

# Nesina®

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## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### **1. Why am I using Nesina?**

Nesina contains the active ingredient alogliptin (as benzoate). Nesina is used to lower blood sugar levels in adults with type 2 diabetes mellitus.

For more information, see Section [1. Why am I using Nesina?](#) in the full CMI.

### **2. What should I know before I use Nesina?**

Do not use if you have ever had an allergic reaction to Nesina or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Nesina?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Nesina and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Nesina?

- Swallow the tablet whole with a glass of water.
- The usual dose for this medicine is one 25 mg tablet once a day. If you have kidney problems your doctor may prescribe lower doses.

More instructions can be found in Section [4. How do I use Nesina?](#) in the full CMI.

### 5. What should I know while using Nesina?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Nesina.</li><li>• Carefully follow your doctor's and/or dietician's advice on</li></ul>
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	<p>diet, drinking alcohol and exercise.</p> <ul style="list-style-type: none"> <li>• Keep all of your doctor's appointments so that your progress can be checked.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Be careful when drinking alcohol. Alcohol increases the risk of your blood glucose becoming too low.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep the medicine in a cool, dry place where the temperature stays below 25°C.</li> </ul>

For more information, see Section [5. What should I know while using Nesina?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include stomach pain, indigestion and heartburn, headache and cold-like symptoms. Serious side effects include a skin reaction called bullous pemphigoid blisters, allergic reaction including

Stevens-Johnson syndrome, hypoglycaemia, pancreatitis-like symptoms and sign of liver problems.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Nesina

**Active ingredient(s):** *Alogliptin (as benzoate)*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Nesina. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nesina.**

**Where to find information in this leaflet:**

- [1. Why am I using Nesina?](#)
- [2. What should I know before I use Nesina?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Nesina?](#)
- [5. What should I know while using Nesina?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Nesina?

**Nesina contains the active ingredient alogliptin (as benzoate).** Alogliptin is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), that lowers blood sugar levels in patients with type 2 diabetes mellitus.

Nesina lowers blood sugar when blood sugar is high, especially after a meal. Nesina by itself is unlikely to cause low blood sugar (hypoglycaemia) because it does not work when blood sugar is low.

**Nesina is used to lower blood sugar levels in adults with type 2 diabetes mellitus.**

Type 2 diabetes is also called non-insulin-dependent diabetes mellitus (NIDDM).

Type 2 diabetes develops if the body does not make enough insulin, or if the insulin that your body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a hormone which helps to lower the level of sugar in your blood, especially after meals. Glucagon is another hormone which triggers the production of sugar by the liver, causing the blood sugar to rise. The pancreas makes both of these hormones.

If your blood glucose is not properly controlled, you may experience hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose). High blood glucose can lead to serious problems with your heart, eyes, circulation and/or kidneys.

The main goal of treating diabetes is to lower your blood sugar to a level deemed appropriate by your doctor. Lowering and controlling blood sugar may help prevent or delay complications of diabetes.

## **2. What should I know before I use Nesina?**

### **Warnings**

#### **Do not use Nesina if:**

- you are allergic to Nesina, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

#### **Check with your doctor if you:**

- have type 1 diabetes, also called insulin-dependent diabetes mellitus (IDDM) or juvenile onset diabetes, where the body does not produce enough insulin.
- have diabetic ketoacidosis, a complication of diabetes where chemicals called ketones build up in the body due to very low insulin levels.
- have kidneys problems.
- have liver disease.
- have heart failure.
- have disease of the pancreas.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

**Check with your doctor if you are pregnant or intend to become pregnant.** Like most medicines of this kind, Nesina is not recommended to be used during pregnancy.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.** It is not known whether Nesina passes into breast milk.

## Use in children and adolescents

- Nesina should not be used in children and adolescents under 18 years.

## 3. What if I am taking other medicines?

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

**Tell your doctor if you are taking an antidiabetic medicine known as sulphonylurea (e.g. glipizide, glimepiride, glibenclamide) or insulin.** Your doctor may want to reduce your dose of sulphonylurea or insulin when you take any of them together with Nesina in order to avoid too low blood sugar (hypoglycaemia).

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Nesina.**



Nesina can be taken with most other medicines.

## **4. How do I use Nesina?**

### **How much to take / use**

- The usual dose for this medicine is one 25 mg tablet once a day.
- If you have kidney problems your doctor may prescribe lower doses. This may be 12.5 mg or 6.25 mg once a day, depending on the severity of your kidney disease.
- Follow the instructions provided and take Nesina until your doctor tells you to stop.

### **When to take Nesina**

- Nesina should be taken at about same time each day.

### **How to take Nesina**

- Swallow the tablet whole with a glass of water.
- You can take Nesina with or without food.

