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**PACKAGE LEAFLET**

# NovoMix® 30 FlexPen®

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### This side of the leaflet:

1. What NovoMix® 30 is and what it is used for
2. Before you use NovoMix® 30
3. How to use NovoMix® 30
4. What to do in an emergency
5. Possible side effects
6. Storing NovoMix® 30

**Overleaf:** How to use your FlexPen

**NovoMix® 30 FlexPen® 100 U/ml**  
**Suspension for injection in a pre-filled pen**  
 Insulin aspart, rDNA.  
**The active substance** is insulin aspart made by recombinant DNA technology in *Saccharomyces cerevisiae* (30% insulin aspart in a soluble fraction and 70% insulin aspart crystallised with protamine).  
 1 ml contains 100 U (3.5 mg) of insulin aspart. 1 pre-filled pen contains 3 ml equivalent to 300 U.  
**The other ingredients** are glycerol, phenol, metacresol, zinc (as chloride), sodium chloride, disodium phosphate dihydrate, protamine sulphate, sodium hydroxide, hydrochloric acid and water for injections.  
 The suspension for injection comes as a white suspension in packs of 5 or 10 pre-filled pens of 3 ml (not all packs may be marketed).  
**The marketing authorisation holder is**  
 Novo Nordisk A/S,  
 Novo Allé, DK-2880 Bagsværd, Denmark  
**and manufacturer is**  
 Novo Nordisk Production SAS,  
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## 1. What NovoMix® 30 is and what it is used for

**NovoMix 30 is an insulin analogue to treat diabetes.** It comes in a 3 ml pre-filled pen, called FlexPen - see overleaf for detailed instructions. NovoMix 30 is a mixture of rapid-acting insulin analogue (30%) and long-acting insulin analogue (70%). This means that it will start to lower your blood sugar 10-20 minutes after you take it, have a maximum effect between 1 and 4 hours and the effect will last for up to 24 hours.

## 2. Before you use NovoMix® 30

### Do not use NovoMix 30

- ▶ **If you feel a hypo** coming on (a hypo is short for a hypoglycaemic reaction and is symptoms of low blood sugar). See 4 *What to do in an emergency* for more about hypos
- ▶ **If you are allergic (hypersensitive)** to this insulin product or any of the other ingredients (see box, below left). Look out for the signs of allergy in 5 *Possible side effects*.

### Take special care with NovoMix 30

- ▶ **If you have trouble** with your kidneys or liver, your doctor may decide to alter your insulin dose
- ▶ **If you are drinking alcohol (also beer, wine):** watch for signs of a hypo and never drink alcohol on an empty stomach
- ▶ **If you are exercising** more than usual or if you want to change your usual diet
- ▶ **If you are ill:** carry on taking your insulin. Your need for insulin may change
- ▶ **If you have an infection, fever or an operation** you may need more insulin than usual
- ▶ **If you suffer from diarrhoea, vomiting or eat less than usual** you may need less insulin than usual
- ▶ **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
- ▶ **If you are planning a pregnancy or if you are pregnant or breast-feeding:** please contact your doctor for advice. There is limited clinical experience with insulin aspart in pregnancy
- ▶ **If you drive or use tools or machines:** watch out for signs of a hypo. Your ability to concentrate or to react may be reduced during a hypo. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). Never drive or use machinery if you feel a hypo coming on. Discuss with your doctor whether you should drive or use machines at all, if you have a lot of hypos or if you find it hard to recognise hypos.

Front

## Using other medicines

Many medicines affect the way your glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines which may affect your insulin treatment. Please consult your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

**Your need for insulin may change** if you also take: oral antidiabetic medicinal products, monoamine oxidase (MAO) inhibitors, beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and glucocorticoids (except topical administration), oral contraceptives, thiazides, thyroid hormones, sympathomimetics, danazol, octreotide and sulphonamides.

## 3. How to use NovoMix® 30

Talk about your insulin needs with your doctor and diabetes nurse. Follow their advice carefully. This leaflet is a general guide.

When NovoMix 30 is used in combination with metformin the dosage should be adjusted. 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. Eat a meal or snack containing carbohydrates within 10 minutes of the injection. NovoMix 30 may also be given soon after the meal. It is recommended that you measure your blood glucose regularly. NovoMix 30 is for use by one person only.

### Injecting the insulin

See overleaf for detailed instructions.

### Before using NovoMix 30

- ▶ **Check the label** to make sure it is the right type of insulin.

