

Nesina Met[®]

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.

1. Why am I using Nesina Met?

Nesina Met contains the active ingredients alogliptin (as benzoate) and metformin hydrochloride. Nesina Met 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 Met?](#) in the full CMI.

2. What should I know before I use Nesina Met?

Do not use if you have ever had an allergic reaction to Nesina Met 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 Met?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Nesina Met 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 Met?

- Swallow your tablet whole with water.
- You should take this medicine with food to reduce your chance of an upset stomach.
- Your doctor will tell you exactly how much Nesina Met you need to take. The usual dose is one tablet twice a day.

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

5. What should I know while using Nesina Met?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Nesina Met. • 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.
Driving or using machines	• Be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.
Drinking alcohol	• Do not take this medicine with alcohol as you could be at greater risk of developing lactic acidosis, a serious complication which must be treated in a hospital.
Looking after your medicine	• Keep the medicine in a cool, dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects include stomach pain, nausea, vomiting, diarrhoea, loss of appetite, indigestion, heartburn, a metallic taste in your mouth, headache, cold-like symptoms and symptoms of vitamin B12 deficiency such as tiredness, a sore and red tongue, pins and needles, or pale or yellow skin. Serious side effects include a skin reaction called bullous pemphigoid blisters, allergic reaction including Stevens-Johnson syndrome, hypoglycaemia, pancreatitis-like symptoms, sign of liver problems, and in rare cases, metformin, one of the medicines in Nesina Met, can cause lactic acidosis (build-up of lactic acid in the blood), a life-threatening medical emergency.

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 Met

Active ingredient(s): Alogliptin (as benzoate) and metformin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nesina Met. **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 Met.**

Where to find information in this leaflet:

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

1. Why am I using Nesina Met?

Nesina Met contains two active ingredients alogliptin (as benzoate) and metformin hydrochloride.

Alogliptin belongs to a group of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). Alogliptin works to increase the levels of insulin in the body after a meal and decrease the amount of sugar in the body.

Metformin belongs to a group of medicines called biguanides which also help to lower blood sugar by lowering the amount of sugar made in the liver and helping insulin to work more effectively.

Both of these groups of medicines are known as "oral antidiabetics".

Nesina Met 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 Met?

Warnings

Do not use Nesina Met if:

- you are allergic to alogliptin or metformin, or any of the ingredients listed at the end of this leaflet.
- you have a condition called metabolic acidosis or have had diabetic ketoacidosis (increased ketones in your blood or urine).
- you are going to get an injection of dye or contrast agents for an x-ray procedure. Nesina Met will need to be stopped for a short time. Talk with your doctor about when you should stop Nesina Met and when you should start Nesina Met again.
- Always check the ingredients to make sure you can use this medicine.

Before you start taking Nesina Met discard any other medicines containing metformin or alogliptin that your doctor may have prescribed to you in the past and that you may still have in your possession. Accidental metformin overdosing is a significant safety risk.

Check with your doctor if you:

- are unsure if you have any other medicines containing metformin or alogliptin. Accidentally taking too much metformin can cause a very serious side effect called lactic acidosis.
- 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. Nesina Met should not be used in individuals with certain kidney problems.
- have liver problems.
- have heart problems.
- have any other medical conditions.
- are older than 80 years. You should not take Nesina Met unless your kidneys have been checked and they are normal.
- drink alcohol excessively either very often, or from time to time ("binge" drinking).
- have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- 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 Met is not recommended to be used during pregnancy. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant. **Talk to your doctor if you are breastfeeding or intend to breastfeed.** It is not known whether Nesina Met passes into breast milk.

Use in children and adolescents

- Nesina Met 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 or pharmacist if you are taking any of the following:

- corticosteroids (e.g., hydrocortisone, prednisolone), used to treat inflammation.
- cimetidine, used to treat stomach problems.
- bronchodilators (beta-2 agonists) which are used to treat asthma (e.g., salbutamol, terbutaline).
- ACE inhibitors, used to treat high blood pressure (e.g., ramipril, lisinopril, enalapril).
- diuretics, also called fluid tablets which increase urine production.
- cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, and vancomycin).
- other drugs that tend to produce hyperglycaemia (high blood sugar) and may lead to a loss of blood sugar control. Some examples of drugs that can increase the blood sugar include: phenothiazines, thyroid products, oestrogens or oestrogens plus progestogen, oral contraceptives, phenytoin, nicotinic acid, isoniazid.
- iodinated contrast agents or medicines containing alcohol.

