

NIDEM

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 NIDEM?

NIDEM contains the active ingredient gliclazide. NIDEM is used to control blood glucose in people with Type 2 diabetes mellitus when diet and exercise are not enough to control your blood glucose.

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

2. What should I know before I use NIDEM?

Do not use if you have ever had an allergic reaction to gliclazide, or other sulphonylurea, sulfonamide (sulfur) antibiotics, certain types of fluid tablets (thiazide diuretics), 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 NIDEM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NIDEM 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 NIDEM?

Swallow the tablets with a glass of water at about the same time each day, usually with breakfast.

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

5. What should I know while using NIDEM?

Things you should do	<ul style="list-style-type: none">• Tell any doctors, dentists and pharmacists who are treating you that you are taking NIDEM.• Check your blood glucose levels regularly to know if your diabetes is being controlled properly.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking it or change the dose without checking with your doctor.• Do not give this medicine to anyone else, even if their symptoms are similar to yours.• Do not skip meals while taking NIDEM.
Driving or using machines	<ul style="list-style-type: none">• NIDEM may cause dizziness in some people. Drinking alcohol can make this worse. If either of these occur, do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol while taking NIDEM, you may get flushing, headache, breathing difficulties, rapid heart beat, stomach pains or feel sick and vomit.
Looking after your medicine	<ul style="list-style-type: none">• Keep NIDEM Tablets in a cool dry place where the temperature is below 30°C.

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

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The serious side effects are: Skin rash, redness itching and/or hives, blisters, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty), and rash progressing to widespread blistering or peeling of the skin and may be the first sign of rare life-threatening conditions. The common side effects are Hypoglycaemia, hyperglycaemia (for more information, see section on recognising and treating hypoglycaemia and hyperglycaemia), runny or blocked nose, sneezing, facial pressure or pain, bronchitis, sore throat and discomfort when swallowing, upper respiratory infection, coughing, back pain, arthralgia, arthrosis, high blood pressure, chest pain, headache, unusual weakness, viral infection, urinary tract infection, dizziness, stomach upset with symptoms like feeling sick, stomach pain, vomiting, diarrhoea, or constipation.

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.

NIDEM Tablets

Active ingredient: *gliclazide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NIDEM tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking NIDEM against the benefits this medicine is expected to have for you.

Talk to your doctor, pharmacist or diabetes educator if you have any concerns about taking this medicine.

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

Where to find information in this leaflet:

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

1. Why am I using NIDEM?

NIDEM is used to control blood glucose in people with Type 2 diabetes mellitus. This type of diabetes is also called non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

NIDEM is used when diet and exercise are not enough to control your blood glucose levels. It can be used alone, or in combination with other medicines for treating diabetes.

NIDEM is available only with a doctor's prescription.

How it works:

NIDEM belongs to a group of medicines called sulphonylureas. These medicines lower blood glucose by increasing the amount of insulin produced by your pancreas.

If your blood glucose is not properly controlled, you may experience hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose).

Hypoglycaemia

Hypoglycaemia (low blood glucose) can occur suddenly. Signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration

- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness

Hyperglycaemia

Hyperglycaemia (high blood glucose) usually occurs more slowly than hypoglycaemia. Signs of hyperglycaemia may include:

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

Long-term hyperglycaemia can lead to serious health problems such as heart disease, blindness, poor blood circulation, gangrene, and kidney damage.

2. What should I know before I use NIDEM?

Warnings

Do not use NIDEM if:

- **you are allergic to:**
 - medicines containing gliclazide or any other sulphonylurea
 - sulfonamide (sulfur) antibiotics
 - certain types of fluid tablets (thiazide diuretics)
 - any of the ingredients listed at the end of this leaflet.
- **you have any of the following medical conditions:**
 - type 1 diabetes mellitus that is well controlled by insulin alone
 - unstable diabetes that is not well controlled
 - diabetic acidosis
 - diabetic coma
 - severe kidney disease
 - you are taking an antibiotic medicine containing the active ingredient miconazole
 - severe liver disease.
- **you are pregnant or plan to become pregnant.**
- **you are breastfeeding or plan to breastfeed.**
- **the expiry date (Exp.) printed on the pack has passed.**
- **the packaging shows signs of tampering or the tablets do not look quite right.**

If you are not sure whether you should be taking NIDEM, talk to your doctor.

