Only for the use of Medical Professionals

Acilog® Biopen

Insulin Aspart (rDNA) BP

Description

Acilog® Biopen (Insulin Aspart [rDNA]) is rapid-acting human insulin analog used to lower blood glucose. **Acilog® Biopen** is homologous with regular human insulin with the exception of a single substitution of the amino acid proline by aspartic acid in position B28 and is produced by recombinant DNA technology utilizing *Saccharomyces cerevisiae(baker's yeast)*. Primary function of insulin, including Insulin Aspart, is regulation of glucose metabolism. Insulin and its analogs lower blood glucose by facilitating the cellular uptake of glucose and simultaneously by inhibiting hepatic glucose production. Insulin inhibits lipolysis and proteolysis and enhances protein synthesis.

Indication

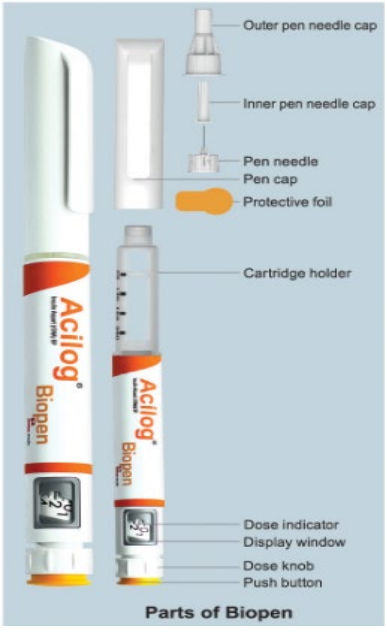
Acilog® Biopen is indicated to improve glycemic control in adults and children with diabetes mellitus.

Instructions of using Acilog® Biopen

Please read this manual completely and follow the directions carefully before using**Acilog® Biopen.**

Important information

- Use Biopen only after receiving adequate training from healthcare professional.
- Always use a new pen needle for each injection.
- Replace the pen needle after every use and do not store the pen with attached pen needle.
- Always keep the cap on the pen when it is not in use.
- Prior to using the pen always check if the proper pen with the correct drug is chosen as per recommendation of healthcare professionals.
- Always check the expiry date before use.
- To clean the Biopen, a moist cloth is sufficient. Do not use other solvents or cleaning agents.
- Always dispose of Biopen in compliance with local regulations after using it.

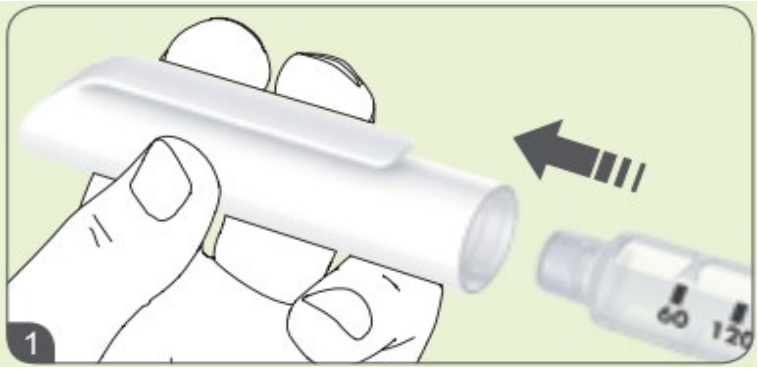


Parts of Biopen

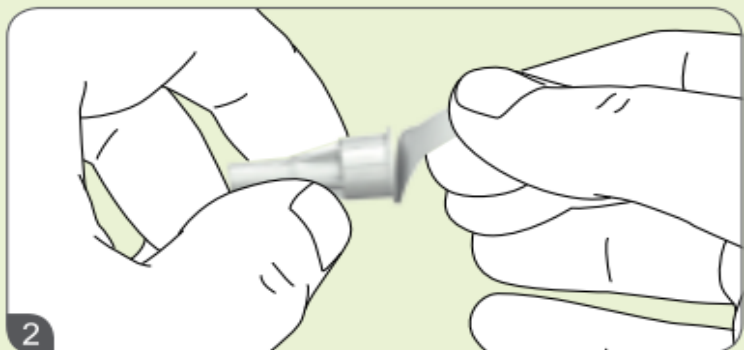
Technical characteristics

Acilog® Biopencan deliver doses between 10 µl (microliter) and 600 µl in 10 µl increments.

