

Using NovoMix® 30

For direct distribution by Healthcare Professionals to users of NovoMix® 30 and Novo Nordisk devices only



MY DETAILS (DOCTOR TO COMPLETE)

NovoMix® 30 starting dose:

once-daily

Injection time: _____ Dose: _____ Units

twice-daily

Injection time: _____ Dose: _____ Units

Injection time: _____ Dose: _____ Units

thrice-daily

Injection time: _____ Dose: _____ Units

Injection time: _____ Dose: _____ Units

Injection time: _____ Dose: _____ Units

Other instructions:

Device:

NovoMix® 30 FlexPen®



WHAT IS IN THIS BOOKLET

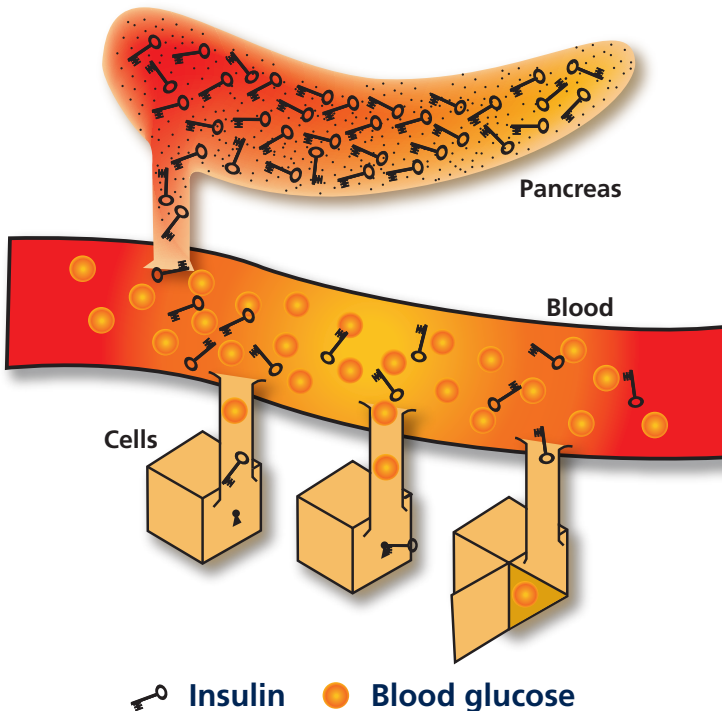
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TREATING DIABETES WITH INSULIN

What does insulin do?

Insulin is a hormone that is produced by the pancreas. It lowers blood glucose levels. Insulin is the key that opens the cells in our body so that they can store glucose and use it for energy. The insulin that you inject works the same way as the insulin made by the body.

Function of Insulin



TREATING DIABETES WITH INSULIN

Why do I need insulin now?

You have been taking medications for your diabetes that control your blood glucose levels by helping your body produce more insulin, or making the insulin you produce more easily used by your body.

Insulin injections may now be required because your pancreas may not be making enough insulin or insulin cannot be used properly by the body. Therefore, your diabetes medications are no longer able to control your blood glucose levels alone.

Will I still have to take tablets for my diabetes?

Some people need to be treated with both insulin injections and tablets, while others only need insulin injections. Your doctor will decide which medication is best for you at this time.

How will insulin help me?

After starting insulin, most people with diabetes say they feel much better and have more energy. This is because their blood glucose levels have improved.

Studies show that you can reduce the risk of complications if you control your blood glucose, blood pressure, and cholesterol.

Using insulin to keep your blood glucose in control will reduce the complications of diabetes that can occur, including blindness, stroke, heart, kidney, and nerve problems.

In the long-term, if your blood glucose and blood pressure levels stay too high, you will increase your risk of developing complications.


NovoMix[®] 30
insulin aspart (rys)

PRODUCT DESCRIPTION

What it looks like

NovoMix® 30 is a white, cloudy suspension for subcutaneous injection.

