

NovoMix® 30 FlexPen®

100 U/ml

Suspension for injection in a pre-filled pen

Insulin aspart (30% soluble insulin aspart and 70% insulin aspart crystallised with protamine)

What is in this leaflet

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1. What NovoMix® 30 is used for

NovoMix® 30 is used to treat patients with diabetes mellitus (diabetes) requiring insulin. Diabetes is a disease where your body does not produce enough insulin to control the level of your blood sugar.

2. How NovoMix® 30 works

NovoMix® 30 is a modern insulin (insulin analogue) with both a rapid-acting and an intermediate-acting effect, in the ratio 30/70. Modern insulin products are improved versions of human insulin. NovoMix® 30 will start to lower your blood sugar 10-20 minutes after you take it, a maximum effect occurs between 1 and 4 hours after the injection and the effect will last for up to 24 hours. In treatment of type 2 diabetes mellitus, NovoMix® 30 may be used in combination with tablets for diabetes and/or with injectable antidiabetic products.

3. Before you use NovoMix® 30

- When you must not use it

- If you are allergic

(hypersensitive) to insulin aspart or any of the other ingredients in NovoMix® 30 (see section 8. *Product description*).

- **If you suspect hypoglycaemia** (low blood sugar) is starting (see section 4. *How to use NovoMix® 30*).
- **In insulin infusion pumps.**
- **If FlexPen® is dropped, damaged or crushed.**
- **If it has not been stored correctly** or if it has been frozen (see section 7. *Storage and disposal of NovoMix® 30*).
- **If the resuspended insulin does not appear uniformly white and cloudy.**
- **If after re-suspension clumps of material are present** or if solid white particles stick to the bottom or the wall of the cartridge.

- Before you start to use it

- **Check the label to make sure** it is the right type of insulin.
- **Always use a new needle** for each injection to prevent contamination.
- **Needles and NovoMix® 30 FlexPen® must not be shared.**

- Taking other medicines

Some medicines affect the way your blood sugar works in your body and this may influence your insulin dose. Tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines than NovoMix® 30, including medicines obtained without a prescription. Listed below are the most common medicines which may affect your insulin treatment.

If you take any of the following medicines, your blood sugar level may fall (hypoglycaemia):

- Other medicines for the treatment

of diabetes.

- Monoamine oxidase inhibitors (MAOI) (used to treat depression).
- Beta-blockers (used to treat high blood pressure).
- Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure).
- Salicylates (used to relieve pain and lower fever).
- Anabolic steroids (such as testosterone).
- Sulfonamides (used to treat infections).

If you take any of the following medicines, your blood sugar level may rise (hyperglycaemia):

- Oral contraceptives (birth control pills).
- Thiazides (used to treat high blood pressure or excessive fluid retention).
- Glucocorticoids (such as 'cortisone' used to treat inflammation).
- Thyroid hormones (used to treat thyroid gland disorders).
- Sympathomimetics (such as epinephrine [adrenaline], or salbutamol, terbutaline used to treat asthma).
- Growth hormone (medicines for stimulation of skeletal and somatic growth and pronounced influence on the body's metabolic processes).
- Danazol (medicines acting on ovulation.)

Octreotide and lanreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess

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growth hormone) may either increase or decrease your blood sugar level.

Beta-blockers (used to treat high blood pressure) may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycaemia.

Thiazolidinediones (class of oral antidiabetic medicines used for the treatment of type 2 diabetes)

Some patients with long-standing type 2 diabetes and heart disease or previous stroke who are treated with thiazolidinediones in combination with insulin may develop heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

4. How to use NovoMix® 30

- How much to use

Talk about your insulin dose with your doctor and nurse. Always use NovoMix® 30 FlexPen® as prescribed by your doctor and follow the doctor's advice carefully. If your doctor has switched you from one type or brand of insulin to another, your dose may have to be adjusted by your doctor. Do not change your insulin unless your doctor tells you to.

Use in children

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

are available for NovoMix® 30 in children below 6 years of age.

Use in special patient groups

If you have reduced kidney or liver function, or if you are above 65 years of age, you need to check your blood sugar more regularly and discuss changes in your insulin dose with your doctor.

How to handle NovoMix® 30 FlexPen®

Read the included 'Instructions on how to use NovoMix® 30 suspension for injection in FlexPen®' carefully. You must use the pen as described in the Instructions for use.

- When to use it

NovoMix® 30 is generally given immediately before a meal. When necessary, NovoMix® 30 can be given soon after a meal.

When NovoMix® 30 is used in combination with tablets for diabetes and/or with injectable antidiabetic products your dose may have to be adjusted by your doctor.