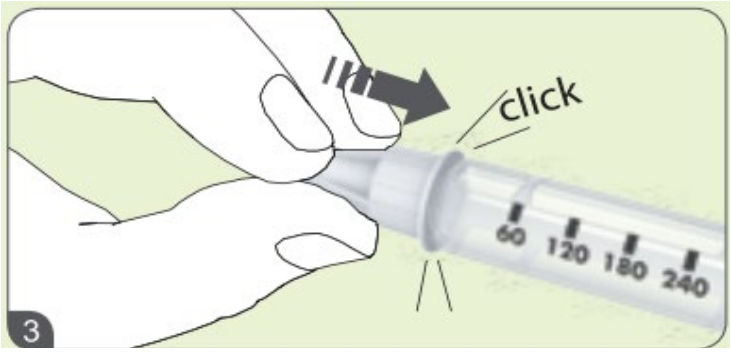
Attaching the pen needle:



Pull off the pen cap.

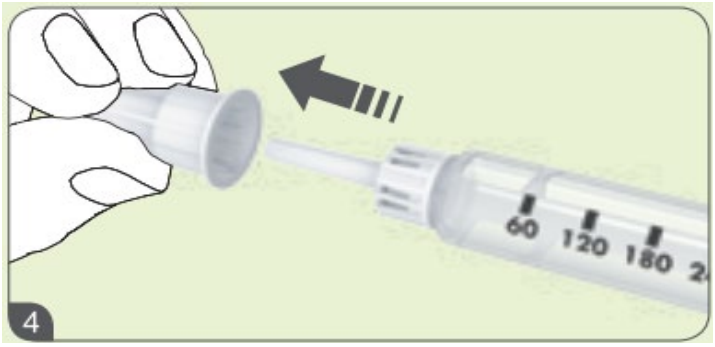


Pull off the protective foil on the pen needle

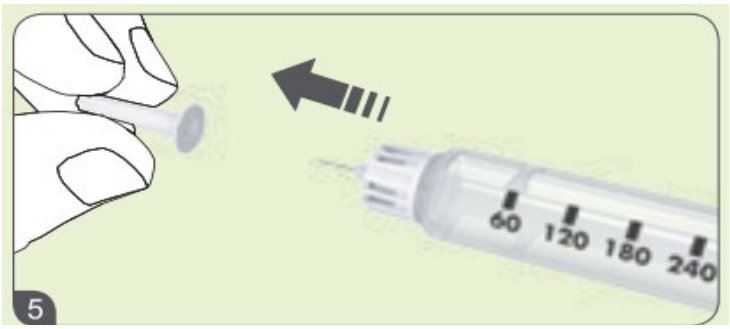


Click the pen needle onto the **Acilog® Biopen**keeping it straight.

Note: Firm seating is ensured when screwed on, even without a perceptible limit stop.



Pull off the outer pen needle cap and keep for use after the injection.