Check with your doctor or pharmacist if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
 - liver problems
 - kidney problems
 - a history of diabetic coma
 - heart failure
 - adrenal, pituitary or thyroid problems.
- have a family history of or know you have the hereditary condition glucose-6- phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur.
- have any medical condition, or do anything, that may increase the risk of hyperglycaemia - for example:
 - you are ill or feeling unwell (especially with fever or infection).
 - you are injured.
 - you are having surgery.
 - you are taking less exercise than normal.
 - you are eating more carbohydrate than normal.
 - drinking alcoholic drinks.
 - not eating regular meals.
 - taking more exercise than usual.
- take any medicines for any other condition.

Alcohol, diet, exercise and your general health all strongly affect the control of your diabetes.

Discuss these with your doctor.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given NIDEM.

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

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

This medicine may affect your developing baby if you take it during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will usually replace NIDEM with insulin while you are pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed.

NIDEM passes into breast milk and your baby may be harmed.

If you have not told your doctor about any of the above, tell him/her before you start taking NIDEM.

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.

Some medicines may be affected by NIDEM or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will advise you.

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

- some medicines used to treat fungal or yeast infections (miconazole which is contraindicated)
- alcohol
- other medicines used to treat diabetes (such as biguanides and insulin)
- some medicines used to treat high blood pressure and other heart conditions (including angiotensin receptor blocker, beta-blockers)
- some medicines used to treat depression and other mental illness (MAOIs)
- some cholesterol-lowering medicines (clofibrate)
- some medicines used to treat arthritis, pain and inflammation (including high dose aspirin, ibuprofen, phenylbutazone)
- some antibiotics (chloramphenicol; tetracyclines; long-acting sulphonamides)
- some medicines used to treat acid reflux and stomach ulcers

Some medicines may lead to high blood glucose (hyperglycaemia) by weakening the blood glucose lowering effect of NIDEM. These include:

- alcohol
- some medicines for epilepsy (danazol)
- some medicines used to treat depression and other mental illness (chlorpromazine)
- some hormones used in hormone replacement therapy and oral contraceptives (oestrogen, progesterone)
- St John's Wort (*Hypericum perforatum*) preparations used to treat depression
- some medicines for asthma (salbutamol, intravenous terbutaline).
- barbiturates, medicines used for sedation
- glucocorticoids

Some medicines may lead to unstable blood glucose (low blood sugar and high blood sugar) when taken at the same time as NIDEM, especially in elderly patients. These include:

- A class of antibiotics called fluoroquinolones.

NIDEM may change the effects of some other medicines. These include:

- some medicines used to prevent blood clots (warfarin)

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 NIDEM.

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

4. How do I use NIDEM?

How much to take

Take Gliclazide tablets exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. 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.

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

When to take / use NIDEM

Swallow the tablets with a glass of water.

NIDEM tablets can be broken in half. However, they should not be crushed or chewed. Crushing or chewing the tablets may change the effectiveness of the tablet.

It is important to take your NIDEM at the same time each day - usually with breakfast. Taking NIDEM with food can help to minimise the risk of hypoglycaemia.

Do not skip meals while taking NIDEM.

If you forget to use NIDEM

NIDEM should be used regularly at the same time each day, usually with breakfast. If you miss your dose at the usual time, take another as soon as possible. Then go on as before.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as you remember (with food), then go back to taking your tablets as you would normally.

Missed doses can cause high blood glucose (hyperglycaemia).

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you double a dose, this may cause low blood glucose (hypoglycaemia).

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much NIDEM

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

If you take too much NIDEM together with other medicines for diabetes or alcohol, you may experience symptoms of low blood glucose (hypoglycaemia).