NovoMix® 30 is for injection under the skin (subcutaneously). Never inject your insulin directly into a vein (intravenously) or muscle (intramuscularly). With each injection, change the injection site within the particular area of skin that you use. This reduces the risk of developing lumps or skin pitting (see section 6. Side effects). The best places to give yourself an injection are: the front of your waist (abdomen); your buttocks; the front of your thighs or upper arms. The insulin will work

more quickly if you inject around the waist. You should measure your blood sugar regularly.

- How long to use it

If you stop taking your insulin

This could lead to severe hyperglycaemia and ketoacidosis. Do not stop taking your insulin without speaking to a doctor, who will tell you what needs to be done.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you forget to use it

If you forget to take your insulin, your blood sugar may get too high (this is called hyperglycaemia). This may also happen:

- ▶ If you have not injected enough insulin.
- ▶ If you repeatedly take less insulin than you need or stop taking insulin.
- ▶ If you get an infection or fever.
- ▶ If you eat more than usual.
- ▶ If you exercise less than usual.

The warning signs appear gradually. They include: increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed, dry skin; dry mouth and a fruity (acetone) smell of the breath. These may be signs of a very serious condition called diabetic ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). If you do not treat it, this could lead to diabetic coma and eventually death.

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If you get any of the signs mentioned above, test your blood sugar level, test your urine for ketones if you can, then seek medical advice immediately.

- If you use too much (overdose)

If you take too much insulin, your blood sugar may get too low (this is called hypoglycaemia or hypo). This may also happen:

- ▶ If you eat too little or miss a meal.
- ▶ If you exercise more than usual.
- ▶ If you drink alcohol.

The warning signs of a hypo may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

If you feel a hypo coming on, take a high sugar snack and then measure your blood sugar. If your blood sugar is too low, eat glucose tablets or another high sugar snack (sweets, biscuits, fruit juice), then rest. Always carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

When the symptoms of hypoglycaemia have disappeared or when your blood sugar level is stabilised, continue insulin treatment as usual.

You may recover more quickly from unconsciousness with an injection of the hormone glucagon by someone who knows how to use it. If you are given glucagon, you will need glucose

or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital.

- ▶ If prolonged severe hypoglycaemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- ▶ If you have such low blood sugar that you pass out, if you have had need for an injection of glucagon, or if you have experienced many incidents of hypoglycaemia, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

5. While you are using it

- Things you must do

Eat a meal or snack containing carbohydrates within 10 minutes of the injection to avoid hypoglycaemia.

Tell relevant people you have diabetes and what the consequences may be, including the risk of passing out (become unconscious) due to a hypo. Tell relevant people that if you pass out (become unconscious), they must turn you on your side and get medical advice straight away. They must not give you any food or drink. It could choke you.

- Things you must not do

Do not take any insulin if you feel a hypo coming on.

- Things to be careful of

▶ **If you have trouble** with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.

▶ **If you exercise** more than usual or if you want to change your usual diet, as this may affect your blood sugar level.

▶ **If you are ill**, carry on taking your insulin and consult your doctor.

▶ **If you are going abroad:** travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travelling.

Drinking alcohol and taking NovoMix® 30

If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. **If you are pregnant or planning a pregnancy**, please contact your doctor for advice. There is limited clinical experience with insulin aspart in pregnancy. Your insulin dose may need to be changed during pregnancy and after delivery. Careful control of your diabetes, particularly prevention of hypoglycaemia, is important for the health of your baby.

There are no restrictions on treatment with NovoMix® 30 during breast-feeding.

Driving and using machines

If your blood sugar is low or high, your concentration and ability to react might be affected, and therefore also your ability to drive or operate a machine. Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car or operate a machine:

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- ▶ If you have frequent hypoglycaemia.
- ▶ If you find it hard to recognise hypoglycaemia.

Skin changes at the injection site

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area (see section 4. *How to use NovoMix® 30*). Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

6. Side effects

Like all medicines, NovoMix® 30 can cause side effects, although not everybody gets them.

Side effects may occur with certain frequencies, which are defined as follows:

- ▶ Very common: affects more than 1 user in 10
- ▶ Common: affects 1 to 10 users in 100
- ▶ Uncommon: affects 1 to 10 users in 1,000
- ▶ Rare: affects 1 to 10 users in 10,000
- ▶ Very rare: affects less than 1 user in 10,000
- ▶ Not known: frequency cannot be estimated from the available data

Very common side effects

Low blood sugar (hypoglycaemia). See the advice in 'If you use too much (overdose)' under section 4. *How to*

use NovoMix® 30.

Uncommon side effects

Signs of allergy. Reactions (pain, redness, hives, inflammation, swelling and itching) at the injection site may occur (local allergic reactions). These usually disappear after a few weeks of taking your insulin. If they do not disappear, see your doctor.

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 heartbeat; feel dizzy.