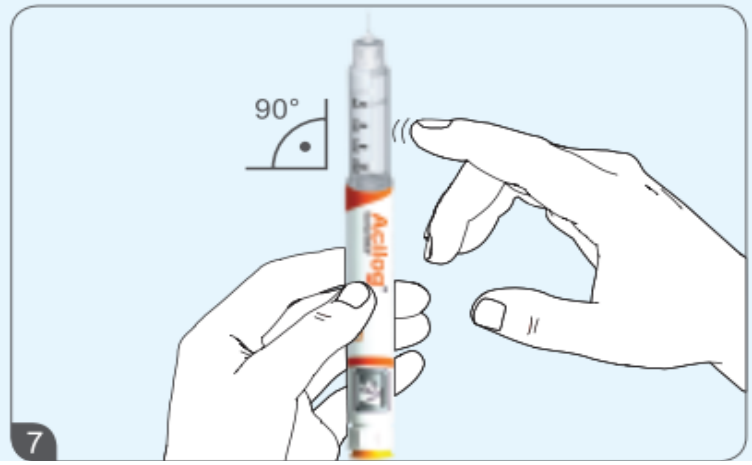
Pull off the inner pen needle cap and dispose of it.

Priming or functional test:

Important:
Prior to the first injection, the Biopen must be primed in order to remove air bubbles from the cartridge for accurate dosing and to ensure that the needle is not clogged.

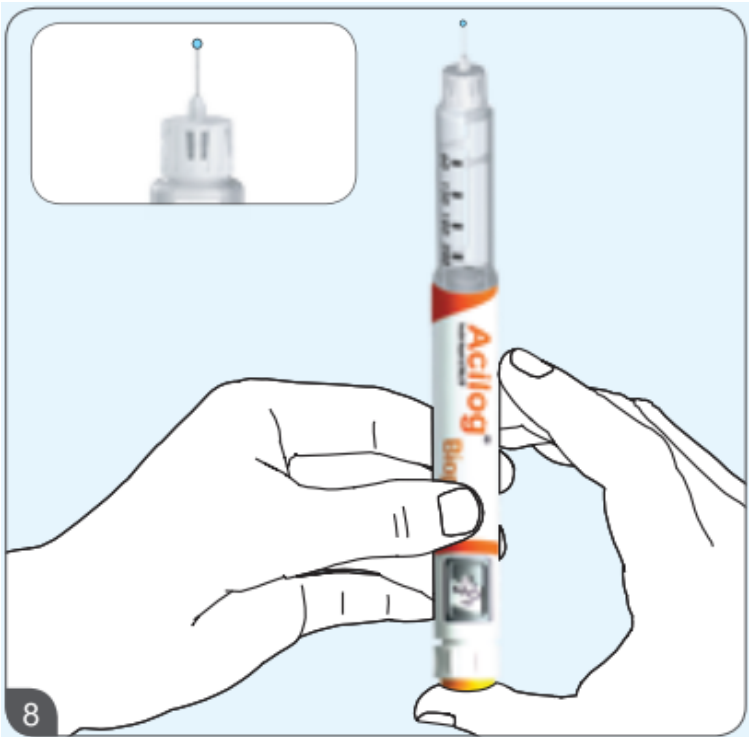
Select a dose of 2 units by turning the dose knob clockwise (2 clicks).

If necessary the selected dose can be corrected by turning the dose knob counter-clockwise.

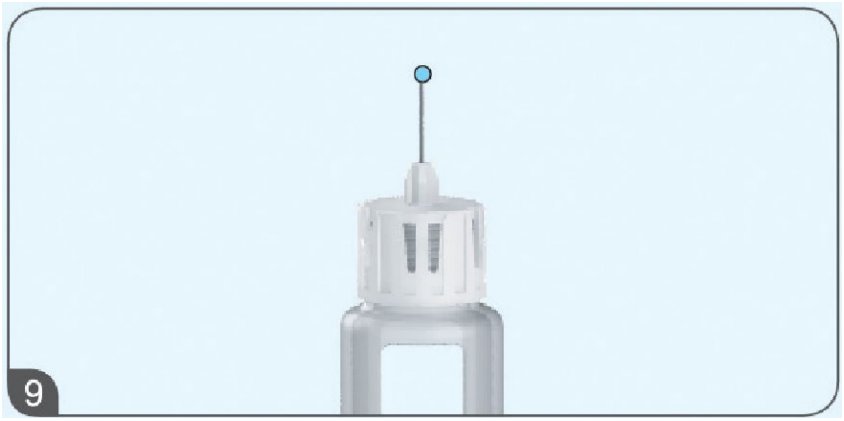


Hold the pen in an upright position (pen needle pointing up). Tap slightly with the finger on the cartridge holder to allow potential air bubbles within the cartridge to rise up.