Ingredients

NovoMix® 30 contains soluble insulin aspart (rys) and protamine-crystallised insulin aspart (rys) 100 units per mL (100 U/mL) as the active ingredient, in the ratio of 30:70.

The abbreviation “rys” indicates the method of genetic engineering used to manufacture the insulin aspart.

NovoMix® 30 also contains the following inactive ingredients: glycerol, phenol, meta-cresol, zinc chloride, sodium chloride, dibasic sodium phosphate dihydrate, sodium hydroxide, protamine sulphate, hydrochloric acid and water for injections.

Sponsor

NovoMix® 30 is supplied in New Zealand by:
Novo Nordisk Pharmaceuticals Ltd. G.S.T 53 966 898
58 Richard Pearse Drive, Airport Oaks, Mangere

INSULIN DELIVERY DEVICE

NovoMix® 30 FlexPen®

NovoMix® 30 FlexPen® is a 3mL pre-filled glass cartridge contained in a dial-a-dose disposable insulin pen for use with pen needles.



NovoMix® 30
insulin aspart (rys)

A GUIDE TO USING NOVOMIX® 30

This booklet answers some common questions about NovoMix® 30. It does not contain all the available information. It does not take the place of talking to your doctor, diabetes educator or pharmacist.

Please read the Consumer Medicine Information which accompanies your medicine before use.

All medicines have risks and benefits. Your doctor has weighed the risks of you using NovoMix® 30 against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, diabetes educator or pharmacist.

Keep this booklet with the medicine.

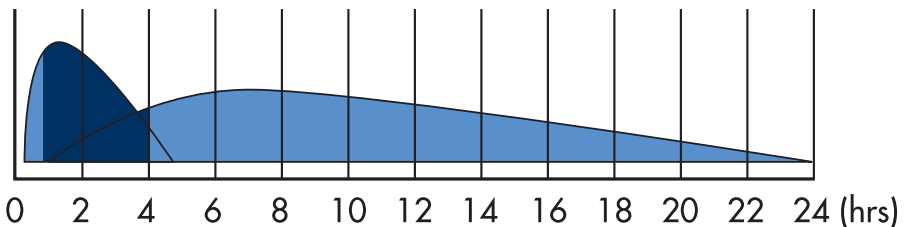
You may need to read it again.

WHAT IS NOVOMIX® 30 USED FOR

NovoMix® 30 is a premixed neutral suspension consisting of rapid-acting insulin aspart(rys) (30%) and long-acting protamine insulin aspart (rys) (70%).

The rapid-acting component of NovoMix® 30 provides insulin to cover the rise in blood glucose after meals and the long-acting component of NovoMix® 30 provides a constant level of background insulin.

Schematic time action profile of NovoMix® 30



As with all insulins, the duration of action of the insulin you inject will vary according to the dose, injection site, blood flow, temperature and level of physical activity.

HOW DOES NOVOMIX® 30 WORK

NovoMix® 30 lowers your blood glucose level after injection. When injected under your skin, NovoMix® 30 has a faster onset of action than soluble human insulin. Therefore NovoMix® 30 should be injected immediately (up to 10 minutes) before or immediately after the meal. It 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.

When to take NovoMix® 30	How long before NovoMix® 30 starts to work?	When is it most active?	How long does NovoMix® 30 last?
Immediately before or immediately after a meal	Within 10 - 20 minutes	1 - 4 hours	Up to 24 hours

NovoMix® 30 is not addictive.

NovoMix® 30 is available only with a doctor's prescription.

Ask your doctor, diabetes educator or pharmacist if you have any questions about why NovoMix® 30 has been prescribed for you.

BEFORE YOU USE NOVOMIX® 30

When you must not use it

Do not use this medicine if:

- 1. You have an allergy to:**
 - any medicine containing insulin
 - any of the ingredients listed in the ‘Ingredients’ section of this booklet.

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site;
- rash, itching or hives on the skin;
- shortness of breath;
- wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body.

- 2. You are experiencing low blood sugar levels (a “hypo”) when your dose is due.**



If you have a lot of hypos discuss appropriate treatment with your doctor.