Vision problems. When you first start your insulin treatment, it may disturb your vision, but the disturbance is usually temporary.

Skin changes at the injection site. If you inject insulin at the same place, the fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy) (affects 1 to 10 users in 1,000). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

Swollen joints. When you start taking insulin, water retention may cause swelling around your ankles and other joints. Normally this soon disappears.

Diabetic retinopathy (an 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. Ask your doctor about this.

Rare side effects

Painful neuropathy (pain due to nerve damage). If your blood sugar levels improve very fast, you may get nerve related pain, this is called acute painful neuropathy and is usually transient.

Very rare side effects

Serious allergic reaction to NovoMix® 30 or one of its ingredients (called a systemic allergic reaction). See also warning in section 3. *Before you use NovoMix® 30.*

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and disposal of NovoMix® 30

- Storage

Keep out of the reach and sight of children.

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

NovoMix® 30 FlexPen® that is not being used is to be stored in the refrigerator at 2°C - 8°C, away from the cooling element. Do not freeze.

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NovoMix® 30 FlexPen® that is being used or carried as a spare is not to be kept in the refrigerator. After removing NovoMix® 30 FlexPen® from the refrigerator, you must resuspend the insulin as instructed every time you use a new FlexPen®. You can carry it with you and keep it at room temperature (below 30°C) for up to 4 weeks.

Always keep the pen cap on your FlexPen® when you are not using it in order to protect it from light. NovoMix® 30 must be protected from excessive heat and light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- What it looks like

NovoMix® 30 comes as a white suspension in a pre-filled pen. The cartridge contains a glass ball to facilitate resuspension. After resuspension the liquid should appear uniformly white and cloudy. Do not use the insulin if it does not look uniformly white and cloudy after resuspension.

Pack sizes of 5 and 10 pre-filled pens of 3 ml. Not all packs may be marketed.

- Ingredients

- Active ingredient

Insulin aspart. NovoMix® 30 is a mixture consisting of 30% soluble insulin aspart and 70% insulin aspart crystallised with protamine. 1 ml contains 100 U of insulin aspart. Each pre-filled pen contains 300 U insulin aspart in 3 ml suspension for injection.

- Inactive ingredients

Glycerol, phenol, metacresol, zinc chloride, disodium phosphate dihydrate, sodium chloride, protamine sulfate, hydrochloric acid, sodium hydroxide and water for injections.

- MAL number

MAL20040739AZ
MAL17035048ASZ
MALXXXXXXXXXASZ

9. Manufacturers

Novo Nordisk A/S Novo Allé
DK-2880 Bagsværd Denmark

Novo Nordisk Produção
Farmacêutica do Brasil Ltda
Avenida C, 1413, Distrito Industrial
Montes Claros - Minas Gerais
Brazil 39404-004

Novo Nordisk Production SAS
45 Avenue d'Orléans, F-28000
Chartres, France

10. Product Registration Holder

Novo Nordisk Pharma (Malaysia)
Sdn. Bhd.
Menara 1 Sentrum, Level 16
No. 201 Jalan Tun Sambanthan
50470 Kuala Lumpur
Malaysia

11. Date of revision

31/03/2021

Serial Number

NPRA (R3) 20/008

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Instructions on how to use NovoMix® 30 suspension for injection in FlexPen®.

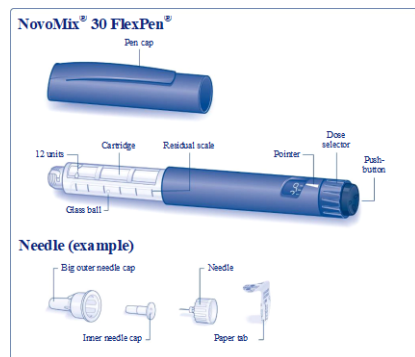
Read the following instructions carefully before using your FlexPen®. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.

Your FlexPen® is a pre-filled dial-a-dose insulin pen.

► You can select doses from 1 to 60 units in increments of 1 unit.

► FlexPen® is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm.

► Always carry a spare insulin delivery device in case your FlexPen® is lost or damaged.



Caring for your pen

► Your FlexPen® must be handled with care. If it is dropped, damaged or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

► You can clean the exterior of your FlexPen® by wiping it with a medicinal swab. Do not soak, wash or lubricate it as it may damage the pen.

Do not refill your FlexPen®.

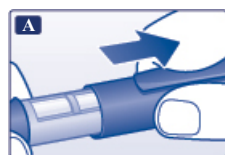
Resuspending your insulin

A
Check the name and coloured label of your pen to make sure that it contains the correct type of insulin. This is especially important if you take more than one type of insulin. If you take the wrong type of insulin, your blood sugar level may get too high or too low.

Every time you use a new pen

Let the insulin reach room temperature before you use it. This makes it easier to resuspend.