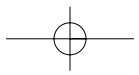
### NovoMix 30 should not be used

- ▶ **In insulin infusion pumps**
- ▶ **If FlexPen is dropped, damaged or crushed,** there is a risk of leakage of insulin
- ▶ **If it hasn't been stored correctly** or if it has been frozen (see 6 *Storing NovoMix 30*)
- ▶ **If the insulin is not uniformly white and cloudy** when it's mixed
- ▶ **If clumps of material are present** or if solid white particles stick to the bottom or the wall of the cartridge giving a frosted appearance.

### How to use this insulin

**NovoMix 30 is for injection under the skin** (subcutaneously). Never inject your insulin directly into a vein or muscle.

**Always vary the sites you inject,** to avoid lumps (see 5 *Possible 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. Your insulin will work more quickly if you inject around the waist.



## 4. What to do in an emergency

### If you get a hypo (hypoglycaemia)

A hypo means your blood sugar level is too low. **The warning signs of a hypo** may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heart beat; 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 get any of these signs,** eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest.

**Don't take any insulin** if you feel a hypo coming on.

Carry glucose tablets, sweets, biscuits or fruit juice with you, just in case it is needed.

**Tell your relatives, friends and close colleagues that if you pass out** (become unconscious), they must: turn you on your side and get medical help straight away. They must not give you any food or drink, as it could choke you.

- ▶ **If severe hypoglycaemia** is not treated, it can cause brain damage (temporary or permanent) and even death
- ▶ **If you have a hypo** that makes you pass out, or a lot of hypos, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

### Using glucagon

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. Contact your doctor or an emergency ward after an injection of glucagon: you need to find the reason for your hypo to avoid getting more.

### Causes of a hypo

You get a hypo if your blood sugar gets too low. This might happen:

- If you take too much insulin
- If you eat too little or miss a meal
- If you exercise more than usual.

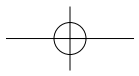
### If your blood sugar gets too high

Your blood sugar may get too high (this is called hyperglycaemia).

**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.

**If you get any of these signs,** test your blood sugar level; test your urine for ketones if you can; then seek medical advice straight away.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.



## Causes of hyperglycaemia

- Having forgotten to take your insulin
- Repeatedly taking less insulin than you need
- An infection or a fever
- Eating more than usual
- Less exercise than usual.

## 5. Possible side effects

Like all medicines, NovoMix 30 can have side effects.

The most common side effect is low blood sugar (hypoglycaemia). See the advice in 4 *What to do in an emergency*.

### Side effects reported uncommonly

(less than 1 in 100)

**Vision problems.** When you first start your insulin treatment, it may disturb your vision, but the condition usually disappears.

**Changes of the injection site.** If you inject yourself too often in the same site, lumps may develop underneath. Prevent this by choosing different injection sites each time within the same region.

**Signs of allergy.** Reactions (redness, swelling, 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 heart beat; feel dizzy.

**You may have a very rare serious allergic reaction** to NovoMix 30 or one of its ingredients (called a systemic allergic reaction). See also the warning in 2 *Before you use NovoMix 30*.

**Diabetic retinopathy.** If you have diabetic retinopathy and your blood glucose levels improve very fast, the retinopathy may get worse. Ask your doctor about this.

### Side effects reported rarely

(less than 1 in 1,000)

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

**Painful neuropathy.** If your blood glucose levels improve very fast, you may get nerve related pain - this is called acute painful neuropathy and is usually transient.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## 6. Storing NovoMix® 30

Keep out of the reach and sight of children.

**NovoMix 30 FlexPen that is not being used** is to be stored in the refrigerator (2°C - 8°C), away from the freezer compartment. Do not freeze.

**NovoMix 30 FlexPen that is being used** or about to be used is not to be kept in the refrigerator. After removing NovoMix 30 FlexPen from the refrigerator it is recommended to mix the insulin as instructed for the first time use.

See 3 *How to use NovoMix 30*. You can carry it with you and keep it at room temperature (not above 30°C) for up to 4 weeks, but any remainder must then be discarded.

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

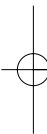
Do not use NovoMix 30 after the expiry date stated on the label and carton.