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not use this medicine after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

BEFORE YOU USE NOVOMIX® 30



Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- liver problems
- adrenal, pituitary or thyroid gland problems.



Tell your doctor if you are pregnant or plan to become pregnant.

Pregnancy may make managing your diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months. Your doctor can discuss with you the risks and benefits involved.



Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor can discuss with you the risks and benefits involved.

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).

If you have not told your doctor about any of the above, tell them before you start using this medicine.

NovoMix® 30
insulin aspart (rys)

BEFORE YOU USE NOVOMIX® 30

Taking other medicines



Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and NovoMix® 30 may interfere with each other. These include:

- oral hypoglycaemic medicines – used to treat type 2 diabetes
- monoamine oxidase inhibitors (MAOI) - used for the treatment of depression
- alpha-blocking agents – used to treat high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate
- non-selective beta-blocking agents – used to treat high blood pressure and certain heart conditions
- angiotensin converting enzyme (ACE) inhibitors – used to treat high blood pressure, certain heart conditions or elevated protein/albumin in the urine
- salicylates e.g. aspirin – used to relieve pain and lower fever
- anabolic steroids – used to promote growth
- glucocorticoids (except when applied locally) – used to treat inflammatory conditions
- oral contraceptives (“the pill”) – used for birth control
- thiazides – used to treat high blood pressure or fluid retention (oedema)
- thyroid hormones – used to treat malfunction of the thyroid gland
- sympathomimetics such as salbutamol or terbutaline – used to treat asthma
- sulphonamides – used to treat bacterial infections

BEFORE YOU USE NOVOMIX® 30

Or other specific medicines including:

- danazol – used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema
- oxymetholone – used to treat certain blood disorders
- octreotide – used to treat gastrointestinal endocrine tumours
- lanreotide – used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal hormone levels
- diazoxide – used to treat high blood pressure
- nicotinic acid – used to treat high cholesterol levels in the blood
- asparaginase – used to treat leukaemia and lymph gland tumours
- quinine – used to treat malaria and relieve muscle cramps
- quinidine – used to treat heart problems
- growth hormone – used to treat growth disorders

Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with thiazolidinediones in combination with insulin may develop heart failure.



Tell your doctor about any other medicines that you are taking.

This is very important. Your doctor will advise you if it is alright to keep taking them or if you should stop taking them.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

HOW TO USE NOVOMIX® 30



Your doctor, diabetes educator or pharmacist will have given you advice on how to use your medicine.

Carefully follow all the directions.

They may differ from the information contained in this booklet.



Any change in dose or type of insulin should be made cautiously and only under medical supervision.

If you change the type of insulin that you use, you may have to use more or less than before. This may happen with the first dose or over a period of time.

If you do not understand the instructions, ask your doctor, diabetes educator or pharmacist for help.

- Carefully follow the instructions on how to use your Novo Nordisk insulin delivery system
- Do not use the insulin level indicator on the insulin delivery system to measure your dose of NovoMix® 30
- If you use more than one type of Penfill® (more than one type of insulin), you must use a separate insulin delivery system for each type of Penfill®
- Take care not to drop or knock NovoMix® 30 FlexPen® or the insulin delivery system that contains NovoMix® 30 Penfill®
- As a precautionary measure, always carry a spare insulin delivery device in case your NovoMix® 30 FlexPen® or NovoMix® 30 Penfill® is lost or damaged
- Do not use NovoMix® 30 in insulin pumps


NovoMix® 30
insulin aspart (rys)

HOW TO USE NOVOMIX® 30

How much to use

Your doctor or diabetes educator will tell you how much NovoMix® 30 you need to use each day. Refer to My Details section on page 2 of this booklet. It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

Checking your NovoMix® 30

**Check your medicine before each preparation and injection.
Make sure you are using the correct type of insulin.**

Do not use NovoMix® 30 if the medicine contains clumps of material or solid white particles sticking to the bottom or wall of the cartridge after resuspending.

