

# Moving ahead with NovoMix<sup>®</sup> 30



A guide for patients who  
have been prescribed  
NovoMix<sup>®</sup> 30

This booklet does not replace the advice of your doctor. If you have questions or concerns, be sure to contact your doctor. Please see professional information for additional information.



PEOPLE LIVING WITH  
TYPE 2 DIABETES  
SHOULD COMBINE  
MEDICINE, A HEALTHY  
MEAL PLAN AND  
PHYSICAL ACTIVITY  
TO CONTROL THEIR  
BLOOD GLUCOSE  
LEVEL<sup>1</sup>

You and your doctor have decided the time is right to add NovoMix® 30 to your treatment plan for blood sugar control. Managing blood sugar levels is important in keeping diabetes under control.

This booklet will introduce you to NovoMix® 30, a modern insulin with both a rapid-acting and a long-acting effect. The rapid-acting component helps control the rise in blood sugar levels after meals and the long-acting component provides a constant level of background insulin.<sup>2</sup> Increased blood sugar levels affect your overall diabetes results, so it is important to monitor and keep this under control. Your doctor or nurse will advise you on when to inject NovoMix® 30.

As you move forward in your diabetes care, you should know that you are not alone. Of course, if you have questions or concerns, always contact your doctor.

The content of this booklet is not intended to replace the advice of your doctor or nurse or medical consultation.

# Getting to know NovoMix® 30

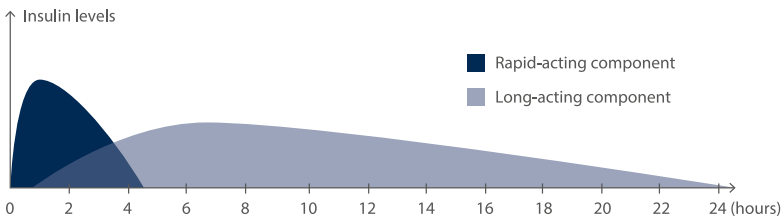
## What is insulin?

Insulin is a naturally occurring hormone secreted by the organ called the pancreas in your body, and it is very important for everyone. It helps sugar move from the bloodstream into the cells of your body that need it to make energy. By doing this, insulin controls the sugar (glucose) level in your blood.<sup>3</sup>

## Insulin therapy

The body produces insulin throughout the day, and after a meal the amount of insulin increases in order to help lower the high blood sugar caused by food intake. If you have diabetes, your body makes very little or no insulin, and/or your body may not use available insulin properly. Your oral diabetes medication may no longer be able to control your blood sugar levels alone and therefore insulin injections should be considered.<sup>2,3</sup>

## Schematic time-action profile of NovoMix® 30



NovoMix® 30 replaces the insulin your body needs immediately after and between meals and helps you to manage episodes of high blood sugar levels during the day.<sup>2</sup>

### **What is NovoMix® 30 and how does it work?**

NovoMix® 30 is a premixed suspension consisting of rapid-acting insulin aspart and long-acting protamine insulin aspart. Together these components help control your blood sugar levels between and after meals.<sup>2</sup>

NovoMix® 30 lowers your blood sugar level after an injection. NovoMix® 30 is generally injected immediately before a meal. Eat a meal or snack within 10 minutes of the injection to avoid low blood sugar. When necessary, NovoMix® 30 can be given soon after a meal.<sup>2</sup>

NovoMix® 30 takes effect within 10 to 20 minutes. The maximum effect will occur between 1 - 4 hours and the effect may last up to 24 hours.<sup>2</sup>

### **What does NovoMix® 30 look like?**

You can identify the NovoMix® 30 printing on the label of your device and Penfill®. You may also recognise it by its insert colours to help patients.

NovoMix® 30 is a sterile, white suspension. The resuspended liquid must appear uniformly white and cloudy after agitation.<sup>2</sup>

NovoMix® 30 comes in a 3 ml FlexPen® and 3 ml cartridges (called Penfill®) for use in your durable Novo Nordisk insulin delivery pen device, such as NovoPen® 4.<sup>2</sup>

# Administering your NovoMix® 30 injection

## Your NovoMix® 30 regimen

NovoMix® 30 should generally be injected immediately before a meal, but when necessary can also be given soon after a meal.<sup>2</sup>

Fill in the details of your NovoMix® 30 treatment. Write down your doses and when to take them, as agreed with your doctor.

The daily starting dose of NovoMix® 30 as agreed with your doctor, is \_\_\_\_\_.

