

Important: Please Read

PART III: CONSUMER INFORMATION

If you have difficulties with reading this document, ask a family member or a friend for help with reading it.

This document is available in large print format by contacting Novo Nordisk Canada Inc., at 1-800-465-4334

**NovoMix[®] 30 Penfill[®] and
NovoMix[®] 30 FlexPen[®]**
30% soluble insulin aspart and
70% insulin aspart protamine crystals

Suspension for injection 3 mL

This leaflet is Part III of a three-part 'Product Monograph' published when NovoMix[®] 30 was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NovoMix[®] 30. Contact your doctor or pharmacist if you have any questions about the drug.

Read all of this leaflet carefully before you start using your insulin. Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor, Diabetes Nurse Educator or pharmacist.

This medicine is 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.

ABOUT THIS MEDICATION

A direction leaflet containing information for the patient is included in each package.

What is NovoMix[®] 30

NovoMix[®] 30 (30% soluble insulin aspart and 70% insulin aspart protamine crystals) is an insulin analogue used to treat diabetes. 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 to 20 minutes after you take it, has a maximum effect of between 1 and 4 hours and the effect lasts for up to 24 hours.

NovoMix[®] 30 is indicated for:

- the treatment of adult patients with diabetes mellitus who require insulin for the control of hyperglycemia.

When NovoMix[®] 30 should not be used

Do not use NovoMix[®] 30:

- ▶ **If you feel a hypo** coming on (a hypo is short for a hypoglycemic reaction or low blood sugar). See '*What to do in an emergency*', for more about hypos.
- ▶ **If you are allergic (hypersensitive)** to soluble insulin aspart with insulin aspart protamine crystals, metacresol or any of the other ingredients in this insulin. Look out for the signs of an allergic reaction (see '*Possible side effects*').

What the medicinal ingredient is

The active ingredient in NovoMix[®] 30 is a mixture of insulin aspart made by recombinant DNA technology in *Saccharomyces cerevisiae* (30% insulin aspart in a soluble fraction and 70% insulin aspart crystallized with protamine).

What the important nonmedicinal ingredients are:

glycerol, phenol, metacresol, zinc (as chloride), sodium chloride, disodium phosphate dihydrate, protamine sulphate, sodium hydroxide, hydrochloric acid, water for injections

What dosage forms NovoMix[®] 30 comes in

NovoMix[®] 30 is available from Novo Nordisk Canada in the following format:

- NovoMix[®] 30 Penfill[®] 3 mL cartridge (designed for use with Novo Nordisk Insulin Delivery Devices)
- NovoMix[®] 30 FlexPen[®] 3 mL prefilled pen

NovoMix[®] 30 Penfill[®] cartridges are designed for use with Novo Nordisk Insulin Delivery Devices. NovoMix[®] 30 Penfill[®] and NovoMix[®] 30 FlexPen[®] are designed for use with NovoFine[®]. Novo Nordisk cannot be held responsible for malfunctions occurring as a consequence of using NovoMix[®] 30 Penfill[®] cartridges in combination with products that do not meet the same specifications or quality standards.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- NovoMix[®] 30 should be given immediately before a meal because of the fast onset of action (start of the meal should be not more than 5-10 minutes after injection) (see "*Proper Use of This Medication*").

Before you use NovoMix[®] 30

Before you use NovoMix[®] 30 talk to your doctor or pharmacist:

- ▶ **If you have trouble** with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- ▶ **If you drink alcohol:** watch for signs of a hypo.
- ▶ **If you exercise more than usual** or if you want to change your usual diet.
- ▶ **If you are ill:** continue taking your insulin.
- ▶ **If you have an infection, fever or an operation** you may need more insulin than usual.
- ▶ **If you go abroad:** travelling over time zones may affect your insulin needs and timing of your injections. Consult your doctor if you are planning such travel..
- ▶ **If you are pregnant, or planning a pregnancy or are breastfeeding** please contact your doctor for advice.
- ▶ **If you drive or use tools or machines:** watch for signs of a hypo. Your ability to concentrate or to react will be less during a hypo. Please keep this 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 recognize hypos.

Before you travel, check with your physician or pharmacist on the availability of NovoMix[®] 30 in other countries. If possible, bring enough NovoMix[®] 30 with you on your trip.

INTERACTIONS WITH THIS MEDICATION

NovoMix[®] 30 should not be mixed with any other insulin product.

When you use other medicines

Many medicines affect the way 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. Talk to your doctor or pharmacist if you take, or change any other medicines, even those not prescribed.

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

PROPER USE OF THIS MEDICATION

How to use NovoMix[®] 30

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Follow their advice carefully. This leaflet is a general guide only.

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.

NovoMix[®] 30 should be given immediately before a meal. When necessary, NovoMix[®] 30 may

also be given soon after the meal. It is recommended that you measure your blood glucose regularly.

A NovoMix[®] 30 FlexPen[®] or Penfill[®] cartridge must not be used by more than one person.

Before using NovoMix[®] 30 Penfill[®]:

- ▶ **Check the label** to make sure you have the right type of insulin.
- ▶ **Always use a new needle** for each injection to prevent contamination.
- ▶ **Always check the Penfill[®] cartridge**, including the rubber stopper (plunger). Don't use it if any damage is seen or if there is a gap between the rubber stopper and the white barcode label. Take it back to your supplier or call Novo Nordisk Canada at 1 800 465-4334 for assistance. See your Novo Nordisk Insulin Delivery Device manual for further instructions.
- ▶ Before use, check that the Penfill[®] cartridge is intact (no cracks). Do not use the Penfill[®] cartridge if any damage is seen or if more of the rubber piston is visible than equal to the width of the white bar code band.
- ▶ The first time you use the NovoMix[®] 30 Penfill[®] allow it to reach room temperature and then roll it horizontally between your palms 10 times and then turn upside down 10 times. (See Package Insert for detailed diagrams and instructions.)
- ▶ Repeat the rolling and moving procedure until the liquid appears uniformly white and cloudy.
- ▶ For all subsequent injections move the insulin delivery device, with the cartridge inside it up and down at least 10 times until the liquid appears uniformly white and cloudy. (See Package Insert for detailed diagrams and instructions.)