**Now turn over for information on how to use your FlexPen.**

**This leaflet was last approved on 04/2007**

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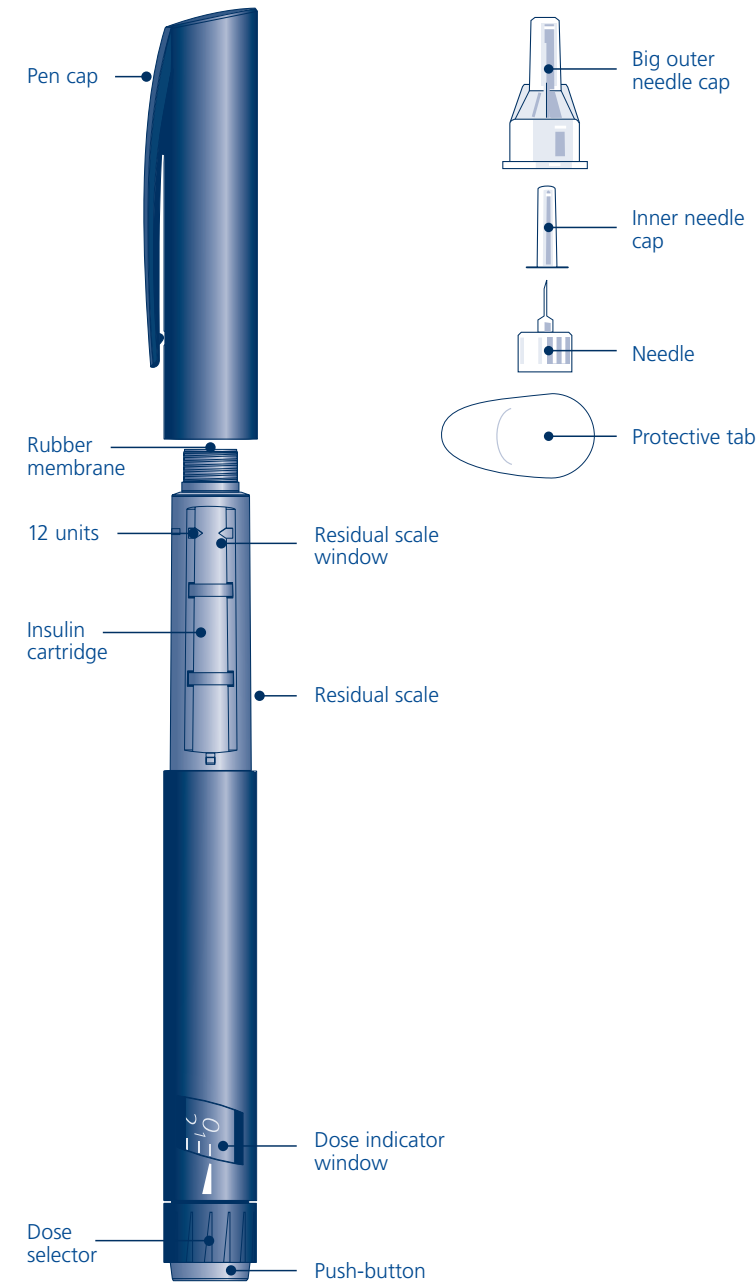
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**Please read the following instructions carefully before using your NovoMix® 30 FlexPen®.**

**Introduction**

NovoMix® 30 FlexPen® is a unique dial-a-dose insulin pen. You can dial doses from 1 to 60 units in increments of 1 unit. NovoMix 30 FlexPen is designed to be used with NovoFine® needles of 8 mm or shorter in length. Look for an **S** on the needle box. The **S** stands for short cap. As a precautionary measure, always carry a spare insulin delivery device in case your FlexPen is lost or damaged.

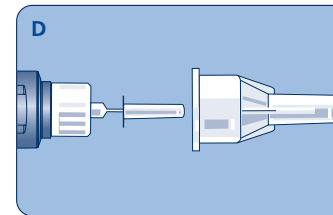
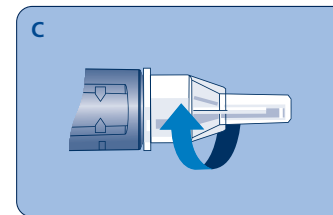
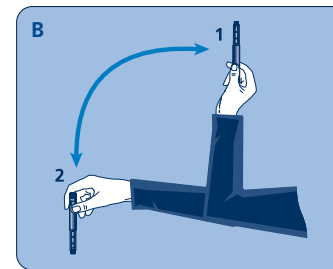
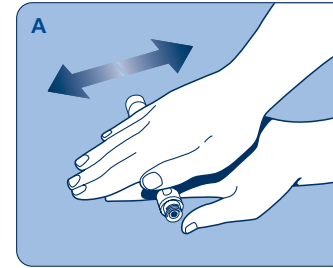


**Getting started**

Check the label to be sure that your NovoMix 30 FlexPen contains the correct type of insulin. Take off the cap.