The best places to inject insulin are your stomach, the front of your thighs, buttocks or back of upper arms. Do not inject insulin in the same spot all the time, because it can cause lumps in your skin. For example, if you inject insulin in your abdomen, you should regularly move the injection from one part of your abdomen to another part of your abdomen.<sup>2</sup>

Always follow the directions from your doctor, and ask for help if you are having trouble injecting NovoMix® 30. Never intentionally skip a dose. It is recommended that any dose changes be done only on the advice of your doctor.

**If you are switching from another insulin to NovoMix® 30**

When transferring from another type of insulin to NovoMix® 30, you can start with the same dose and regimen followed by individual dosage adjustments, as agreed with your doctor. If an adjustment is needed, it may occur with the first dose of NovoMix® 30 or during the first few weeks or months. As with all insulin, when switching from one to another, blood sugar levels should be closely monitored for the following weeks.<sup>2</sup>



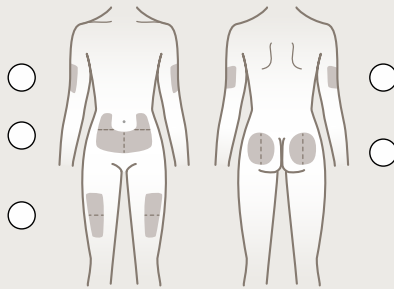
# Before you inject NovoMix® 30

Here are a few tips that will help you give a comfortable injection.<sup>2,4</sup>

## Injection sites

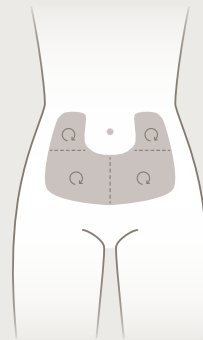
The main injection sites are the thighs, stomach, buttocks or backs of the upper arms. Ask your doctor or nurse which sites are recommended for you.

Make a mark of your recommended injection site



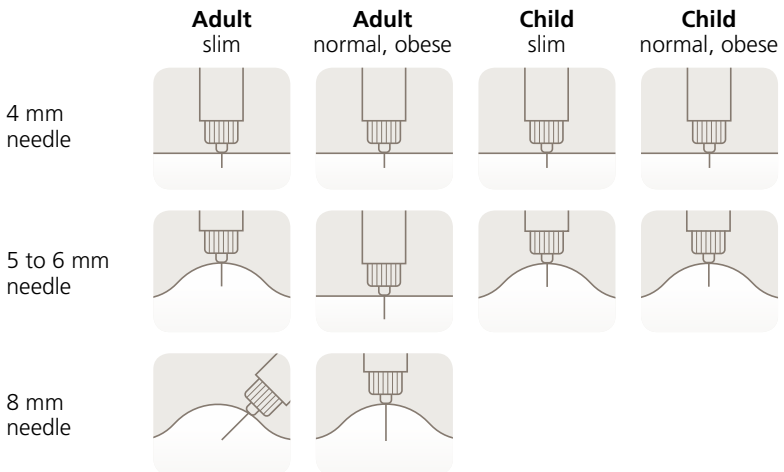
To increase comfort, make sure you choose a different place to inject for every injection.

- Divide the injection sites into halves or quarters and use a different half/quarter every week.
- In each half or quarter, rotate the place of injection clockwise by about the width of a finger from the last injection point.



## Injection technique<sup>4</sup>

Insulin is injected under the skin in the subcutaneous tissue. How you should inject depends on your build and the length of the needle. You can see the different injection techniques below. Always make sure to use the injection technique and needle length recommended by your doctor or nurse.



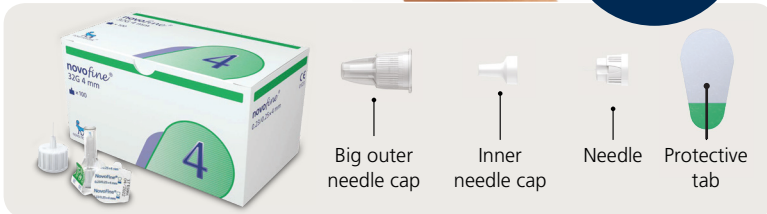
## How to lift the skin<sup>4</sup>

To make sure insulin is injected under the skin, it can be helpful to inject into a skin fold. Lift a fold of skin between your thumb and index fingers. Keep it raised for 5 to 10 seconds after injection and until you have removed the needle from the skin.