Note: Air bubbles are not always present. Nevertheless this step should be performed to check drug flow through the pen needle prior to each injection.



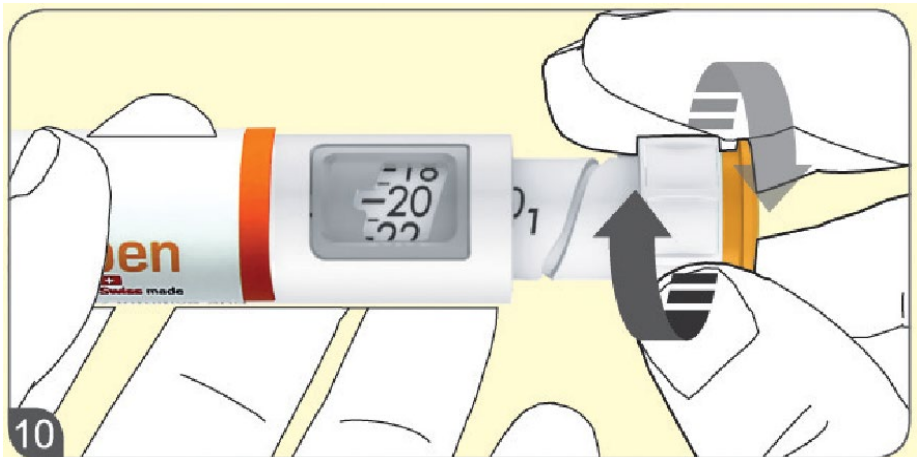
Press the push button all the way until a hard stop is felt to discharge the dose. Number ‘0’ is visible in the display window and aligns with the dose indicator.



Check whether a droplet of liquid shows at the tip of the penneedle. If no drops appear repeat steps 6-9 (priming or functional test) until a drop appears.

Important:
In case no drops emerge after 6 attempts (6×2 units), replace the pen needle (see step 13) and repeat the priming or functional test (see steps 6-9).

Setting the dose:



Turn the dose knob clockwise until the prescribed dose aligns with the dose indicator in the display window. If necessary the dose can be corrected by turning the dose knob counter-clockwise.

Important:
Make sure not to press the push button while dialing the dose to avoid loss of drug.

Notes:

- A dose larger than the amount of drug remaining in the pen cannot be dialed.
- If the dose is larger than the remaining drug volume in the cartridge a new pen should be used for the remaining dose.
- Either inject the residual drug and complete the dose with a new pen, or apply the full dose with a new pen.

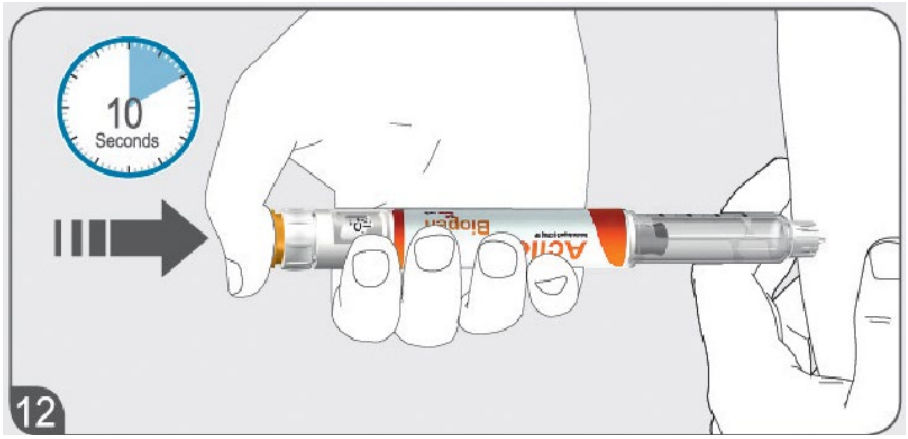
Injection:

Important:
Read steps 11 and 12 first before proceeding with the injection.

