Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking MINIDIAB?

MINIDIAB contains the active ingredient glipizide. MINIDIAB is used in addition to diet and exercise to control blood sugar in patients with Type II diabetes mellitus. For more information, see Section <u>1. Why am I taking MINIDIAB</u>? in the full CMI.

2. What should I know before I take MINIDIAB?

Do not take if you have ever had an allergic reaction to: glipizide or any ingredients listed at the end of the CMI, other sulphonylureas, sulfur antibiotics (e.g. sulphonamides) or thiazide diuretics (e.g. chlorothiazide). Do not take if you have or have had Type I diabetes mellitus (insulin dependent diabetes mellitus), diabetic ketoacidosis with or without coma, severe kidney or liver disease, severe thyroid disease, you are pregnant, severe or unstable diabetes, infection or high temperature, gangrene, severe trauma, major surgery. Tell your doctor if you have or ever had kidney or liver problems, adrenal or pituitary or thyroid problems, haemolytic anaemia or G6PD deficiency. Tell your doctor if you drink alcohol, do not eat regular meals, do a lot of heavy exercise, you are feeling ill or unwell. **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 take MINIDIAB? in the full CMI.

3. What if I am taking other medicines?

Some medicines and MINIDIAB may interfere with each other. A list of these medicines is in Section <u>3. What if I am taking other</u> <u>medicines?</u> in the full CMI.

4. How do I take MINIDIAB?

The dose varies from patient to patient. Your doctor will recommend how many tablets to take each day. Swallow your tablets with a glass of water. More instructions can be found in Section <u>4. How do I take MINIDIAB?</u> in the full CMI.

5. What should I know while taking MINIDIAB?

| Things you should do | Tell your doctor if you become pregnant, ill or experience extra stress, injury, fever, infection or need surgery. Tell your doctor immediately if you experience signs of high blood glucose or notice the return of any symptoms you had before starting MINIDIAB. Remind any doctor, dentist or pharmacist you visit that you are taking MINIDIAB. |
|--------------------------------|---|
| Things you should not do | Do not stop taking MINIDIAB or change the dose without first checking with your doctor. Do not skip meals while taking MINIDIAB. |
| Driving or using machines | MINIDIAB may cause dizziness and drowsiness in some people. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery. |
| Drinking alcohol | Tell your doctor if you drink alcohol. Drinking alcohol while taking MINIDIAB may make you feel sick. Drinking alcohol may also give you a headache, stomach pains, flushing, breathing difficulties or a rapid heartbeat. |
| Looking after your medicine | Store below 30 °C. Keep your tablets in the blister pack until it is time to take them. |

For more information, see Section 5. What should I know while taking MINIDIAB? in the full CMI.

6. Are there any side effects?

Side effects: low blood glucose (weakness, trembling/shaking, sweating, light-headedness, headache, dizziness, sleepiness, irritability, tearfulness/crying, hunger, lack of concentration), confusion, loss of appetite, feeling generally unwell, nausea, vomiting, stomach cramps/pain, diarrhoea, constipation, rashes, sores, redness, itching, eczema, sunburn, blistering, visual disturbances, yellow skin/eyes, dark coloured urine, bleeding/bruising, reddish/purplish blotches, frequent infections, fever, tiredness, shortness of breath, looking pale, seizures, allergic reaction (wheezing, swelling of face/mouth/tongue/throat, difficulty swallowing or breathing, hives, raised red, itchy spots). For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

Active ingredient(s): glipizide

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- 1. Why am I taking MINIDIAB?
- 2. What should I know before I take MINIDIAB?
- 3. What if I am taking other medicines?
- 4. How do I take MINIDIAB?
- 5. What should I know while taking MINIDIAB?
- 6. <u>Are there any side effects?</u>
- 7. Product details

1. Why am I taking MINIDIAB?

MINIDIAB contains the active ingredient glipizide.

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

MINIDIAB is used in addition to diet and exercise to control blood sugar in patients with Type II diabetes mellitus. This type of diabetes is also known as non-insulin-dependent diabetes mellitus (NIDDM).

MINIDIAB is used when diet and exercise are not enough to control blood sugar (glucose). MINIDIAB can be used alone, or together with insulin or other medicines for treating diabetes.

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 or kidneys.

Hypoglycaemia (low blood glucose) 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 properly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- loss of consciousness or fitting.

Hyperglycaemia (high blood glucose) usually occurs more slowly than low blood glucose.

Signs of high blood glucose may include:

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

Ask your doctor if you have any questions about why MINIDIAB has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

There is no evidence that MINIDIAB is addictive.

2. What should I know before I take MINIDIAB?

Warnings

Do not take MINIDIAB if you are allergic to or have experienced allergic reactions to:

- glipizide or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- other sulphonylureas
- sulfur antibiotics (e.g. sulphonamides)
- thiazide diuretics (e.g. chlorothiazide).

Do not take MINIDIAB if you have or have had any of the following medical conditions:

- Type I diabetes mellitus (insulin dependent diabetes mellitus)
- you have diabetic ketoacidosis with or without coma
- severe kidney disease
- severe liver disease
- severe thyroid disease
- you are pregnant
- severe or unstable diabetes
- you have an infection or high temperature
- you have gangrene
- you have severe trauma
- you are about to undergo major surgery.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- adrenal or pituitary or thyroid problems
- haemolytic anaemia or G6PD deficiency (a condition where the body does not have enough of the enzyme glucose-6-phosphate dehydrogenase).

Tell your doctor if:

you ever drink alcohol

- you do not eat regular meals
- you do a lot of heavy exercise
- you are feeling ill or unwell.

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

Discuss these things with your doctor.