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

Hypoglycaemia may occur when Nesina Met is taken in combination with insulin or sulphonylureas (e.g., gliclazide, 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.

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 Met.

4. How do I use Nesina Met?

How much to take

- The usual dose is one tablet twice a day.
- Your doctor will tell you exactly how much you need to take. The amount of Nesina Met will vary depending on your condition and the doses you currently take of metformin alone, metformin in combination with a thiazolidinedione (e.g., pioglitazone), insulin and/or individual tablets of alogliptin and metformin.
- Follow the instructions provided and use Nesina Met until your doctor tells you to stop.

When to take Nesina Met

- Nesina Met should be taken at the same time each day.

How to take Nesina Met

- Swallow your tablet whole with water.
- You should take this medicine with food to reduce your chance of an upset stomach.

If you forget to use Nesina Met

Nesina Met 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 Met

If you think that you have used too much Nesina Met, 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 Met?

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.
- Your doctor will do blood tests to check how well your kidneys are working and to check your vitamin B12

levels before and e and/or during your treatment with Nesina Met.

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 Met.

Things you should not do

- Do not skip meals while taking Nesina Met.
- Do not take this medicine with alcohol as you could be at greater risk of developing lactic acidosis, a serious complication which must be treated in a hospital.

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.

Driving or using machines

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

Nesina Met 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 and may increase the risk of developing lactic acidosis.

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

Less serious side effects	What to do
• stomach pain • nausea • vomiting • loss of appetite • indigestion, heartburn • a metallic taste in your mouth • diarrhoea • headache • cold-like symptoms such as stuffy or runny nose, sore throat, feeling tired • rash • itchy skin with or without hives • joint pain • symptoms of vitamin B12 deficiency such as tiredness, a sore and red tongue, pins and needles, or pale or yellow skin.	Speak to your doctor if you have any of these less serious side effects and they worry you.
• blisters or the breakdown of the outer layer of your skin (erosion). Some people who take medicines called DPP-4 inhibitors, like alogliptin, may develop a skin reaction called bullous pemphigoid.	Speak to your doctor immediately if you have any of these side effects. These side effects may require medical attention.

Serious side effects

Serious side effects	What to do
Related to allergic reaction: • rash • hives • swallowing or breathing problems • swelling of your lips, face, throat or tongue • feeling faint • Stevens-Johnson syndrome: severe allergic reaction with general itching and feeling of heat – especially affecting the	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.

Serious side effects	What to do
scalp, mouth, throat, palms of hands or soles of feet. Related to possible pancreatitis: - severe and persistent pain around the top of your stomach which might reach into your back, often with nausea and vomiting. Related to possible liver problems: - yellowing of your skin or the whites of your eyes - nausea, loss of appetite - unusual or unexplained tiredness - dark urine Hypoglycaemia-related: - trembling, sweating, anxiety - blurred vision - tingling lips - pale skin - mood change - feeling confused Related to possible lactic acidosis: - feeling cold or uncomfortable - feeling tired or weak - feeling dizzy or lightheaded - severe nausea with or without vomiting - abdominal pain - muscle pain - slow or irregular heartbeat - unexplained weight loss - rapid or difficult breathing	

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. 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 Met contains

Active ingredient (main ingredient)	alogliptin (as benzoate) and metformin hydrochloride
Other ingredients (inactive ingredients)	- mannitol - microcrystalline cellulose - povidone - croscopovidone - magnesium stearate - hypromellose - purified talc - titanium dioxide - iron oxide yellow (CI77492)

Do not take this medicine if you are allergic to any of these ingredients.

What Nesina Met looks like

Nesina Met comes in three strengths of tablets:

- Nesina Met 12.5mg/500 mg** tablets are pale yellow, oblong, biconvex, with "12.5/500" debossed on one side and "322M" debossed on the other side. AUST R 202308
- Nesina Met 12.5mg/850 mg** tablets are light yellow, oblong, biconvex, with "12.5/850" debossed on one side and "322M" debossed on the other side. AUST R 202306
- Nesina Met 12.5mg/1000 mg** tablets are pale yellow, oblong, biconvex, with "12.5/1000" debossed on one side and "322M" debossed on the other side. AUST R 202309

Nesina Met is available in blister packs of 14 (sample) and 56 tablets.

* Not all pack sizes may be available.

Who distributes Nesina Met

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