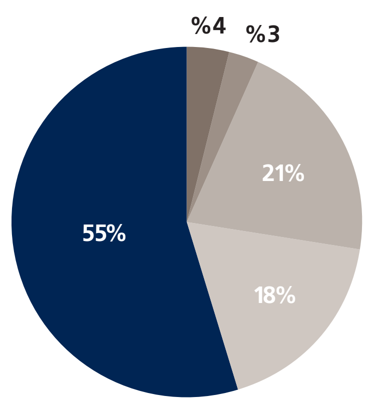
NovoMix® 30
(biphasic insulin aspart)

NovoMix®30 vs. BHI:
Advantages of analogue pens vs vials & safety and efficacy vs Biphasic Human insulins

Hospitalisation alone accounts for ~55% of direct medical costs for type 2 diabetes[1]

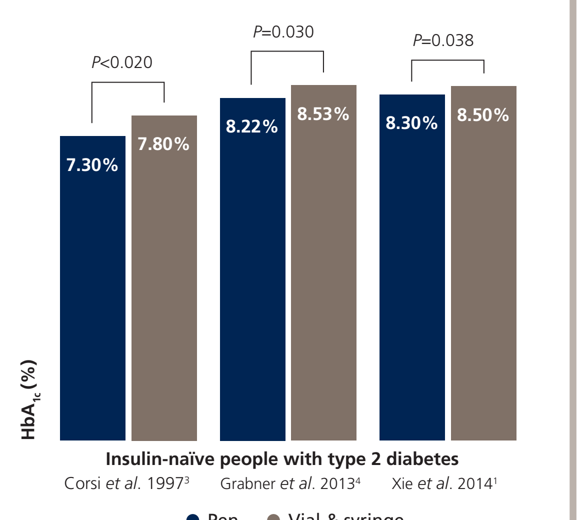


Distribution of overall costs for people with type 2 diabetes[1]

Adapted from Petersen MP. et al. 2018.[1]
Due to rounding, numbers may not add up to 100%.

PEN USE OFFERS IMPROVED HEALTH ECONOMIC BENEFITS VS VIAL AND SYRINGE[2,3,4,5,6]

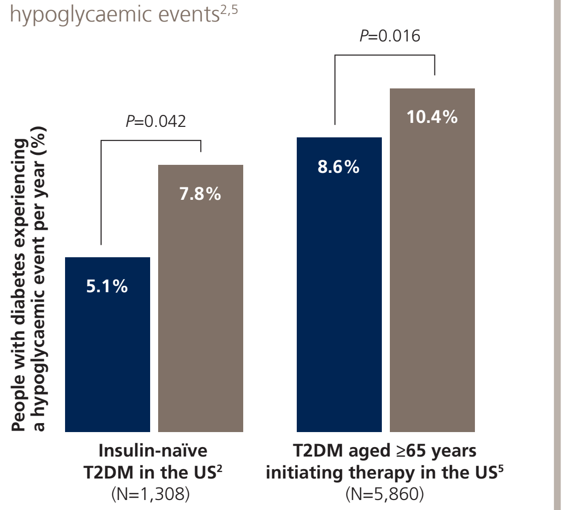
Improved glycaemic control



- Improved glycaemic control, with significantly lower HbA_{1c} values[2,3,4]

Improved safety

Pens are associated with a lower risk of hypoglycaemic events[2,5]



- Greater dose accuracy[7]
- Fewer hypoglycaemic events after switching from vial and syringe, or vs vial and syringe[2,5,6]

Hypoglycaemia

Hypoglycaemic episodes can be a considerable problem with BHI[8,9]

Major hypoglycaemia

55%

REDUCTION in the likelihood of **major hypoglycaemic** events vs BHI[9]

Nocturnal hypoglycaemia

50%

REDUCTION in the likelihood of **nocturnal hypoglycaemic** events vs BHI[9]

