

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Ryzodeg[®] 70/30 FlexTouch[®] 3 mL

70% insulin degludec / 30% insulin aspart

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ryzodeg[®] 70/30 FlexTouch[®]. It does not contain all the available information. It does not take the place of talking to your doctor, diabetes education nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Ryzodeg[®] 70/30 FlexTouch[®] against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Ryzodeg[®] 70/30 is used for

Ryzodeg[®] 70/30 is used to treat diabetes mellitus in patients aged 6 years and older. It helps your body reduce your blood sugar level.

Ryzodeg[®] 70/30 contains two types of insulin:

- Basal insulin called insulin degludec - this has a long blood sugar lowering effect.

- Rapid acting insulin called insulin aspart - this lowers your blood sugar soon after you inject it.

Ryzodeg[®] 70/30 is a modified insulin, also called an insulin analogue, which is similar to the insulin produced by the pancreas.

Diabetes mellitus is a condition in which your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

- type 1 diabetes
- type 2 diabetes

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets.

Ryzodeg[®] 70/30 may be used in combination with other antidiabetic drugs (for example, diabetes tablets) or with a meal-related short- or rapid-acting insulin, such as NovoRapid[®].

Ryzodeg[®] 70/30 can either be used once or twice each day. Ryzodeg[®] 70/30 can be used once- or twice-daily with the main meal(s). When needed, you can change the time of dosing as long as Ryzodeg[®] 70/30 is dosed with the main meal(s). The effect may last for more than 24 hours.

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

FlexTouch[®] is a pre-filled dial-a-dose insulin pen able to deliver from 1 to 80 units in steps of 1 unit.

This medicine is not addictive.

Ryzodeg[®] 70/30 FlexTouch[®] is available only with a doctor's prescription.

Ask your doctor if you have any questions about why Ryzodeg[®] 70/30 has been prescribed for you.

Ryzodeg[®] 70/30 can be used in adolescents and children from the age of 6 years. Ryzodeg[®] 70/30 should be used with special caution in children and adolescents.

The risk for very low blood sugar levels may be higher in children and adolescents. There is no experience with the use of Ryzodeg[®] 70/30 in children below the age of 2 years.

Before you use Ryzodeg[®] 70/30 FlexTouch[®]

When you must not use it

Do not use Ryzodeg[®] 70/30 if:

1. you have an allergy to:

- any medicine containing insulin

- any of the ingredients listed in the 'Ingredients' section at the end of this leaflet.

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 a low blood sugar level (a 'hypo') when the dose is due.

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

3. the product does not appear clear and colourless, or if the pen is damaged or has not been stored correctly.

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 start to use it

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 of the following medical conditions:

- kidney problems
- liver problems
- adrenal, pituitary or thyroid gland problems
- heart disease or stroke.

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

It is not known if Ryzodeg® 70/30 affects the baby in pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or are planning

to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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. Avoiding too low blood sugar (hypoglycaemia) is particularly important for the health of your baby. 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/pharmacist can discuss with you the risks and benefits involved.

Tell your doctor if you notice any 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 How to use Ryzodeg® 70/30 FlexTouch®). 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.

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

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 Ryzodeg® 70/30 may interfere with each other.

Your blood sugar level may fall (hypoglycaemia), if you take:

- other medicines for diabetes (oral and injectable)

- sulphonamides - used to treat bacterial infections
- anabolic steroids - used to promote growth
- non-selective beta blockers -used to treat high blood pressure and certain heart conditions
- salicylates e.g. aspirin - used to relieve pain and lower fever
- monoamine oxidase inhibitors (MAOI) - used for the treatment of depression
- alpha blockers - used to treat high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate
- ACE inhibitors - used to treat high blood pressure, certain heart conditions or elevated protein/albumin in the urine
- quinine - used to treat malaria and relieve muscle cramps
- quinidine - used to treat heart problems.

Your blood sugar level may rise (hyperglycaemia), if you take:

- danazol - used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema
- glucocorticoids (except when applied locally) - used to treat inflammatory conditions
- oral contraceptives ('the pill') - used for birth control
- diuretics e.g. thiazides, frusemide or ethacrynic acid - used to treat high blood pressure or fluid retention (oedema)
- thyroid hormones - used to treat malfunction of the thyroid gland
- sympathomimetics - adrenaline and medicines used to treat asthma, such as salbutamol or terbutaline
- growth hormone - used to treat growth disorders
- oxymetholone - used to treat certain blood disorders
- 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.

Your blood sugar level may either fall or rise if you take:

- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide - used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels.

Beta-blockers may mask the symptoms of hypoglycaemia and delay recovery from hypoglycaemia.

Thiazolidinediones - some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with thiazolidinediones in combination with insulin developed heart failure. Inform your doctor immediately if you experience signs of heart failure such as shortness of breath, rapid weight gain or localised swelling.