How to use NovoMix[®] 30 FlexPen[®]

- Allow the **NovoMix[®] 30 FlexPen[®]** to reach room temperature and then roll it horizontally between your palms 10 times and then turn upside down 10 times. (See Package Insert for detailed diagrams and instructions.)
- Remove air from the prefilled insulin pen before each injection until a drop of insulin appears at the tip of the needle.
- Do not use **NovoMix[®] 30 FlexPen[®]** if you need to make **more** than 6 air shots before the first injection.
- Take care not to drop or knock your prefilled insulin pen.

- Do not use the residual scale to measure your dose of insulin.
- Do not refill **NovoMix[®] 30 FlexPen[®]**.

Do not use NovoMix[®] 30:

- ▶ **In insulin infusion pumps.**
- ▶ **If the Penfill[®] cartridge, Novo Nordisk Insulin Delivery Device or FlexPen[®] containing the insulin is dropped, damaged or crushed;** there is a risk of leakage of insulin.
- ▶ **If the insulin has not been stored correctly** or if it has been frozen (see 'How to Store NovoMix[®] 30').
- ▶ **If the insulin is not uniformly white and cloudy** when it is 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.

Do not refill a NovoMix[®] 30 Penfill[®] cartridge.

NovoMix[®] 30 Penfill[®] cartridges are designed to be used with Novo Nordisk Insulin Delivery Devices and NovoFine[®] needles as part of The All In-One System[®].

If you are treated with NovoMix[®] 30 Penfill[®] and another insulin in Penfill[®] cartridge, you should use two Novo Nordisk Insulin Delivery Devices, one for each type of insulin.

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 site you inject within the same region, to avoid lumps (see 'Possible side effects'). The best places to give yourself an injection are: the front of your thighs; the front of your waist (abdomen); or the upper arm. Your insulin will work more quickly if you inject around the waist.

You should always measure your blood glucose regularly.

How to inject this insulin

- ▶ **Inject the insulin under the skin.** Use the injection technique advised by your doctor or Diabetes Nurse Educator and described in your Novo Nordisk Insulin Delivery Device manual.

- ▶ **Keep the needle under your skin** for at least 6 seconds to make sure that the full dose has been delivered.
- ▶ **After each injection** be sure to remove the needle. Otherwise, insulin may leak out when the temperature changes.

Overdose

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 hyperglycemia).

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; a dry mouth and a fruity (acetone) smelling 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 right 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 hyperglycemia:

- Forgetting to take your insulin.
- Repeatedly taking less insulin than you need.
- An infection or fever.
- Eating more than usual.
- Exercising less than usual.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

What to do in an emergency

If you get a hypo:

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; and difficulty 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.

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 right away. They must not give you anything to eat or drink as it could choke you.

- ▶ **If severe hypoglycemia 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 if you get a lot of hypos, talk to your doctor. The amount or timing of your insulin dose, the amount of food you eat or the amount of exercise you do, may need to be adjusted.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon given by someone who knows how to use it. If you are given glucagon you will need to eat 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 hospital emergency after an injection of glucagon: you need to find the reason for your hypo in order to avoid getting more.

Possible side effects

Like all medicines, NovoMix[®] 30 can have side effects although not everybody gets them. The most common side effect is low blood sugar (hypoglycemia). See the advice in '*What to do in an emergency*'.

Less commonly reported side effects (less than 1 in 100)

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

Changes at the injection site (Lipodystrophy)

If you inject yourself too often in the same site, fatty tissue under the skin at this injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Changing the site with each injection may help to prevent such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or Diabetes Nurse Educator because these reactions can become more severe, or they may change the absorption of your insulin at this site.

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-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). Also read the information 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.

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

Rarely reported side effects
(less than 1 in a 1,000)

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 any of the side effects get serious, or if you notice any side effects, including those not

mentioned in this leaflet, please inform your doctor, Diabetes Nurse Educator or pharmacist.

HOW TO STORE IT

How to store NovoMix[®] 30

Keep out of the reach and sight of children.

NovoMix[®] 30 that is not being used is to be stored in the fridge between 2°C - 10°C, not in or near the freezer section or cooling element. Do not freeze.

NovoMix[®] 30 that is being used or is about to be is not to be kept in the refrigerator. You can carry it with you and keep it at room temperature (not above 30°C) for up to 4 weeks.

Always keep your Penfill[®] cartridge and FlexPen[®] in the outer carton when you are not using it, in order to protect it from light.

NovoMix[®] 30 should be protected from excessive heat and sunlight.

Do not use NovoMix[®] 30 after the expiry date printed on the label and carton. The expiry date refers to the last day of that month.

NovoMix[®] 30 should not be disposed of in waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse drug reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of the side effect, please contact your health care professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

How to store NovoMix® 30 looks like and package content:

NovoMix® 30 comes as a white suspension in packages of 5 x 3 ml Penfill® cartridge per carton.

1 ml contains 100 U (units) of insulin aspart
1 prefilled pen contains 3 ml equivalent to 300 U

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Novo Nordisk A/S

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Reference: 1 Canadian Diabetes Association
2003 Clinical Practice Guidelines for the
Prevention and Management of Diabetes in
Canada. *Can. J Diabetes*. 2003;27(suppl. 2):
S1-S152

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