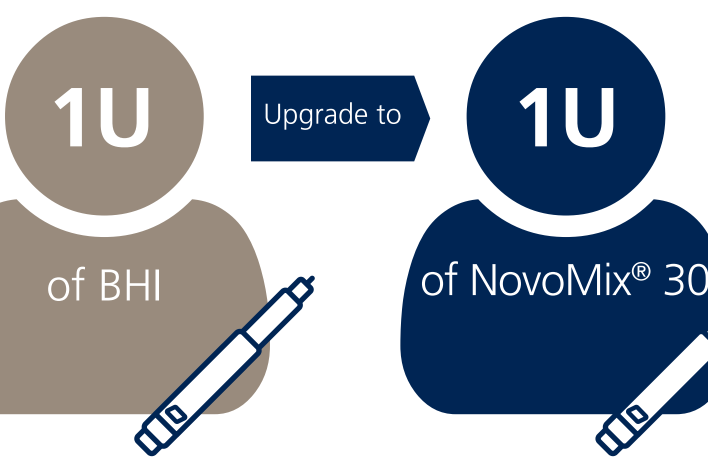
NOVOMIX® 30 reduces the risk of hypoglycaemia events vs BHI[9-12]

Mealtime flexibility

NOVOMIX®30 allows flexible injection timing[8-13]

- BHI needs to be administered at least 30 minutes before a meal[8]
- Adherence to BHI injection timing is poor[8]
- NOVOMIX® 30 can be taken just before or immediately after a meal[8-13]

It's easy to upgrade your patients to NovoMix® 30 from BHI by using a simple 1:1 conversion.[13] Start NovoMix® 30 with the same total daily insulin dose as their BHI regimen.*[13]



The dose can be administered up to **three times daily**.[14,15]

Why choose NovoMix® 30 over BHI?

To find out more about how initiating with NovoMix® 30 can benefit your patients, find out what key opinion leaders have to say about their experiences in real world clinical practice.

Watch video

References

1. Petersen MP et al. Diabetes Care 2018;41:917–928.
2. Xie L,et al. Impact of initiating insulin glargine disposable pen versus vial/syringe on real-world glycemic outcomes and persistence among patients with type 2 diabetes mellitus in a large managed care plan: a claims database analysis. Diabetes Technol Ther. 2014;16(9):567–75.
3. Corsi A, et al. Pre-fi lled insulin pen in newly insulin-treated diabetic patients over 60 years old. Diabetes Nutr Metab. 1997;10(2):78–81.
4. Grabner M, et al. Clinical and economic outcomes among patients with diabetes mellitus initiating insulin glargine pen versus vial. Postgrad Med. 2013;125(3):204–213.
5. Miao R, et al. Does device Make Any Difference? A Real-world Retrospective Study of Insulin Treatment Among Elderly Patients With Type 2 Diabetes. Diabetes Sci Technol. 2014;8(1):150–158.
6. Lee W, et al. Medication adherence and the associated health-economic impact among patients with type 2 diabetes mellitus converting to insulin pen therapy: an analysis of third-party managed care claims data. Clin Ther. 2006;28:1712–1725.
7. Asakura T, et al. A Comparison of the Handling and Accuracy of Syringe and Vial Versus Prefi lled Insulin Pen (FlexPen®). Diabetes Technol Ther. 2009;11(10):657–661
8. Garber AJ et al. Premixed insulin treatment for type 2 diabetes: analogue or human? Diabetes Obes Metab 2007;9(5):630–63.
9. Davidson JA et al. Risk for nocturnal hypoglycemia with biphasic insulin aspart 30 compared with biphasic human insulin 30 in adults with type 2 diabetes mellitus: a meta-analysis. Clin Ther 2009;31(8): 1641–165.
10. Shah S et al. Safety and effectiveness of biphasic insulin aspart 30/70 (NovoMix® 30) when switching from human premix insulin in patients with type 2 diabetes: subgroup analysis from the 6-month IMPROVE observational study. Int J Clin Pract 2009;63(4):574–582.
11. El Naggar NK et al. Switching from biphasic human insulin 30 to biphasic insulin aspart 30 in type 2 diabetes is associated with improved glycaemic control and a positive safety profile: results from the A1chieve study. Diabetes Res Clin Pract 2012;98(3):408–41.
12. Shestakova M et al. Transferring type 2 diabetes patients with uncontrolled glycaemia from biphasic human insulin to biphasic insulin aspart 30: experiences from the PRESENT study. Curr Med Res Opin 2007;23(12):3209–321.
13. NovoMix®30 Locally approved Labeling in Iran (STF-Dec-2019).
14. Unnikrishnan A et al. Int J Clin Pract 2009;63:1571–1577.
15. Khamseh M et al. ADA 2012; Poster 1074–P.