If not treated quickly, these symptoms 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 quickly by following the instructions at "Recognising and treating hypoglycaemia", [Section 5. What should I know while using NIDEM?](#)

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

5. What should I know while using NIDEM?

Things you should do

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

Tell all doctors, dentists, pharmacists and diabetes educators who are involved with your treatment that you are taking NIDEM.

If you are about to start any new medicine, tell your doctor or pharmacist that you are taking NIDEM.

Take NIDEM exactly as your doctor has prescribed. Otherwise you may not get the full benefits from treatment.

Continue taking NIDEM for as long as your doctor recommends. Make sure you keep enough NIDEM to last over weekends and holidays. NIDEM will help control your diabetes but will not (cure) it. Therefore, you may have to take it for a long time.

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.

Make sure that you, your friends, family, and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them. Instructions for recognising and treating hypoglycaemia and hyperglycaemia in this section can help you with this.

Visit your doctor regularly so that they can check on your progress. Carefully follow your doctor's and dietician's advice on diet, drinking alcohol and exercise.

Tell your doctor immediately if you notice the return of any symptoms of hyperglycaemia that you had before starting NIDEM.

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

Protect your skin when you are in the sun, especially between 10am and 3pm.

Sulphonylureas (the group of medicines that Gliclazide Lupin MR belongs to) may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn.

If outdoors, wear protective clothing and use a 30+ sunscreen. Also, be especially careful not to let your blood glucose levels fall too low.

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 Gliclazide Lupin MR readily available.

If you become sick with a cold, fever or flu, it is very important to continue taking Gliclazide Lupin MR, 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 dietician can give you a list of foods to use for sick days.

Call your doctor straight away if you:

- notice the return of any symptoms of NIDEM. These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision. These may be signs that NIDEM is no longer working, even though you.
- are pregnant or planning to become pregnant, or are breastfeeding.
- notice your skin does appear to be burning despite wearing protective clothing and using a 30+ sunscreen outdoors.
- Develop/get any new medical condition, or do anything unusual, that may increase the risk of hyperglycaemia-for example:
 - you are ill or feeling unwell (especially with fever or infection);
 - you are injured;
 - you are having surgery;
 - taking less Gliclazide Lupin MR than prescribed;
 - you are taking less exercise than normal;
 - you are eating more carbohydrate than normal;
 - drinking alcoholic drinks;
 - not eating regular meals;
 - taking more exercise than usual.

Remind any doctor, dentist, pharmacist, or diabetes educators you visit that you are NIDEM

Things you should not do

- Do not stop using this medicine or change the dosage, without checking with your doctor.
- Do not give NIDEM to anyone else, even if they have the same condition as you.
- Do not use NIDEM to treat other complaints unless your doctor tells you to.
- Do not skip meals while taking NIDEM

Recognising and treating hypOGlycaemia (very LOW blood sugar levels)

Hypoglycaemia may occur during NIDEM treatment.

The first signs of hypoglycaemia are usually weakness, trembling or shaking, sweating, lightheadedness, dizziness, headache or lack of concentration, irritability, tearfulness, hunger, and/ or numbness around the lips and tongue.

At the first signs of hypoglycaemia take some sugar to raise your blood sugar level quickly.

Do this by eating 5 to 7 jelly beans, 3 teaspoons of sugar or honey, drinking half a can of non-diet soft drink, taking 2-3 glucose tablets or a tube of glucose gel.

Then take some extra carbohydrates

such as plain biscuits, fruit or milk - unless you are within 10-15 minutes of your next meal. Taking this extra carbohydrate will help to prevent a second drop in your blood glucose level.

If not treated quickly, hypoglycaemia symptoms may progress to loss of co-ordination, slurred speech, confusion, fits or loss of consciousness.

If hypoglycaemia symptoms do not get better straight away after taking sugar then go to the Accident and Emergency department at your nearest hospital - if necessary by calling an ambulance.