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

This is very important. Your doctor will advise you if it is all right 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 Ryzodeg® 70/30 FlexTouch®

Your doctor, diabetes education nurse or pharmacist will have shown you how to use your medicine. Carefully follow all the directions.

They may differ from the information contained in this leaflet.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use the pen without help. Get help from a person with good eyesight who is trained to use the FlexTouch® pen.

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 education nurse or pharmacist for help.

How much to use

Your doctor or diabetes education nurse will decide with you:

- how much Ryzodeg® 70/30 you will need each day and at which meal(s)
- when to check your blood sugar level and if you need a higher or lower dose.

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

Based on your blood sugar level your doctor may change your dose.

When using other medicines, ask your doctor if your treatment needs to be adjusted.

When to use it

- Always follow your doctor's recommendation for dose
- Ryzodeg® 70/30 can either be used once or twice each day
- Use with the main meal(s) - you can change the time of dosing as long as Ryzodeg® 70/30 is dosed with the main meal(s)
- If you want to change your usual diet, check with your doctor, pharmacist or nurse first as a change in diet may alter your need for insulin.

How to use it

- Inject Ryzodeg® 70/30 under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse. Never inject Ryzodeg® 70/30 into a vein or muscle.

Follow the detailed instructions on how to inject Ryzodeg® 70/30 FlexTouch® in the instructions for use supplied with the product. These instructions are also available via the following hyperlink:

<https://medsinfo.com.au/media/noirzft>

- Ryzodeg® 70/30 may be injected into the abdomen, thigh or upper arm.
- Remember to change your injection site regularly as shown to you by your doctor or diabetes education nurse.
- Always use a new needle for each injection to prevent contamination. Needles must not be shared.
- Ensure the correct length of needle is selected for use in children.
- As a precautionary measure, always carry a spare FlexTouch® in case your in-use FlexTouch® is lost or damaged.
- Do not use Ryzodeg® 70/30 in insulin infusion pumps.

Checking your Ryzodeg® 70/30 FlexTouch® pen:

Check your Ryzodeg® 70/30 FlexTouch® pen before each preparation and injection. Check the name and strength on the label of the pen to make sure it is Ryzodeg® 70/30 FlexTouch® 100 U/mL.

Do not use this medicine if it is thickened, coloured, or has solid bits in it.

Read the instructions printed at the end of this leaflet carefully in order to prepare and handle your Ryzodeg® 70/30 FlexTouch® correctly.

Always check your insulin injection device for insulin flow (priming) before each injection.

The priming procedure may highlight a malfunction with your insulin injection device. Priming also removes any air bubbles and helps indicate whether or not a needle is broken.

Injecting a dose:

Choose a site for injection.

Inject Ryzodeg® 70/30 under the skin (subcutaneous injection) as shown by your doctor or diabetes education nurse. Never inject Ryzodeg® 70/30 into a vein or muscle.

Ryzodeg® 70/30 may be injected into the abdomen, thigh or upper arm.

Change the injection site so that the same position is not used more often than once a month.

This will reduce the chance of local skin reactions developing.

Pinch the skin between two fingers, push the needle into the raised skin, and inject the full dose of insulin under the skin.

Keep the needle under the skin for at least 6 seconds. Keep the dose button fully depressed until the needle has been withdrawn from the skin.

Apply gentle pressure over the injection site for several seconds. Do not rub the area.

After injecting:

Using the outer needle cap, remove the needle and dispose of it safely into a sharps container.

Always dispose of the needle after each injection.

This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Healthcare professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles, to

eliminate the risk of needlestick injury.

Do not share needles, cartridges and pens.

How long to use it

Do not stop using Ryzodeg® 70/30 FlexTouch® unless your doctor tells you to.

If you take too much (overdose) - Hypoglycaemia

If you use too much insulin, your blood sugar level may get too low (hypoglycaemia).

Immediately telephone your doctor or the Poisons Information Centre (telephone in Australia: 13 11 26; in New Zealand: 0800 764 766) for advice if you think that you or anyone else may have used too much Ryzodeg® 70/30. Do this even if there are no signs of discomfort or poisoning.

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 or miss a meal
- are ill
- drink alcohol.

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
- vision changes
- headache, nausea.

Always carry some sugary food or fruit juice with you.

If you experience any of these symptoms of a hypo:

- Eat glucose tablets or another high sugar snack, like sweets, biscuits or fruit juice (always carry glucose tablets or a high sugar snack, just in case).
- Measure your blood sugar level if possible and rest. You may need to measure your blood sugar level more than once, as with all basal insulin products improvement from the period of low blood sugar levels may be delayed.
- Wait until the signs of too low blood sugar levels have gone or when your blood sugar level has settled. Then carry on with your insulin as usual.

Tell your relatives, friends, close workmates, teachers 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, teacher 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 education nurse, or the closest hospital.

If you do not respond to glucagon treatment, you will have to be treated in a hospital.

See your doctor if you keep having hypo reactions, or if you have ever

become unconscious after using insulin.