Abbreviated prescribing information NovoMix® 30 (biphasic insulin aspart)

Qualitative and quantitative composition: 1ml of the suspension contains 100 U of soluble insulin aspart/protamine-crystallised insulin aspart in the ratio 30/70.1 pre-filled pen contains 3 ml equivalent to 300 U. **Pharmaceutical form:** White Suspension for injection in a pre-filled pen FlexPen®. **Pharmaco-therapeutic group:** Intermediate or long acting insulin combined with fast-acting insulin. **Therapeutic Indication:** Patients with diabetes mellitus requiring insulin. **Posology:** To be individualized and determined in accordance with the needs of the patient. Insulin dose adjustments based on blood glucose monitoring is recommended. In patients with type 2 diabetes, NovoMix® 30 can be given as monotherapy or in combination with oral antidiabetic agents (OADs) if the patient's blood glucose is inadequately controlled with OADs alone and/or with GLP-1 receptor agonists. **How to start, switch and intensify:** For patients with type 2 diabetes, the recommended starting dose is 6 U at breakfast and 6 U at dinner. NovoMix® 30 can also be initiated once daily with 12 U at dinner. When transferring a patient from biphasic human insulin to NovoMix® 30, start with the same dose and regimen. Then titrate according to individual needs and glucose monitoring is recommended during the transfer and in the initial weeks. NovoMix® can be intensified from once to twice and thrice daily. **Special populations:** Elderly: There is limited experience with the use of NovoMix® 30 in patients older than 75 years. **Renal and hepatic impairment:** May reduce the patient's insulin requirements. Paediatric population: NovoMix® 30 can be used in children and adolescents aged 10 years and above when premixed insulin is preferred. Limited clinical data exists for children aged 6-9 years, no data available for children below 6 years of age. **Method of administration:** NovoMix® 30 is for subcutaneous administration only. Must not be administered intravenously as it may result in severe hypoglycaemia. Intramuscular administration should be avoided. NovoMix® 30 is not to be used in insulin infusion pumps. NovoMix® 30 should be administered subcutaneously by injection in the thigh or in the abdominal wall. It can also be administered subcutaneously in the Gluteal or deltoid region if convenient. Injection sites should always be rotated within the same region in order to reduce lipodystrophy. NovoMix® 30 has faster onset of action **than biphasic human insulin** and should generally be given immediately before a meal and when necessary can be given soon after a meal. **Contraindications:** Hypersensitivity to insulin aspart or any of the excipients. **Warnings and precautions:** Before travelling between different time zones, the patient should seek the doctor's advice. **Hyperglycaemia:** Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis. **Hypoglycaemia:** Omission of a meal or unplanned strenuous physical exercise may lead to hypoglycaemia. Hypoglycaemia may occur if the insulin dose is too high. Compared to biphasic human insulin, NovoMix® 30 may have more pronounced glucose lowering effect up to 6 hours after injection. This may have to be compensated for in the individual patient, through adjustment of insulin dose and /or food intake. Patients, whose blood glucose control is greatly improved by intensified insulin therapy, may experience a change in their usual warning symptoms of hypoglycaemia. Tighter control of glucose levels can increase the potential for hypoglycaemic episodes and require special attention during dose intensification. Concomitant illness, infection and fever usually increase insulin requirements in patients. Concomitant disease of the kidney, liver, adrenal, pituitary or thyroid gland may require changes in insulin dose. **Transfer from other insulin products:** Should be done under strict medical supervision. **Injection site reactions:** May occur and includes pain, redness, hives, inflammation, bruising, swelling and itching. **Combination of thiazolidinediones and insulin:** Cases of congestive heart failure have been reported when thiazolidinediones were used in combination with insulin. Thiazolidinediones should be discontinued if any deterioration in cardiac symptoms occurs. **Insulin antibodies:** Insulin administration may cause insulin antibodies which may necessitate adjustment of the insulin dose. **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 NovoMix® and other insulin products. **Interactions with other medicinal products:** Oral antidiabetic agents, GLP-1 receptor agonists, monoamine oxidase inhibitors (MAOIs), beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulfonamides may reduce insulin requirement in patients. Oral contraceptives, thiazides, glucocorticoids, thyroid hormone, sympathomimetic, growth hormone and