Contact your doctor or diabetes educator for advice if you are concerned about hypoglycaemia.

Recognising and treating hyperGlycaemia (HIGH blood sugar levels)

Some people may feel fine when their glucose levels are high. Others notice symptoms of hyperglycaemia like tiredness, lack of energy, thirst, passing large amounts of urine, headache, and/or blurred vision.

If you notice symptoms of hyperglycaemia, or your blood sugar levels are high, tell your doctor immediately. You may need adjustments of the dose or type of medicines you are taking.

It is very important to control high blood glucose whether or not you feel unwell. This really helps to avoid serious long-term health Problems, which can involve the heart, eyes, circulation, and/or kidneys.

If you experience any of the signs of hyperglycaemia (high blood glucose) contact your doctor or diabetes educator for advice immediately

Driving or using machines

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

Also, be especially careful not to let your blood glucose levels fall too low.

Gliclazide may cause dizziness or drowsiness in some people. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery.

If this occurs, do not drive, operate machinery or do things that could be dangerous if you are not alert.

A section at the end of this leaflet contains advice about recognising and treating hypoglycaemia.

Drinking alcohol can make this worse. If either of these occurs, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol while taking NIDEM, you may get flushing, headache, breathing difficulties, rapid heart beat, stomach pains or feel sick and vomit.

Looking after your medicine

- Keep NIDEM tablets in the original pack until it is time to take them.
- Keep NIDEM tablets in a cool dry place where the temperature is below 30°C.

Do not store NIDEM, or any other medicine, in the bathroom or near a sink.

Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

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.

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

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • HyPOglycaemia and hyPERglycaemia. Section 5 of this leaflet contains advice about recognising and treating hyPOglycaemia and hyPERglycaemia. • Runny or blocked nose, sneezing, facial pressure or pain, bronchitis, sore throat and discomfort when swallowing, upper respiratory infection, coughing. • Back pain, arthralgia, arthrosis. • High blood pressure, chest pain. • Headache, unusual weakness. • Viral infection, urinary tract infection. • Dizziness. • Stomach upset with symptoms like feeling sick, stomach pain, vomiting, diarrhoea, or constipation. • Decrease in the number of cells in the blood (eg. platelets, red and white blood cells) which may cause paleness, prolonged bleeding, bruising, sore throat and fever have been reported. These symptoms usually vanish when the treatment is discontinued. • Increase of some hepatic enzyme levels, and exceptionally a liver disease. • Your vision may be affected for a short time especially at the start of treatment. This effect is due to changes in blood sugar levels. 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Skin rash, redness itching and/or hives, blisters, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue, or throat that may result in breathing difficulty) have been reported. Rash may progress to widespread blistering or peeling of the skin and may be 	<p>Stop taking NIDEM and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

<p>the first sign of rare life-threatening conditions (eg. Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and severe hypersensitivity reactions (DRESS)). Exceptionally, DRESS have been reported initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature.</p> <ul style="list-style-type: none"> As for other sulphonylureas, the following adverse events have been observed: cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), symptoms of liver impairment (eg. jaundice) which in most cases disappeared after withdrawal of the sulphonylurea, but may lead to life-threatening liver failure in isolated cases. 	<p>notice any of these serious side effects.</p>
---	---

Potential allergens	The tablets contain sugars as lactose.
----------------------------	--

NIDEM does not contain gluten, sucrose, tartrazine or any other azo dyes.

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

What NIDEM looks like

NIDEM is a white to off white round, bevel-edged, uncoated tablet with cross score (+) on one face and plain on the other. AUST R 79023

The tablets are available in blister pack of 100's.

Who distributes NIDEM

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in January 2025

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 available with a doctor's prescription.

What NIDEM contains

Active ingredient (main ingredient)	gliclazide
Other ingredients (inactive ingredients)	<p>NIDEM tablets contain:</p> <ul style="list-style-type: none"> lactose monohydrate microcrystalline cellulose povidone sodium starch glycollate type A purified talc magnesium stearate.