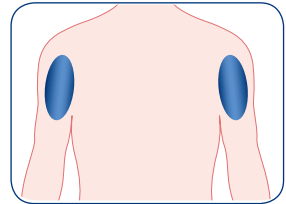
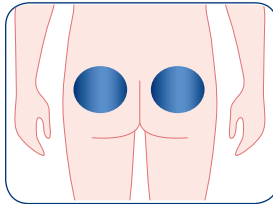
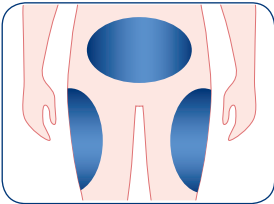
Do not use NovoMix® 30 if your FlexPen® or Penfill® is damaged.

Do not use NovoMix® 30 Penfill® if there is a gap between the plunger and the white label band.

Carefully read the instructions in the NovoMix® 30 FlexPen® or NovoMix® 30 Penfill® Consumer Medicine Information, and NovoPen® 4 instruction manual, depending upon which device you have been instructed to use.

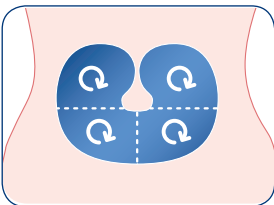
INJECTION SITES

NovoMix® 30 may be injected into the abdomen, thighs, upper arms or buttocks.

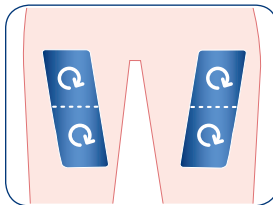


Rotate your injection site

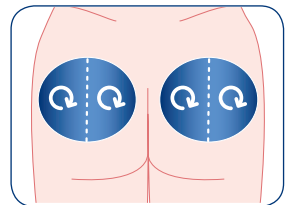
- It is important that injections are not made into the same spot every time.
- Rotating injection sites will give each site the opportunity to recover properly and will make injections more comfortable and effective.
- One way of keeping track is to divide the injection site into halves or quarters and use a different half/quarter every week – moving in a clockwise direction by about the width of a finger from the last injection point.
- Always choose the most suitable injection sites and site rotation regime with a diabetes specialist.



Abdominal rotational pattern by quarters



Thigh rotational pattern by halves



Buttocks rotational pattern by halves

INJECTING NOVOMIX® 30

Resuspending NovoMix® 30

Before every injection you must resuspend NovoMix® 30.

The first use of a new NovoMix® 30 FlexPen® or Penfill®

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

If you are using NovoMix® 30 FlexPen®

Pull off the pen cap. Roll the pen between your palms 10 times as shown on figure A1 – it is important that the pen is kept horizontal.

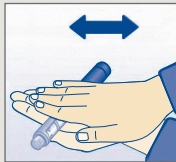


Figure A1

If you are using NovoMix® 30 Penfill®

Before inserting NovoMix® 30 Penfill® into a Novo Nordisk insulin delivery system (e.g. NovoPen® 4), roll the cartridge between your palms 10 times as shown on figure A2 – it is important that cartridge is kept horizontal.

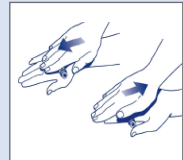


Figure A2

Move the pen up and down 10 times between the two positions as shown in Figure B1 – so the glass ball moves from one end of the cartridge to the other.

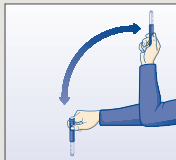


Figure B1

Move the cartridge up and down between positions a and b 10 times – as shown in Figure B2 – so that the glass ball moves from one end of the insulin cartridge to the other.