# How to use NovoMix® 30 FlexPen®

Is this the first time you are administering an injection?  
Ask your doctor or nurse about injection training.<sup>5</sup>



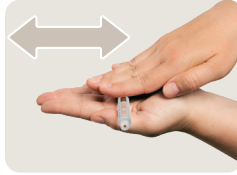
Do not share your NovoMix® 30 FlexPen® with other people. Sharing the pen can result in the spread of infections from one person to another, even if the needle is changed.

Please see the Instructions for Use that came with your NovoMix® 30 FlexPen® for complete instructions.<sup>5</sup>



### 1. Check your pen

- Check the name and coloured label of your pen to make sure that it contains the correct type of insulin.
- Pull off the pen cap.



### 2. Resuspend the insulin

- Hold the pen horizontally between your palms and roll it 10 times.



### 3.

- Then move the pen up and down 10 times.
- Make sure that the insulin is uniformly white and cloudy.



### 4. Attach a new needle

- Remove the protective tab from a new needle.
- Screw the needle straight and tightly onto your pen.
- Pull off both needle caps. Keep the big outer needle cap.



### 5. Check the insulin flow

- Turn the dose selector to select 2 units.
- Press the push-button all the way in. The dose selector returns to 0. A drop of insulin should appear at the needle tip.



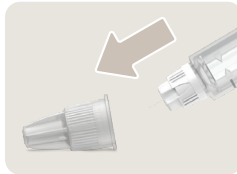
### 6. Select your dose

- Check that the dose selector is set at 0.
- Turn the dose selector to select the number of units you need to inject.
- You can turn the dose selector up or down to adjust the dose.



### 7. Inject your dose

- Insert the needle into your skin.
- Press the push-button all the way in until 0 lines up with the pointer.
- The needle must remain under the skin for at least 6 seconds. This will ensure that the full dose has been injected.



### 8. Remove the needle

- Lead the needle into the big outer needle cap.
- When the needle is covered carefully push the big outer needle cap completely on.
- Unscrew the needle and dispose of it carefully.
- Then put the pen cap back on.

# Some frequently asked questions

## **How do I store my NovoMix® 30?<sup>2</sup>**

Keep NovoMix® 30 out of the sight and reach of children.

Do not use NovoMix® 30 after the expiry date which is stated on the Penfill®, pen label and carton, after 'EXP'. The expiry date refers to the last day of that month.

## **Before first use<sup>2</sup>**

Store NovoMix® 30 in a refrigerator (2 °C to 8 °C). Keep away from the freezing element. Do not freeze. Keep the cap on the pen in order to protect from light.

## **After first opening or when carried as a spare<sup>2</sup>**

Do not refrigerate. You can carry your pen with you and keep it at room temperature (not above 30 °C) for up to 4 weeks. Always keep the cap on the pen when you are not using it in order to protect from light.

## **What are the important things I should know about NovoMix® 30?<sup>2</sup>**

NovoMix® 30 can cause side effects. Everyone reacts to insulin differently. Some people may experience side effects and others may not. Contact your doctor if you experience any of the following symptoms, or any others that you think might relate to your insulin injection.

The following side effects may occur during NovoMix® 30 treatment:<sup>5</sup>

- Anaphylactic reactions (serious allergic reaction)

Seek medical advice immediately:

If signs of allergy spread to other parts of your body or if you suddenly feel unwell and you start sweating, start being sick (vomiting), have difficulty in breathing, have a rapid heart-beat, feel dizzy.

- Low blood sugar (hypoglycaemia) develops very frequently

The following side effects are less frequent<sup>5</sup>

- Signs of allergy: Pain, redness, swelling and itching at the injection site.
- Refraction disorders (vision problems): When you first start your NovoMix® 30 treatment, it may disturb your vision, but the disturbance is usually temporary.
- Swollen joints (Oedema): When you start taking NovoMix® 30, water retention may cause swelling around your ankles and other joints usually this soon disappears.
- Diabetic retinopathy (eye disease related to diabetes which can lead to loss of vision): If you have diabetic retinopathy and your blood sugar levels improve very fast, the retinopathy may get worse.
- Lipodystrophy (Changes at injection site): The fatty tissue under the skin at injection site may shrink or thicken.
- Peripheral neuropathy (pain due to nerve damage):  
If your blood sugar level improves very fast, you may get nerve related pain, this is called acute neuropathy and is usually transient.