This is because the dosing or timing of your insulin injections, food or exercise may need to be changed. If a 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 sugar level and test your urine for ketones as soon as possible.

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

Do not use a double dose of your insulin.

If you forget a dose, inject the missed dose with your next large meal on that day, 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
- drink alcohol.

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 education nurse or pharmacist.

While you are using Ryzodeg® 70/30 FlexTouch®

Things you must do

Measure your blood sugar level regularly.

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

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 sugar 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 sugary 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 education nurse or pharmacist if you are travelling.

Ask your doctor 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 education nurse or pharmacist can provide you with some helpful information.

Tell your doctor if you are having trouble with your eyesight.

Visual disturbances in uncontrolled diabetes are reversed during the early stages of treatment. Once established on insulin, if your vision changes, see your doctor as soon as possible.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Ryzodeg® 70/30 FlexTouch®.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

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

If you stop using your insulin this could lead to a very high blood sugar level and ketoacidosis (a condition with too much acid in the blood).

If you are blind or have poor eyesight and cannot read the dose

counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the FlexTouch® pen.

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 refill your Ryzodeg® 70/30 FlexTouch®.

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 share needles.

Things to be careful of

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

Having too low or too high blood sugar levels can affect your ability to drive or use any tools or machines. If your blood sugar level is too low or too high your ability to concentrate and react might be affected. This could be dangerous to yourself or others. Ask your doctor whether you can drive if:

- you often get too low blood sugar levels
- you find it hard to recognise too low blood sugar levels.

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 sugar 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 thigh 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 education nurse or pharmacist as soon as possible if you do not feel well while you are using Ryzodeg® 70/30 FlexTouch®.

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 attention 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 your doctor, diabetes education nurse or pharmacist to answer any questions you may have.

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

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

- hypos (mild to moderate).
- pain, redness, hives, swelling or itching at the injection site (local allergy). Usually these symptoms disappear within a few weeks during continued use. If you have serious or continuing reactions, you may need to stop using Ryzodeg® 70/30 and use another insulin.

- 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.

Tell your relatives, friends, close workmates, teachers or carers that you have diabetes.

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
- signs of heart failure, such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

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.

Skin changes at the injection site

If you inject insulin at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis). 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.

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

After using Ryzodeg® 70/30 FlexTouch®

Storage

Before first use:

Store Ryzodeg® 70/30 FlexTouch® that are not being used between 2°C and 8°C in a refrigerator (not in or too near the freezer section or cooling element).

After first opening or if carried as a spare:

When Ryzodeg® 70/30 FlexTouch® is being used or carried as a spare, you can keep it at room temperature (not above 30°C) or in a refrigerator (2°C to 8°C) for up to 28 days.

Discard your Ryzodeg® 70/30 FlexTouch® after 28 days even if there is still some medicine left in it.

Ryzodeg® 70/30 must not be frozen, or exposed to excessive heat and light. Protect the medicine in Ryzodeg® 70/30

FlexTouch® from light by keeping the cap on when not in use.

Never use Ryzodeg® 70/30 FlexTouch® after the expiry date printed on the label and carton.

The expiry date refers to the last day of that month.

Never use Ryzodeg® 70/30 FlexTouch® if the insulin does not appear clear and colourless.

Keep out of the reach of children.

Disposal

Dispose of used needles safely into a sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Ryzodeg® 70/30 is a clear colourless solution for subcutaneous injection.

Ryzodeg® 70/30 FlexTouch® is a 3 mL pre-filled glass cartridge contained in a dial-a-dose insulin pen.

Ingredients

Ryzodeg® 70/30 contains soluble insulin degludec and insulin aspart 100 units per mL (100 U/mL) as the active ingredient, in the ratio of 70:30.

Ryzodeg® 70/30 also contains the following inactive ingredients:

- glycerol
- phenol (as preservative)
- metacresol (as preservative)
- zinc acetate
- sodium chloride
- sodium hydroxide
- hydrochloric acid
- water for injections.

Sponsor

Ryzodeg® 70/30 FlexTouch® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 10

118 Mount Street

North Sydney NSW 2060

Australia

Ryzodeg® 70/30 FlexTouch® is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

11-19 Customs Street West
Commercial Bay Tower, Level 18
Office 1834
Auckland 1010
New Zealand.

Ryzodeg®, FlexTouch®, NovoRapid® and NovoFine® are registered trademarks of Novo Nordisk A/S.

Australian Registration Number:
AUST R 280432

This leaflet was prepared in April 2023.

Further information

For further information call the Novo Nordisk Customer Care on 1800 668 626 (Australia) or 0800 733 737 (NZ).

www.novonordisk.com.au

www.novonordisk.co.nz

You can also get more information about diabetes and insulin from Diabetes Australia and Diabetes New Zealand:

- freecall helpline 1300 136 588 (Australia)
- www.diabetesaustralia.com.au
- www.diabetes.org.nz

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