Hold the pen so that the display window is visible during the injection. Insert the pen needle into the skin and press the push button all the way in until a hard stop is felt and the number '0' is visible in the display window and aligns with the dose indicator.

Note: Use the injection technique recommended by the doctor or healthcare professional

Holding after injection:

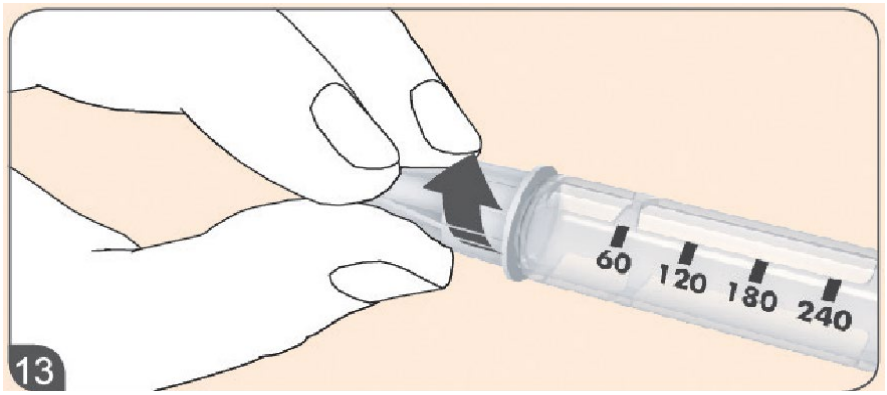


When the complete dose has been delivered, keep the push button pressed for another 10 seconds. Then slowly remove the pen from the injection site at a 90º angle.

Note: Holding the push button for 10 seconds which ensures a complete discharge of the drug dose.

Important:
Do not tilt the pen during injection and removal from skin to avoid pen needle damage.

Disposal of the pen needle:

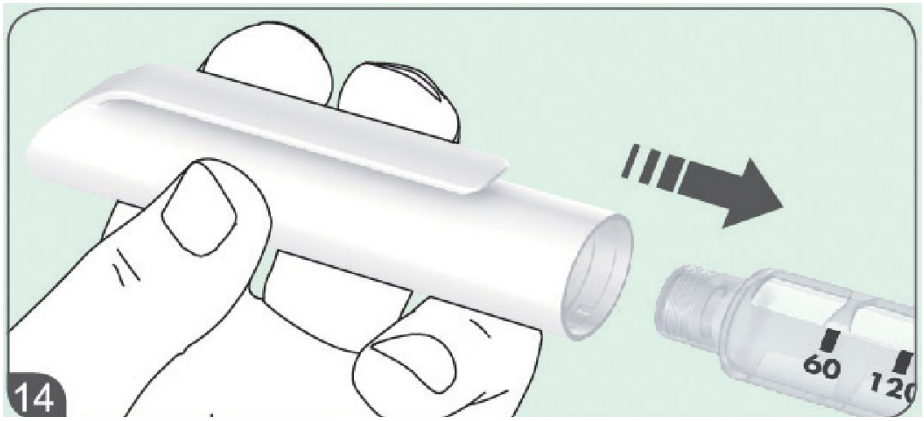


Replace the outer needle cap carefully.

Unscrew the pen needle counter-clockwise and dispose of the pen needle safely in accordance with local regulations.

Note for healthcare professionals: Always adhere to the specific regulations that apply for concerning replacement of the needle cap (recapping) and disposal.

Pen cap mounting:



Firmly attach the pen cap to the pen for protection between injections.

Note: After each use, remove (dispose of) the attached pen needle and attach the pen cap properly.