Before every injection:

- **Check there are at least 12 units** of insulin left in the cartridge to allow even mixing. If there are less than 12 units left, use a new NovoMix 30 FlexPen
- **The first time you use NovoMix 30 FlexPen** roll the pen between your palms 10 times - it is important that the pen is kept horizontal (see picture **A**). Move the pen up and down between positions 1 and 2 (see picture **B**) 10 times so that the glass ball moves from one end of the cartridge to the other. Repeat the rolling and moving procedure until the liquid appears uniformly white and cloudy. Mixing is easier when the insulin has reached room temperature
- **For every following injection** move the pen up and down between positions 1 and 2 (see picture **B**) at least 10 times until the liquid appears uniformly white and cloudy
- **After mixing complete all the following stages of injection without delay**
- **Disinfect the rubber membrane** with a medicinal swab
- **Remove the protective tab** from a NovoFine **S** short cap needle
- **Screw the needle straight and tightly** onto NovoMix 30 FlexPen (picture **C**)
- **Pull off the big outer needle cap and the inner needle cap** (picture **D**). Do not discard the big outer needle cap.

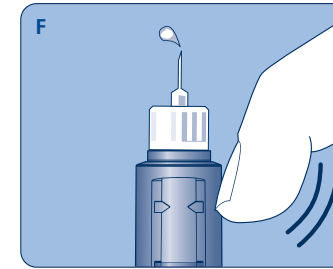
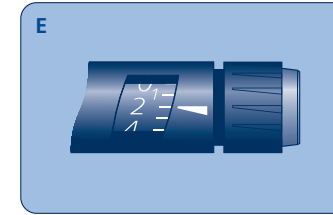


**Priming to expel air**

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

- **Dial 2 units** (picture **E**)
- **Hold NovoMix 30 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 (picture **F**)
- **Keeping the needle upwards, press the push-button all the way in.** The dose selector returns to zero
- **A drop of insulin must appear at the needle tip.** If not, change the needle and repeat the procedure no more than 6 times.

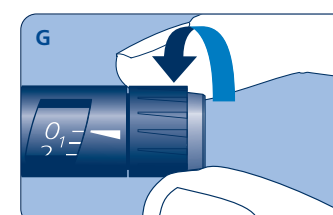
**If a drop of insulin still does not appear, the device is defective, and must not be used.**



**Setting the dose**

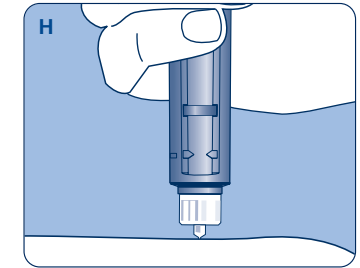
- **Check that the dose selector is set at zero**
- **Dial the number of units you need to inject** (picture **G**).

The dose can be corrected either up or down by turning the dose selector in either direction. When dialling back, be careful not to push the push-button as insulin will come out. Do not use the residual scale to measure your dose of insulin. You cannot set a dose larger than the number of units left in the cartridge.



**Injecting the insulin**

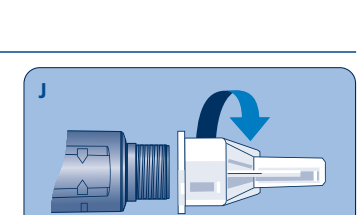
- **Insert the needle into your skin** (picture **H**). Use the injection technique advised by your doctor
- **Deliver the dose by pressing the push-button all the way in** (picture **I**). Be careful only to push the push-button when injecting
- **Keep the push-button fully depressed after the injection until the needle has been withdrawn from the skin.** The needle must remain under the skin for at least 6 seconds. This will ensure that the full dose has been delivered.



**Removing the needle**

- **Replace the big outer needle cap and unscrew the needle** (picture **J**)
- **Dispose of it carefully.**

Use a new needle for each injection. Remove the needle after each injection. Otherwise, the liquid may leak out when the temperature changes and the strength of the insulin may change. Health care professionals, relatives and other carers must follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle penetration. Dispose of your used NovoMix 30 FlexPen carefully without the needle attached.



**Maintenance**

Your NovoMix 30 FlexPen is designed to work accurately and safely. It must be handled with care. If it is dropped or crushed, there is a risk of damage and leakage of insulin.

You can clean the exterior of your NovoMix 30 FlexPen by wiping it with a medicinal swab. Do not soak, wash or lubricate it as this may damage the mechanism. Do not refill NovoMix 30 FlexPen.

Commodity no.:

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