**Not all side effects reported for NovoMix® 30 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NovoMix® 30, please consult your doctor, pharmacist or other health care professional for advice.<sup>5</sup>**

### **What is low blood sugar (a “hypo”)?<sup>2,6</sup>**

Sometimes, blood sugar can get too low. This is called hypoglycaemia. As with any insulin product, NovoMix® 30 may cause hypoglycaemia. To help reduce the risk of hypoglycaemia, always follow your doctor’s instructions. Too low blood sugar may happen if you use too much insulin, exercise more than usual, drink alcohol, miss a meal, or eat too little.

### **How do I know if I have low blood sugar?<sup>2,6</sup>**

Low blood sugar can happen quickly. You might feel different symptoms including: cold sweat, confusion, and a fast heartbeat. Some people may feel sick, tired, or dizzy, or experience a headache or anxiety.

Some symptoms of hypoglycaemia are nausea, hunger, feeling nervous or jittery, trembling, slurred speech, clamminess, difficulty concentrating, and short-lasting changes in your sight.

Every person responds differently to low blood sugar. Your doctor will help you recognise the symptoms and teach you what to do if you have them.

### **What should I do if my blood sugar is too low?<sup>6</sup>**

- Eat glucose tablets or another high-sugar snack, like sweets, or fruit juice (always carry glucose tablets or a high-sugar snack, just in case).
- Measure your blood sugar if possible and rest. You may need to measure your blood sugar more than once.
- Rest until the signs of low blood sugar have gone or until your blood sugar has settled. Then carry on with your NovoMix® 30 as usual.

- If you pass out and need help from someone, they should get medical help straight away, and not give you any food or drink because you may choke.

Tell your friends and family about low blood sugar, and what the symptoms are, so they can get you help if you need it. Your doctor can teach you how to prevent and treat low blood sugar. The best way is to take proper care for your diabetes. Also, try not to skip or delay meals.

Be sure to talk to your doctor if you want to change your diet or exercise routine.

### **What should I do to keep my diabetes in control with NovoMix® 30?<sup>2,6</sup>**

Adhere to the guidance provided by your doctor and if you have any concerns do not hesitate to discuss these with your doctor, diabetes educator or pharmacist. Remember to:

- measure your blood sugar level regularly
- inform your friends, relatives and workmates that you are living with diabetes
- keep using NovoMix® 30 even if you feel well
- inform your doctor if you often have hypo's or have trouble recognising the symptoms of hypo's
- always carry some sugary food or fruit juice with you.

# Team up

Stay on top of managing your diabetes. For the best results, start thinking about what your daily routine for success will be. When you find something that works for you, stick to it. The results will add up.<sup>1,7</sup>



**Take your medication as recommended by your doctor.** Measure your blood sugar levels. Track your daily progress in your diary. Keep it in a convenient place so you'll be more inclined to use it.



**Make healthy food choices.** Portion control can be a good way to manage your weight. Losing just a few kilos may help you better manage your diabetes and health.



**Stay active.** Find simple ways to exercise during your daily routine. Physical activity will naturally reduce the blood sugar in your body and make your medication work more effectively.



**Team up.** Be an active part of your diabetes care team (i.e. doctor, spouse, colleagues, friends, children etc.) and find the best treatment plan for yourself.









**References:** 1. Type 2 Diabetes and Insulin. When dietary changes, exercise and medications don't work. *Endocrineweb*. Available from <https://www.endocrineweb.com/conditions/type-2-diabetes/type-2-diabetes-insulin>. Accessed March 2024. 2. NovoMix<sup>®</sup> approved professional information, 12 July 2023. 3. What is Insulin? - Important hormone allows your body to use sugar (glucose). *Endocrineweb*. Available from <https://www.endocrineweb.com/conditions/type-1-diabetes/what-insulin>. Accessed March 2024. 4. Injection Technique Working Group of The Diabetes Education Society of South Africa (DESSA). Injection technique guidelines for diabetes: sharp and to the point. *JEMDSA* 2014;19(1):8-13. 5. NovoMix<sup>®</sup> approved patient information leaflet 12 July 2023. 6. Hypoglycemia - Low Blood Glucose (Blood Sugar): American Diabetes Association<sup>®</sup>. 7. The Society for Endocrinology, Metabolism and Diabetes of South Africa Type 2 Diabetes Guidelines Expert Committee. The SEMDSA 2017 Guidelines for the Management of Type 2 diabetes mellitus. *Journal of Endocrinology, Metabolism and Diabetes of South Africa*. Vol 22(1): S1-S189.