Dosage and administration

Subcutaneous injection:Acilog® Biopen should be administered by subcutaneous injection in the abdomen, buttocks, thigh or upper arm. Because **Acilog® Biopen** has a more rapid and a shorter duration of activity than human regular insulin, it should be injected immediately. Blood glucose monitoring is essential in all patients with diabetes. Patients who change their level of physical activity or meal plan may require adjustment of insulin dosage. Injection sites should be rotated within the same region (abdomen, buttocks, thigh or upper arm) from one injection to the next.

Intravenous injection:Acilog® Biopen can be administered intravenously under medical supervision for glycemic control with close monitoring of blood glucose and potassium levels to avoid hypoglycemia and hypokalemia. For intravenous use, **Acilog® Biopen** should be used at concentrations from 0.5 U/ml to 1.0 U/ml insulin aspart in infusion systems using polypropylene infusion bags. **Acilog® Biopen** has been shown to be stable in infusion fluids such as 0.9% sodium chloride. Inspect **Acilog® Biopen** for particulate matter and discoloration prior to parenteral administration.

Use in pregnancy and lactation

Pregnancy

Insulin aspart is pregnancy category B. Careful monitoring of glucose control is essential in pregnant patients because insulin requirements change during different stages of pregnancy. Therefore female patients should be advised to tell their physician if they intend to become or if they become pregnant while taking insulin aspart.

Lactation

It is unknown whether insulin aspart is excreted in human milk. Use of insulin aspart is compatible with breastfeeding, but women with diabetes who are lactating may require adjustments of their insulin doses.

Side effects

The most common side effects of insulin aspart are hypoglycemia, allergic reactions, local injection site reaction, lipodystrophy, pruritus and rash.

Contraindications

Insulin aspart is contraindicated in patients with known history of hypersensitivity to insulin aspart or any components of this product. It is also contraindicated during the episodes of hypoglycemia.

Warnings and precautions

Dose adjustment and monitoring: Blood glucose should be monitored in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision.

Renal or hepatic impairment

Reduction in the insulin aspart dose may require in these cases.

Drug interactions

A number of drugs affect glucose metabolism and may require dose adjustment.

• The following substances may reduce the insulin as well as insulin aspart requirements: oral anti-diabetic products, pramlintide and angiotensin converting enzyme (ACE) inhibitors, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, propoxyphene, pentoxifylline, salicylates, somatostatin analog and sulfonamide antibiotics.
• The following substances may decrease blood-glucose-lowering effect of insulin: corticosteroids, niacin, danazol, diuretics, hormones, sympathomimetic agents, isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, estrogen, progestogens and atypical antipsychotics.
• Beta-blockers, clonidine, lithium salts, and alcohol may either potentiate or weaken the blood-glucose-lowering effect of insulin.

Overdose
Insulin aspart overdose may result in hypoglycemia particularly when given intravenously. Mild episodes of hypoglycemia can usually be treated with oral carbohydrates. Severe hypoglycemia may be treated with parenteral glucose or injections of glucagon. Adjustments in drug dosage, meal patterns or exercise may be needed. Hypokalemia must be corrected appropriately.

Pharmaceutical precautions
Store at 2ºC to 8ºC in a refrigerator. Do not freeze. Do not mix with other insulin. In case of insulin for recent use need not be refrigerated, try to keep it in a cool place and keep away from heat and light. The insulin in use can be kept under the room temperature (below 30ºC) for a month.

Special precaution for disposal and other handling
Acilog® Biopen is designed to be used with disposable needles up to length of 8 mm. The pre-filled pen is for single patient use only.

Presentation
Acilog® Biopen Injection 100 U/ml: Each ml solution contains Insulin Aspart (rDNA) BP 100 units (equivalent to 3.5 mg).

Package quantities
Acilog® Biopen Injection 100 U/ml: Carton of 5 pens and each pen contains 3 ml sterile solution in a glass cartridge.

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