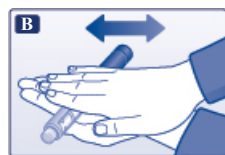
Pull off the pen cap.



B

Before your first injection with a new FlexPen®, you must resuspend the insulin:

Roll the pen between your palms 10 times – it is important that the pen is kept **horizontal** (level with the ground).



C

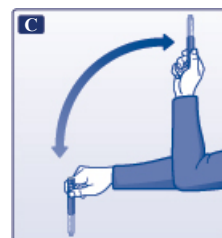
Then move the pen up and down 10 times between the two positions as shown, so the **glass ball moves** from one end of the cartridge to the other.

Repeat rolling and moving the pen until the liquid appears uniformly white and cloudy.

For every following injection

Move the pen up and down between the two positions at least 10 times until the liquid appears uniformly white and cloudy.

► Always make sure that you have resuspended the insulin prior to each injection. This reduces the risk of too high or too low blood sugar level. After you have resuspended the insulin, complete all the following steps of injection without delay.



⚠ Always check there are at least **12 units of insulin** left in the cartridge to allow resuspension. If there are less than 12 units left, use a new FlexPen®. 12 units are marked on the residual scale. See the big picture on top of this instruction.

⚠ Do not use the pen if the **resuspended** insulin does not look **uniformly white and cloudy**.

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Attaching a needle

D

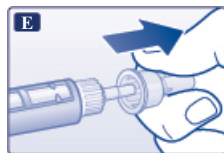
Take a new needle and tear off the paper tab.

Screw the needle straight and tightly onto your FlexPen®.



E

Pull off the big outer needle cap and keep it for later.



F

Pull off the inner needle cap and dispose of it.

Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.



⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

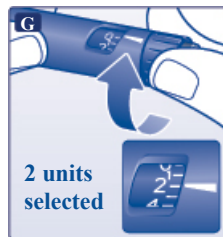
⚠ Be careful not to bend or damage the needle before use.

Checking the insulin flow

Prior to each injection, small amounts of air may collect in the cartridge during normal use. To avoid injection of air and ensure proper dosing:

G

Turn the dose selector to select 2 units.



H

Hold your FlexPen® with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.



I

Keeping the needle upwards, press the push-button all the way in. The dose selector returns to 0.

A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than 6 times.

If a drop of insulin still does not appear, the pen is defective, and you must use a new one.



⚠ Always make sure that a drop appears at the needle tip before you inject. This makes sure that the insulin flows. If no drop appears, you will not inject any insulin, even though the dose selector may move. This may indicate a blocked or damaged needle.

⚠ Always check the flow before you inject. If you do not check the flow, you may get too little insulin or no insulin at all. This may lead to too high blood sugar level.

Selecting your dose

Check that the dose selector is set at 0.

J

Turn the dose selector to select the number of units you need to inject.

The **dose can be corrected** either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. When turning the dose selector, be careful not to push the push-button as insulin will come out.

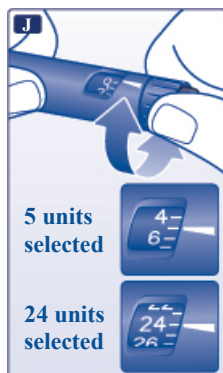
You cannot select a dose larger than the number of units left in the cartridge.

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⚠ Always use the dose selector and the pointer to see how many units you have selected before injecting the insulin.

⚠ Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

Making the injection

Insert the needle into your skin. Use the injection technique shown by your doctor or nurse.

K

Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.

Turning the dose selector will not inject insulin.



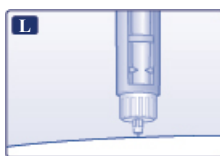
L

► Keep the **push-button fully depressed** and let the needle remain under the skin for **at least 6 seconds**.

This will make sure you get the full dose.

► Withdraw the needle from the skin, then release the pressure on the push-button.

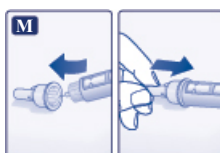
► Always make sure that the dose selector returns to 0 after the injection. If the dose selector stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.



M

Lead the needle into the big outer needle cap without touching it. When the needle is covered, carefully push the big outer needle cap completely on and then unscrew the needle.

Dispose of it carefully and put the pen cap back on.



⚠ Always remove the needle after each injection and store your FlexPen® without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Further important information

⚠ Caregivers must be very careful when handling used needles to reduce the risk of needle sticks and cross-infection.

⚠ Dispose of your used FlexPen® carefully without the needle attached.

⚠ Never share your pen or your needles with other people. It might lead to cross-infection.

⚠ Never share your pen with other people. Your medicine might be harmful to their health.

⚠ Always keep your pen and needles out of sight and reach of others, especially children.