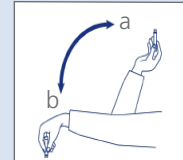
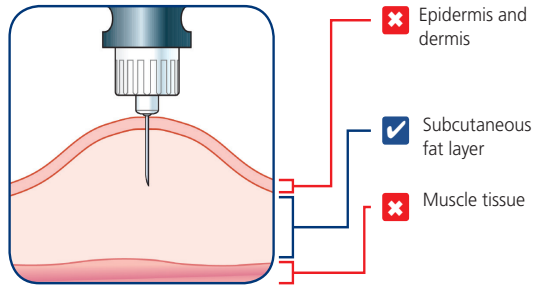


Figure B2

The rolling and moving procedures must be repeated until the liquid appears uniformly white and cloudy (resuspended). Inject NovoMix® 30 immediately.

INJECTING NOVOMIX® 30

- NovoMix® 30 has to be injected into the fatty layer of the skin (called the subcutaneous layer) and not into the muscle or dermis.
- The depth of this subcutaneous layer is different from person to person and at different parts of the body.



- Injecting into the muscle can be painful, and so it is important to ensure that NovoMix® 30 is injected into the subcutaneous tissue. Two things may help with this:
 - An appropriate injection technique
 - The correct needle length.

Injection technique and needle length

- Your doctor or diabetes educator will recommend the appropriate needle length for you.
- Injection technique will vary depending on the length of the pen needle used, body weight and favoured injection site.
- Keep the needle under the skin for at least 6 seconds after injecting.

It is important to inject NovoMix® 30 according to the recommendations given to you by your doctor or diabetes educator.

IF YOU USE TOO MUCH – HYPOGLYCAEMIA

Your blood sugar level may become too low (you may experience hypoglycaemia or a “hypo”) if you:

- accidentally use too much of this medicine
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill

The first symptoms of mild to moderate hypos can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- headache, nausea



Always carry some sugary food or fruit juice with you.

If you experience any of these symptoms of a hypo, immediately eat some sugary food or have a sugary drink, e.g. lollies, biscuits or fruit juice and measure your blood glucose level.

Tell your relatives, friends, close workmates or carers that you have diabetes. It is important that they recognise the signs and symptoms of a hypo.



Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of a hypo.



If you lose consciousness, make sure they know:

- to turn you on your side and get medical help immediately
- not to give you anything to eat or drink

This is because you could choke.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, eat some sugary food or have a sugary drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes educator, or the closest hospital.

If you do not respond to glucagon treatment, you will require medical attention.



See your doctor if you keep having hypo reactions, or if you have ever become unconscious after using insulin.

Your insulin dose may need to be changed.

If a prolonged, severe hypo is not treated, it can cause brain damage and death.

IF YOU MISS A DOSE – HYPERGLYCAEMIA



If you forget your insulin dose, test your blood glucose level as soon as possible.

If you are not sure what to do, talk to your doctor, diabetes educator or pharmacist.



Do not use a double dose of your insulin.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember – don't forget to eat some carbohydrate within 10 minutes of your injection – and then go back to using it as you would normally.

Your blood sugar levels may become high (hyperglycaemia) if you:

- miss doses of insulin or use less insulin than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed

High blood sugar levels over a long period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is high or you recognise any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness

Severe hyperglycaemia can lead to unconsciousness and in extreme cases death if untreated.

Discuss any worries you may have about this with your doctor, diabetes educator or pharmacist.

WHILE YOU ARE USING NOVOMIX® 30

Things you must do

Measure your blood sugar level regularly.

Make sure all friends, relatives, workmates or carers know that you have diabetes.

If your child has diabetes it is important to tell their carers.

Keep using your insulin even if you feel well.

It helps to control your condition, but does not cure it.

Tell your doctor if you often have hypos (low blood glucose levels).

Your doctor may need to adjust your insulin dose.

Always carry some sugary food or fruit juice with you.

If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Tell your doctor if you have trouble recognising the symptoms of hypos.

Under certain conditions, the early warning signs of hypos can be different or less obvious. Your doctor may need to adjust your insulin dose.

Make sure that you tell every doctor, dentist, pharmacist or other healthcare professional who is treating you that you have diabetes and are using insulin.



Tell your doctor, diabetes educator or pharmacist if you are travelling.

Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject your insulin and eat your meals at different times because of time differences in and between countries.

You may not be able to get the same type of insulin in the country you are visiting.

Your doctor, diabetes educator or pharmacist can provide you with some helpful information.



AFTER USING NOVOMIX® 30



Disposal

Always remove the needle after each injection and store your insulin delivery system without the needle attached. Otherwise, the insulin may leak out which can cause inaccurate dosing. Dispose of your used needle safely into a yellow plastic sharps container.

It is recommended that you eat a meal or snack containing carbohydrate within 10 minutes of the injection.



Storage

Store the NovoMix® 30 that is not being used between 2°C and 8°C in a refrigerator (not in or too near the freezer section or cooling element).

Do not keep the NovoMix® 30 that you are using, or that you are carrying as a spare, in a refrigerator. You can use it up to 4 weeks at or below 30°C after taking it out of the refrigerator.

Resuspend NovoMix® 30 – whether it is to be used immediately or whether it is to be carried as a spare – upon removing it from the refrigerator.

NovoMix® 30 must not be frozen, or exposed to excessive heat and light. Protect the medicine from light by keeping the cap on, or spare cartridges in the carton, when not in use.

Never use NovoMix® 30 after the expiry date printed on the label and carton.

Never use NovoMix® 30 if the NovoMix® 30 does not appear white and uniformly cloudy after resuspending.

Keep out of the reach of children.

Discard NovoMix® 30 after 4 weeks even if there is still some medicine left in it.

THINGS YOU MUST NOT DO

Do not stop using your medicine unless your doctor tells you to.

Do not use the medicine if you think it has been frozen or exposed to excessive heat. It will not work as well.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not refill your NovoMix[®] 30 Penfill[®] or FlexPen[®].

Do not share needles.

Do not stop using NovoMix[®] 30 unless your doctor tells you to.

THINGS TO BE CAREFUL OF

Be careful driving or operating machinery until you know how the insulin affects you.

If your blood glucose 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:

- if you have frequent hypos
- if you find it hard to recognize hypoglycaemia

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypos. If you drink alcohol, your need for insulin may change as your blood glucose level may either rise or fall. Careful monitoring is recommended.

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for this medicine. Exercise may also speed up the effect of a dose of it, especially if the exercise involves the area of the injection site (e.g. the leg should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your insulin needs to change.

SIDE EFFECTS



Tell your doctor, diabetes educator or pharmacist as soon as possible if you do not feel well while you are using NovoMix® 30.

This medicine helps most people for whom it is prescribed, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.



Ask you doctor, diabetes educator or pharmacist to answer any questions you may have.

The most common side effect when using insulin is low blood glucose levels (a hypo).

Tell your doctor if you notice any of the following and they worry you:

- hypos (mild to moderate)
- pain, redness, hives, bruising, swelling or itching at the injection site. Usually these symptoms disappear within a few weeks during continued use. If you have serious or continuing reactions, you may need to stop using NovoMix® 30 and use another insulin
- a depression or thickening of the skin around the injection site (lipodystrophy)
- when you first start your insulin treatment you may get visual problems or swollen hands and feet

This list includes the more common side effects of your medicine. They are usually mild and short-lived.



If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

More severe symptoms of low blood sugar levels, including:

- disorientation
- seizures, fits or convulsions
- loss of consciousness

If a severe hypo is not treated, it can cause brain damage and death.



Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- skin rashes over a large part of the body
- shortness of breath, wheezing
- swelling of the face, lips or tongue
- fast pulse
- sweating

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.



Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.



Ask your doctor, diabetes educator or pharmacist to answer any questions you have.

NOTES

This booklet is designed for people who have been prescribed NovoMix® 30 by their doctors and is intended to answer the most frequently asked questions about NovoMix® 30. This booklet is not intended to replace any discussions you would normally have with your doctor or any other member of your diabetes care team.



For further information call NovoCare® Customer Care Centre (New Zealand) **0800 733 737** or visit our website **www.novonordisk.co.nz**

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