

# NovoNorm<sup>®</sup>

Repaglinide

## Consumer Medicine Information

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### What is in this leaflet

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What NovoNorm<sup>®</sup> is used for.. 1

Before you take NovoNorm<sup>®</sup> ... 1

How to take NovoNorm<sup>®</sup> ..... 2

While you are taking NovoNorm<sup>®</sup>  
..... 3

Side effects..... 4

After using NovoNorm<sup>®</sup> ..... 4

Product Description ..... 4

Further Information..... 5

This leaflet answers some common questions about NovoNorm<sup>®</sup>. It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NovoNorm against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### What NovoNorm<sup>®</sup> is used for

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NovoNorm is used to control blood glucose levels in patients with type 2 diabetes mellitus. This type of diabetes is also known as non-insulin-dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

NovoNorm is used when diet and exercise are not enough to control your blood glucose level.

NovoNorm can be used alone, or together with insulin or other medicines for treating diabetes.

NovoNorm lowers high blood glucose levels by helping your pancreas to produce more insulin.

This medicine is only available with a doctor's prescription.

There is no evidence that NovoNorm is addictive.

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### Before you take NovoNorm<sup>®</sup>

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#### **When you must not take it**

#### **Do not take NovoNorm if:**

1. You have an allergy to NovoNorm or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to these medicines may include itching and rash.

**If you are not sure if you have an allergy to NovoNorm, check with your doctor.**

2. You have any of the following conditions:

- type 1 diabetes mellitus (insulin-dependent diabetes mellitus, also known as IDDM, or juvenile onset diabetes)
- diabetic acidosis (ketone bodies and sugar in your urine)
- diabetic coma or pre-coma
- severe liver disease

**If you are not sure if you have any of the above, ask your doctor.**

3. You are currently taking a medicine containing gemfibrozil to lower your cholesterol.

Common tradenames of medicines containing gemfibrozil include Lopid, Lipazil, Gemhexal, Ausgem and Jezil.

4. You are pregnant or planning to become pregnant.

Insulin is more suitable for controlling blood glucose levels during pregnancy. Your doctor will replace NovoNorm with insulin.

5. You are breast-feeding or plan to breast-feed.

NovoNorm is not recommended while you are breast-feeding. It is not known whether NovoNorm passes into breast milk.

6. You are under 12 years of age.
7. The packaging is torn or shows signs of tampering (or the tablets do not look quite right).
8. The expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

**Do not give NovoNorm to children.**

#### **Before you start to take it**

#### **Tell your doctor if:**

1. You have allergies to any other medicines or any other substances such as foods, preservatives or dyes.
2. You are breast-feeding or plan to breast-feed.

3. You have or have had any of the following medical conditions:

- kidney problems
- liver problems

or

- you are about to have major surgery or you have recently suffered a severe illness or infection. At these times control of your diabetes may be difficult.

**Tell your doctor if:**

- you drink alcohol
- you do not eat regular meals
- you do a lot of exercise
- you are ill or feeling unwell
- you take other medicines (see ‘Taking other medicines’)

Alcohol, diet, exercise and your general health all strongly affect the control of your diabetes. You should discuss these things with your doctor.

**If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you start taking NovoNorm.**

***Taking other medicines***

**Tell your doctor, pharmacist or diabetes educator if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may lead to low blood glucose levels (hypoglycaemia) by increasing the blood glucose lowering effect of NovoNorm. These include:

- alcohol
- some medicines used to treat high blood pressure (beta blockers, ACE Inhibitors)
- some medicines used to treat arthritis, pain and inflammation (salicylates, non steroidal anti-inflammatory drugs)
- (anabolic) steroids

- other medicines used to treat diabetes
- some medicines used to treat depression (MAOI)
- octreotide
- gemfibrozil
- cyclosporin
- clarithromycin
- itraconazole (antifungal drug)
- ketoconazole (antifungal drug)
- trimethoprim (antibacterial drug)

Some medicines may lead to loss of control of your diabetes by weakening the blood glucose lowering effect of NovoNorm. These include:

- corticosteroids such as prednisone and cortisone
- oestrogens and oral contraceptives
- diuretics, also known as fluid tablets (thiazides)
- some asthma medicines, preparations for coughs and colds, and weight-reducing medicines (sympathomimetics)
- thyroid hormones
- danazol
- octreotide
- rifampicin (antibacterial drug)
- carbamazepine (anti-epileptic drug)

Some medicines may hide the symptoms of low blood glucose levels (hypoglycaemia). These include:

- alcohol
- certain medicines used to treat high blood pressure (beta blockers)

You may need different amounts of your medicine or you may need to take different medicines. Your doctor, pharmacist or diabetes educator can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking NovoNorm.

**Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.**

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## **How to take NovoNorm®**

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**Follow all directions given to you by your doctor, pharmacist or diabetes educator carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### ***How much to take***

The usual dose of NovoNorm ranges from 0.5mg to 4mg, with each main meal. You should not take NovoNorm more than 4 times a day.

Your doctor will tell you how many tablets to take with each main meal. Your doctor may increase or decrease the dose, depending on your blood glucose levels.

### ***When to take it***

**Swallow the tablets with a glass of water.**

**Take NovoNorm immediately before your main meals.**

**If you skip a main meal, do not take your NovoNorm dose.**

### ***How long to take it***

**Continue taking NovoNorm for as long as your doctor recommends. Make sure you keep enough NovoNorm to last over weekends and holidays.**

NovoNorm will help control your diabetes but will not cure it. Therefore, you may have to take it for a long time.

### ***If you take too much (overdose)***

**Immediately telephone your doctor, Poisons Information Centre, Diabetes Australia or closest hospital for advice if you think that you or anyone else may have taken too much NovoNorm. Do this even if there are no signs of discomfort or poisoning.**

If you take too much NovoNorm, you may experience symptoms of low blood glucose levels (hypoglycaemia).

Low blood glucose levels can occur suddenly. Signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- tearfulness or crying
- irritability
- hunger
- numbness around the lips and tongue

If not treated promptly, these may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and fitting.

**At the first signs of hypoglycaemia, raise your blood glucose level quickly by taking jelly beans, sugar or honey, (non-diet) soft drink or glucose tablets.**

**If you experience any of these symptoms, immediately get medical help.**

### ***If you forget to take it***

**If you forget to take a dose, take the next dose as usual. Do not take a double dose to make up for the dose you have missed.**

If you double a dose, this may cause hypoglycaemia.

If you miss too many doses, your blood glucose level may become too high (hyperglycaemia). High blood glucose levels usually occur more slowly than low blood glucose levels. **If you are not sure whether to skip the dose, talk to your doctor or pharmacist.**

Signs of high blood glucose levels may include:

- lethargy or tiredness
- headache
- thirst
- passing large amounts of urine
- blurred vision

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## **While you are taking NovoNorm®**

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### ***Things you must do***

**If you become pregnant while you are taking NovoNorm, tell your doctor.**

**If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking NovoNorm.**

**Tell all doctors, dentists, pharmacists and other health care professionals, who are treating you that you have diabetes and are taking NovoNorm.**

**Make sure you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia, and know how to treat them.**

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose level urgently. You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- ½ can of ordinary (non-diet) soft drink
- 2-3 concentrated glucose tablets
- unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates, e.g. plain biscuits, fruit or milk - when over the initial symptoms. Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

If you are elderly or are taking other medicines for diabetes such as insulin or sulphonylureas/metformin, the risk of hypoglycaemia is increased.

The risk of hypoglycaemia is increased in the following situations:

- too much NovoNorm
- too much or unexpected exercise
- delayed meal or snack
- too little food

**If you experience any of the signs of high blood glucose levels (hyperglycaemia), contact your doctor immediately.**

The risk of hyperglycaemia is increased in the following situations:

- undiagnosed or uncontrolled diabetes
- illness, infection or stress
- too little NovoNorm
- certain other medicines
- too little exercise
- eating more carbohydrate than normal

**If you become ill or experience extra stress, injury, fever, infection or need surgery, tell your doctor.**

Your blood glucose level may become difficult to control at these times. Your doctor may decide to change your treatment and use insulin instead of NovoNorm.

**Make sure you check your blood glucose levels regularly.**

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

**Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood, and blood pressure.**

**Carefully follow your doctor's and/or dietitian's advice on diet, drinking alcohol and exercise.**

**Tell your doctor immediately if you notice the return of any symptoms you had before starting NovoNorm.**

These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision. These may be signs that NovoNorm is no longer working, even though you may have been taking it successfully for some time.

