bacteria, viruses or other germs from one person to another.
• Adult supervision is highly recommended when a child uses the InsuJet™. Make sure that children are told that the InsuJet™ is not a toy.
• Keep all medications and injection devices out of the reach of children.
• Never use, or attempt to repair a damaged or broken InsuJet™ or consumable.
• In case provided hygiene practices and warnings are not followed, the consumables may be contaminated during use, possibly resulting in infections.
• The device delivers insulin using high pressure injection. The device has various safety features to ensure safe use. If any safety feature fails, stop using the device to avoid injury.
• In case a serious incident has occurred in relation to the device, this should be reported to EPG BV and the Competent Authority in your country.
• Temperature limits for use: 4-50C
• Replace the InsuJet™ injector V5 in time. The same device should never be used for more than 5000 injections. Do not use the device past the indicated expiry date. Device performance and safety may be affected when using the device beyond the indicated lifetime.
• Replace the InsuJet™ Nozzle regularly. The same Nozzle should never be used for more than 56 injections, or longer than 14 days after its blister packaging is breached. It is advised to replace the Nozzle every time a new cartridge or vial is used. Using the Nozzle beyond the indicated lifetime will cause insulin leakage, may cause bacterial contamination and may result in device malfunction, with loss of warranty.

InsuJet™ Contraindications

This product is not recommended for patients who are:

• Severely visually impaired

• Physically unable to operate the system

• Not able to understand or memorize the operating instructions for using the InsuJet™

• Have a special skin type (e.g. psoriasis patients), which might impair a successful use of the InsuJet™.

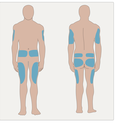
• In case of doubt please consult your Diabetes Care Specialist.

• Patients who bruise or bleed easily (e.g. people using antithrombotic drugs) may use the device with caution.

• If you experience any prolonged or severe bruising or bleeding, it is recommended to stop and consult your doctor.

InsuJet™ Administration site selection guide

NOTE: It is advised that your first InsuJet™ insulin administration takes place under the supervision of a Diabetes Care Specialist.



Any of the sites that are normally recommended for your insulin administration can be used with the InsuJet™. Choose an area with some fatty tissue. Avoid areas with low fat, or high muscle content.

Abdomen: Use the areas on the same level or slightly below your belly button, as illustrated above. If you are unable to find a suitable administration site in the abdominal area, please consider another area.

Legs: Sit on a chair with the back of your legs supported and both feet flat on the floor. Relax your thigh muscle. The administration should take place on the front or outer portion of the thigh.

Buttocks: Find a sitting position that allows you to reach the buttocks. The administration should take place in the upper outer portion of your buttock.

NOTE: For relatively soft or sensitive administration areas, it is recommended to use a Comfort Ring during administration. See page 37 for instructions to install a Comfort Ring on the Nozzle.

InsuJet™ Safety information

For diabetes management, the application of insulin by the InsuJet™ results in a complete administration of medicinal product in the subcutaneous layer. Tolerability, total insulin absorption, total insulin action and total blood glucose lowering effects are equivalent to conventional needle injections.

Clinical benefits

• Greater patient acceptance among patients with needle-phobia, or patients who wish to administer insulin without needle

• Administration of insulin by jet injection enhances insulin absorption and reduces the duration of glucose-lowering action. This profile resembles more closely the pattern of endogenous insulin secretion and may help to achieve better meal insulin coverage and correction of postprandial glucose excursions

• The removal of needle sharps helps reduce the occurrence of needle stick injuries and cross contamination, making the InsuJet™ suitable for the treatment of patients from high-risk categories.

• The InsuJet™ targets the subcutaneous tissue just below the dermis reducing the chance of intramuscular injection.

Possible InsuJet™ Side effects

Always read the patient information leaflet of your prescribed insulin. The possible side effects are listed in this leaflet. Side effects which you may experience with the use of the InsuJet are listed in this section:

Bleeding - Common
A tiny pinprick bleed following administration is not unusual for some people and can simply be wiped off. If a larger amount of blood is present you may have hit a capillary, this should be a random observation from time to time. Apply pressure to the administration site. This will stop the bleeding in most cases.
If you experience any prolonged or severe bleeding, it is recommended to consult your doctor

Bruising - Common
If you tend to bruise easily with a needle-based device, you may bruise with the InsuJet™ as well. Consult your doctor, as various injection locations may provide to either improve to decrease or eliminate bruising.
Also, consider using a Comfort Ring to reduce the pressure of the Nozzle on your skin and consult your doctor, as various injection locations may provide to either improve, decrease or eliminate bruising.
If you require a relatively large amount of insulin, it may be worth splitting your dose; E.g. 2 doses of 25 units each instead of 50 units at once.
If you experience any prolonged or severe bruising, consult your doctor.

Infection - Very rare
Although very rare, infections potentially can be caused by microbial contamination being introduced into the body at the injection site.

Using an alcohol swab on the site you're going to inject, and timely replacement of the consumables will help to prevent infections.
If you notice (signs of) an infection at the injection site, please consult your doctor.

Irritation – Rare
Individuals may develop slight red swelling and irritation at the site of an injection. This most commonly occurs when someone first begins insulin therapy and usually resolves over time. If the itching is troublesome, notify your health care provider.

Raised white bump - Common
This may indicate that, while successful, your administration did not penetrate sufficiently into your skin. If this happens, practice your administration technique.
If you require a relatively large amount of insulin, it may be worth splitting your dose; E.g. 2 doses of 25 units each instead of 50 units at once.

Possible InsuJet™ Side effects

Intramuscular (IM) injection - Uncommon
The InsuJet™ is intended for the delivery of insulin to the subcutaneous layer of the skin. Accidental intramuscular injection, may occur at injection sites without fat, causing the insulin to be injected in the muscle instead. Intramuscular injections may considerably increase the variability of insulin absorption and may impair glycemic control in insulin-dependent diabetic patient.

Uncomfortable administration - Common
Similar to administration with a needle, an uncomfortable administration can occur if you administer insulin close to a nerve ending. This cannot be foreseen, although some people may find that particular areas are more sensitive and should be avoided. Note: Administration of cold insulin can be painful. Remove the insulin from the refrigerator some time before administration.

Scar-tissue / skin hardening - Common
Rotating your injection sites is crucial in preventing the build-up of scar tissue. If you inject into the same area of your body over and over every day, your body will build-up a harder fibrous tissue every time it heals from the injury of that injection.
Over time that build-up of scar tissue may interfere with your body's ability to properly absorb the insulin you injected.
By making an effort to inject in different areas of the body (thigh, belly, back of the arm, buttocks, etc.) and different parts of each area (upper thigh vs. lower thigh, etc.) you can prevent the rapid build-up of scar tissue.

Possible side effects of insulin injection
Insulin side effects amongst diabetics are rare, but when they occur, allergic reactions can be severe and pose a significant risk to health.
Always read the patient information leaflet of your prescribed insulin. The possible side effects are listed in this leaflet.
If you are in doubt, contact your Diabetes Care Specialist for medical advice about the side effects of insulin injection.

Hyperglycemia / Hypoglycemia - Common
Hyperglycemia, or high blood sugar is a condition in which an excessive amount of glucose circulates in the blood.
Hypoglycemia, also known as low blood sugar, is when blood sugar decreases to below normal levels. Too much insulin can lead to Hypoglycemia. Too little insulin may result in Hyperglycemia.
Refer to the drug safety information or consult your diabetes care specialist for more information on how to recognize symptoms of hyperglycemia and hypoglycemia and how to maintain normal blood glucose levels.

nuGen MEDICAL DEVICES

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