### **If you forget to use Nesina**

Nesina should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

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

**Do not take a double dose to make up for the dose you missed.**

## **If you use too much Nesina**

If you think that you have used too much Nesina, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using Nesina?**

### **Things you should do**

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

**Keep all of your doctor's appointments so that your progress can be checked.**

- **Your doctor will do regular checks to help prevent you from having side effects from the medicine or developing serious complications of diabetes.**

**If you become ill or experience extra stress, injury, fever, infection or need surgery, tell your doctor.** Your blood glucose may become difficult to control at these times.

- **Make sure you keep enough medicine to last over weekends and holidays.** It is important to keep your blood glucose controlled at all times to prevent serious complications of diabetes from happening.

Remind any doctor, dentist or pharmacist you visit that you are using Nesina.

## **Things you should not do**

- Do not skip meals while taking Nesina.

## **Things to be careful of**

Be careful when doing any of the following things, which increases the risk of your blood glucose becoming too low:

- drinking alcohol
- not eating enough
- doing unexpected or vigorous exercise.

Hypoglycaemia may occur when Nesina is taken in combination with insulin or sulphonylureas (e.g. glipizide, glimepiride, glibenclamide). Your blood sugar could fall below the normal level and can be increased by taking sugar. Your doctor, pharmacist or diabetes educator

may have recommended that you carry some glucose tablets, sugar lumps, sweets, biscuits or sugary fruit juice.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Nesina affects you.**

Nesina may cause dizziness in some people.

If your blood glucose level becomes too low, you may feel dizzy, lightheaded, weak or tired and your reaction time may be slower than usual. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Alcohol increases the risk of your blood sugar becoming too low.

## **Looking after your medicine**

- Keep your tablets in the blister pack until it is time to take them.
- Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• stomach pain</li> <li>• indigestion, heartburn</li> <li>• headache</li> <li>• cold-like symptoms such as stuffy or runny nose, sore throat, feeling tired</li> <li>• rash</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• itchy skin</li> <li>• joint pain</li> </ul>	
<ul style="list-style-type: none"> <li>• blisters or the breakdown of the outer layer of your skin (erosion). Some people who take medicines called DPP-4 inhibitors, may develop a skin reaction called bullous pemphigoid.</li> </ul>	<p><b>Speak to your doctor immediately if you have any of these side effects.</b></p> <p><b>These side effects may require medical attention.</b></p>

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Related to allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• rash</li> <li>• hives</li> <li>• swallowing or breathing problems</li> <li>• swelling of your lips, face, throat or tongue</li> <li>• feeling faint</li> <li>• Stevens-Johnson syndrome: severe allergic reaction with</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p><b>Call your doctor straight away, or go straight to the Emergency Department at your</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>general itching and feeling of heat – especially affecting the scalp, mouth, throat, palms of hands or soles of feet.</p> <p><b>Related to possible pancreatitis:</b></p> <ul style="list-style-type: none"> <li>• severe and persistent pain around the top of your stomach which might reach into your back, often with nausea and vomiting.</li> </ul> <p><b>Related to possible liver problems:</b></p> <ul style="list-style-type: none"> <li>• yellowing of your skin or the whites of your eyes</li> <li>• nausea, loss of appetite</li> <li>• unusual or unexplained tiredness</li> <li>• dark urine</li> </ul> <p><b>Hypoglycaemia-related:</b></p> <ul style="list-style-type: none"> <li>• trembling, sweating, anxiety</li> <li>• blurred vision</li> <li>• tingling lips</li> <li>• paleness</li> </ul>	<p><b>nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• mood change</li> <li>• feeling confused</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

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

### **What Nesina contains**

<b>Active ingredient (main ingredient)</b>	alogliptin (as benzoate)
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<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• mannitol</li> <li>• microcrystalline cellulose</li> <li>• hypromellose</li> <li>• croscarmellose sodium</li> <li>• magnesium stearate</li> <li>• hypromellose</li> <li>• titanium dioxide (E171)</li> <li>• iron oxide red (CI77491) (present in 25 mg and 6.25 mg tablets)</li> <li>• iron oxide yellow (CI77492) (present in 12.5 mg tablets)</li> <li>• macrogol</li> <li>• edible ink gray F1 (printing ink)</li> </ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Nesina looks like**

Nesina comes in three strengths of tablets:

- **Nesina 25 mg** tablets are light red, oval, biconvex, with "TAK" and "ALG-25" printed in grey ink on one side. AUST R 199539
- **Nesina 12.5 mg** tablets are yellow, oval, biconvex, with "TAK" and "ALG-12.5" printed in grey ink on one side. AUST R 199543

- **Nesina 6.25 mg** tablets are light pink, oval, biconvex, with "TAK" and "ALG-6.25" printed in grey ink on one side. AUST R 199541

Nesina is available in blister packs of 28 tablets.

## **Who distributes Nesina**

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney, NSW 2000

Australia

Tel: 1800 012 612 [www.takeda.com/en-au](http://www.takeda.com/en-au)

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