### ***Things you must not do***

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

## Things to be careful of

If you have to be alert, for example, when driving, be especially careful not to let your blood glucose levels fall too low.

Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. However, NovoNorm by itself is unlikely to affect how you drive or operate machinery.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, for example, sugar sachets or jelly beans
- carry emergency food rations in case of a delay, for example, dried fruit, biscuits or muesli bars
- keep NovoNorm readily available

If you become sick with a cold, fever or flu, it is very important to continue taking NovoNorm, even if you feel unable to eat your normal meal.

**If you have trouble eating solid food, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food.**

Your diabetes educator or dietitian can give you a list of foods to use for sick days.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NovoNorm.**

NovoNorm helps most people with diabetes, 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.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following:**

- signs of hypoglycaemia which may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers
- stomach upset including nausea, vomiting, heartburn, indigestion, cramps
- diarrhoea, constipation or a feeling of fullness in the stomach
- headache
- tingling or numbness of the hands or feet
- eye problems including blurred or double vision
- unusual weight gain
- teeth problems
- muscle pain
- respiratory infections

**Tell your doctor immediately or go to Casualty at your nearest hospital if you notice any of the following:**

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- symptoms of lactic acidosis (too much acid in the blood) which may include loss of appetite, unexplained weight loss, nausea, vomiting, stomach pain, trouble breathing, feeling weak or tired or uncomfortable, unusual muscle pain, slow heart beat
- rash, sores, redness or itching of the skin/itchy hives-like rash or spots
- chest pain
- yellowing of the skin or eyes, also called jaundice
- a change in the colour of urine passed, blood in the urine

- a change in the amount of urine passed

**Tell your doctor if you notice any other effects.**

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

**Do not be alarmed by this list of possible side effects.** You may not experience any of them.

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## After using NovoNorm®

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### Storage

**Keep your tablets in the blister pack until it is time to take them.**

If you take the tablets out of the blister pack, they may not keep well.

**Keep them in a cool, dry place where it stays below 25°C. Do not refrigerate. Do not store them, or any other medicine, in a bathroom or near a sink. Do not leave them in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep out of the reach and sight of children.**

**Do not use after the expiry date.** The expiry date refers to the last date of that month. This is stated on the outer carton and the blister foil.

### Disposal

**If your doctor tells you to stop taking NovoNorm, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.**

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## Product Description

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### What it looks like

NovoNorm comes as tablets for you to swallow and is available in packs of 30 and 90 tablets. NovoNorm tablets are round tablets with the Novo Nordisk logo imprinted on them. The 0.5mg tablets are white, the 1mg tablets are yellow and the 2mg tablets are peach-coloured.

## **Ingredients**

The active ingredient in NovoNorm is repaglinide.

NovoNorm 0.5mg contains 0.5 milligrams of repaglinide.

NovoNorm 1mg contains 1 milligram of repaglinide.

NovoNorm 2mg contains 2 milligrams of repaglinide.

NovoNorm tablets also contain inactive ingredients, i.e. poloxamer, povidone, meglumine, maize starch, calcium hydrogen phosphate anhydrous, cellulose-microcrystalline, glycerol, polacrillin potassium, magnesium stearate, iron oxide yellow CI77492 (in the 1mg tablet only) and iron oxide red CI77491 (in the 2mg tablet only).

NovoNorm does not contain gluten, lactose, sucrose, tartrazine CI19140 or any other azo dyes.

## **Sponsor**

### ***Novo Nordisk Pharmaceuticals Pty Ltd***

Level 3, 21 Solent Circuit  
Baulkham Hills NSW 2153

Australian Registration Numbers:

0.5mg tablets: AUST R 67270

1mg tablets: AUST R 67269

2mg tablets: AUST R 67271

This leaflet was prepared on 20 March 2009.

NovoNorm<sup>®</sup> is a trademark owned by Novo Nordisk A/S, Denmark

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## **Further Information**

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For further information call the NovoCare Customer Care Centre on 1800 668 626.

[www.novonordisk.com.au](http://www.novonordisk.com.au)

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

- freecall helpline 1300 136 588 (Australia)
- [www.diabetesaustralia.com.au](http://www.diabetesaustralia.com.au)