danazol may increase the patient's insulin requirements. Beta blockers may mask the symptoms of hypoglycaemia. Octreotide/lanreotide may either increase or decrease insulin requirement. Alcohol may intensify or reduce the hypoglycaemic effect of insulin and may increase insulin requirements. **Pregnancy and lactation:** There is limited clinical experience with NovoMix® 30 in pregnancy. NovoMix® 30 has not been investigated in pregnant women. There are no restrictions on treatment with NovoMix® 30 during lactation. Insulin treatment of the breast-feeding mother presents no risk to the baby. However, the dosage of NovoMix® 30 may need to be adjusted. **Effects on ability to drive and use machines:** Patients should be advised to take precautions to avoid hypoglycaemia while driving or operating machines. **Undesirable effects:** The most frequently reported adverse reaction during treatment is hypoglycaemia. 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 a 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. **Anaphylactic reactions:** The occurrence of generalised hypersensitivity reactions (including generalised skin rash, itching, sweating, gastrointestinal symptoms, angioneurotic oedema, difficulty 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. **Lipodystrophy:** Lipodystrophy (including lipohypertrophy, lipoatrophy) may occur at the injection site. Continuous rotation of the injection site within the particular area reduces the risk of developing these reactions. **Overdose:** 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 a healthcare professional. 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. **Pharmacodynamics properties:** Pharmacotherapeutic group: Drugs used in diabetes. Insulins and analogues for injection, intermediate- or long-acting insulin combined with fast-acting insulin. ATC code: A10AD05. **Mechanism of action:** 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 output from the liver. When NovoMix® 30 is injected subcutaneously, the onset of action will occur within 10 to 20 minutes of injection. The maximum effect is exerted between 1 and 4 hours after injection. The duration of action is up to 24 hours. **Pharmacokinetic properties:** In insulin aspart, substitution of amino acid proline with aspartic acid at position B28 reduces its tendency to form hexamers as observed with human insulin. Elderly: The pharmacokinetic properties of NovoMix® 30 have not been investigated in the elderly patients. **Renal and hepatic impairment:** The pharmacokinetics of NovoMix® 30 has not been investigated in patients with renal or hepatic impairment. Paediatric population: The pharmacokinetics of NovoMix® 30 has not been investigated in children or adolescents. **Special precautions for storage:** Storage when not in use: Store in a refrigerator (2°C – 8°C). Keep away from the cooling element. Do not freeze. The expiry date is printed on the label and carton. After removing NovoMix® 30 FlexPen® from the refrigerator, it is recommended to allow NovoMix® 30 FlexPen® to reach room temperature before re-suspending the insulin as instructed. Storage during use or when carried as a spare: NovoMix® 30 FlexPen® that is being used or carried as a spare is not to be kept in the refrigerator. It can be kept at room temperature (below 30°C) for up to 4 weeks. Keep the pen cap on FlexPen® in order to protect from light. NovoMix® 30 must be protected from excessive heat and light. **Nature and contents of container:** 3 ml suspension cartridge (type 1 glass) with a plunger (bromobutyl)and a rubber closure (bromobutyl/polyisoprene) contained in a prefilled multidose disposable pen made of polypropylene in a carton. The cartridge contains a glass ball to facilitate resuspension. Pack sizes of 5 and 10 pre-filled pens. Not all pack sizes may be marketed. **Special precautions for disposal and other handling:** Needles and NovoMix® 30 FlexPen® must not be shared. The cartridge must not be refilled. NovoMix® 30 must not be used if the resuspended liquid does not appear uniformly white and cloudy. The necessity of resuspending the NovoMix® 30 FlexPen® suspension immediately before use is to be stressed to the patient. NovoMix® 30 which has been frozen must not be used. The patient should be advised to discard the needle after each injection. **Marketing authorisation holder:** Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark **Manufactured by:** Novo Nordisk Produção Farmacêutica do Brasil Ltda.Avenida C, 1413, Distrito Industrial, Montes Claros – Minas Gerais, Brazil 39404-004 Prescription only medicine Full prescribing information can be obtained free of charge from Novo Nordisk. IRC number: 5142151711249730. **Locally approved labelling** in Iran based on STF-Dec-2019 (Approved by IFDA- July 2020).

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diabetes journey

NovoMix® 30 (biphasic insulin aspart)