**Proprietary Name:** NovoMix<sup>®</sup> 30. **Scheduling Status:** [S3] **Composition:** Soluble insulin aspart/protamine-crystallised insulin aspart 100 U/ml in the ratio of 30/70. **Therapeutic indications:** NovoMix<sup>®</sup> 30 is indicated for the treatment of insulin requiring patients with diabetes mellitus. **Contraindications:** Hypoglycaemia, hypersensitivity to insulin aspart or to any of the excipients, intravenous injection. **Special warnings and precautions for use:** Do not use NovoMix<sup>®</sup> 30 in insulin pumps. Before travelling between different time zones the patient should seek the doctor's advice since this may mean that the patient has to take the insulin and meals at different times. Inadequate dosing or discontinuation of treatment may, especially in Type 1 diabetes (insulin-dependent diabetes mellitus), lead to hyperglycaemia and diabetic ketoacidosis. The first symptoms of hyperglycaemia usually come on gradually, over a period of hours or days. Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycaemia. Hypoglycaemia may occur if the insulin dose is too high in relation to the insulin requirement. The symptoms of hypoglycaemia usually occur suddenly. Compared with biphasic human insulin, NovoMix<sup>®</sup> 30 may have a 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, e.g. by intensified insulin therapy, may experience a change in their usual warning symptoms of hypoglycaemia, and should be advised accordingly. Transferring a patient to a new type or brand of insulin should be done under strict medical supervision. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site from an affected to an unaffected area, and dose adjustment of antidiabetic medicines may be considered. Cases of congestive heart failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors. If the combination is used, patients should be observed for signs and symptoms of congestive heart failure, weight gain and oedema. Insulin administration may cause insulin antibodies to form. In some cases, the presence of such insulin antibodies may necessitate adjustment of the insulin dose in order to correct a tendency to hyperglycaemia or hypoglycaemia. **Pregnancy and lactation:** Intensified blood glucose control and monitoring of pregnant women with diabetes are recommended throughout pregnancy and when contemplating pregnancy. Insulin requirements usually fall in the first trimester and increase subsequently during the second and third trimesters. After delivery, insulin requirements normally return to pre-pregnancy values. **Posology and method of administration:** NovoMix<sup>®</sup> 30 should not be administered intravenously (see contraindications). The dosage of NovoMix<sup>®</sup> 30 for each patient is individualised. In patients with type 1 diabetes the individual insulin requirement is usually between 0,5 and 1,0 Units/kg/day. NovoMix<sup>®</sup> 30 may fully or partially meet this requirement. In patients with type 2 diabetes, NovoMix<sup>®</sup> 30 can be given as monotherapy if oral antidiabetic medicines cannot be tolerated or are contraindicated or in combination with oral antidiabetic medicines, when the blood glucose is inadequately controlled with oral antidiabetic medicines alone. For patients with type 2 diabetes, the recommended starting dose of NovoMix<sup>®</sup> 30 is 6 U at breakfast and 6 U at dinner (evening meal). In patients with type 2 diabetes, a dose reduction of 20% is recommended for patients with an HbA<sub>1c</sub> less than 8% when a GLP-1 receptor agonist is added to NovoMix<sup>®</sup> 30, to minimise the risk of hypoglycaemia. For patients with an HbA<sub>1c</sub> higher than 8% a dose reduction should be considered. When using NovoMix<sup>®</sup> 30 once daily, it is generally recommended to move to twice-daily subcutaneous injections when reaching 30 units by splitting the dose into equal breakfast and dinner doses. NovoMix<sup>®</sup> 30 is administered subcutaneously in the thigh or in the abdominal wall. If convenient, the gluteal or deltoid region may be used. Injection sites should be rotated within the same region in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. **Undesirable effects:** Hypoglycaemia is the most common occurring adverse reactions reported during treatment. The occurrence of generalised hypersensitivity reactions (including generalised skin rash, itching, sweating, gastrointestinal upset, angio oedema, difficulties in breathing, palpitations and reduction in blood pressure) is very rare but can potentially be life threatening. Refraction anomalies may occur at the beginning of the insulin treatment and are usually of transitory nature. 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. Lipodystrophy (including lipohypertrophy, lipostrophy) and cutaneous amyloidosis may occur at the injection site and delay local insulin absorption. **Reg. No.:** 35/21.1/0031.

For full prescribing information refer to professional information approved by the medicines regulatory authority.

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