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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

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

You should not take MINIDIAB if you are pregnant or intend to become pregnant.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor may replace MINIDIAB with insulin.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should not take MINIDIAB if you are breastfeeding or intend to breastfeed.

It is not known whether MINIDIAB passes into breast-milk. There could be a possibility that your baby may be affected.

Use in Children

MINIDIAB should not be used in children.

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

3. What if I am taking other medicines?

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

Some medicines and MINIDIAB may interfere with each other.

Some medicines may lead to low blood glucose (hypoglycaemia) by increasing the blood-glucoselowering effect of MINIDIAB.

These include:

- alcohol
- some medicines used to treat high blood pressure or other heart conditions (beta-blockers, ACE inhibitors, diazoxide)
- some medicines used to treat arthritis, pain and inflammation (salicylates e.g. aspirin; non-steroidal anti-inflammatory drugs)
- some antibiotics (e.g. chloramphenicol, sulphonamides and others)

Tell your doctor or pharmacist if you are on antibiotic treatment.

- some medicines used to treat fungal infections (miconazole, fluconazole, voriconazole)
- medicines used to prevent blood clots (coumarin derivatives)
- some cholesterol-lowering medicines (clofibrate)
- other medicines used to treat diabetes (biguanides)
- probenecid (a medicine used to treat gout or to increase the blood levels of some antibiotics)
- some medicines used to treat depression (monoamine oxidase inhibitors)
- some medicines used to treat reflux and ulcers (H2 receptor antagonists e.g. cimetidine)
- some medicines used to treat cancer (cyclophosphamide).

Some medicines may lead to a loss of control of your diabetes by lowering the effect of MINIDIAB on blood glucose.

These include:

- some medicines used to treat high blood pressure (calcium channel blocking medicines)
- glucagon, a medicine used to treat low blood glucose
- corticosteroids such as prednisone and cortisone
- some medicines used to treat tuberculosis (isoniazid)
- nicotinic acid (used for the lowering of blood fats)
- estrogens, progestogens, oral contraceptives and certain other hormonal treatments such as danazol.

These medicines are used for example in birth control, menopausal hormone therapy (MHT) or to treat other women's health problems.

- some medicines used to treat mental illness or psychotic disorders (phenothiazines)
- phenytoin, a medicine used to treat epilepsy (convulsions)
- diuretics, also known as fluid tablets (thiazides)
- some asthma medicines, preparations for coughs and colds, and weight-reducing medicines
- thyroid hormones
- some medicines used to treat cancer (cyclophosphamide).

MINIDIAB may change the effect of some other medicines. These include:

barbiturates (used for sedation).

You may need different amounts of your medicine or you may need to take different medicines.

Tetracycline, a type of antibiotic, can interfere with the measurement of glucose in the urine.

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 MINIDIAB.

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

4. How do I take MINIDIAB?

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

These 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 dose varies from patient to patient.

Your doctor will recommend how many tablets to take each day.

The usual starting dose is 1 tablet taken before breakfast. However, a lower starting dose may be needed in older people or those with liver problems.

Your doctor may increase or decrease the dose depending on your blood glucose levels.

How to take it

Swallow your tablets with a glass of water.

When to take it

For best control of blood sugar, MINIDIAB should be taken about half an hour before meals. Your doctor may recommend that you take your tablet(s) just once a day or may divide the dose so that it is taken more than once a day.

Do not skip meals while taking MINIDIAB.

How long to take it

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

If you forget to take it

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 soon as you remember, then go back to taking your tablets as you would do normally.

Missed doses can cause high blood glucose (hyperglycaemia).

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

If you miss more than one dose or are not sure what to do, check with your doctor or pharmacist.

If you take too much

If you think that you have taken too much MINIDIAB, 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.

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

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

If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, loss of consciousness and fitting. If you experience any of these symptoms, immediately get medical help.

5. What should I know while taking MINIDIAB?

Things you should do

Call your doctor straight away if you:

become pregnant while taking MINIDIAB

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

Remind any doctor, dentist or pharmacist you visit that you are taking MINIDIAB.

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

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

If you experience any of the signs of high blood glucose (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 MINIDIAB
- taking 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 may be difficult to control at these times. Your doctor may decide to change your treatment and use insulin instead of MINIDIAB.

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 regularly so that they can check on your progress.

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

Tell your doctor immediately if you notice the return of any symptoms you had before starting MINIDIAB. These may include lethargy or tiredness, headache, thirst, passing of large amounts of urine and blurred vision. These may be signs that MINIDIAB is no longer working, even though you may have been taking it successfully for some time.

Things you should not do

- Do not stop taking MINIDIAB or change the dose without first checking with your doctor
- Do not give MINIDIAB to anyone else even if they have the same condition as you
- Do not skip meals while taking MINIDIAB.

Things to be careful of

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

MINIDIAB may cause your skin to be more sensitive to sunlight than it is normally.

If outdoors, wear protective clothing and use a minimum of SPF 30+ sunscreen. If your skin does appear to be burning, tell your doctor immediately.

Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.

Driving or using machines

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

Be careful not to let your blood glucose levels fall too low. MINIDIAB may cause dizziness and drowsiness in some people. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol while taking MINIDIAB may make you feel sick. You may also have a headache, stomach pains, flushing, breathing difficulties or rapid heartbeat.

Things that would be helpful for your condition

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

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 e.g. jelly beans, sugar sachets
- carry emergency food rations in case of delay e.g. dried fruit, biscuits
- keep MINIDIAB readily available.

If you become sick with a cold, fever or flu, it is very important to continue taking MINIDIAB, 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.

Looking after your medicine

- Store below 30°C
- Keep your tablets in the blister pack until it is time to take them. The blister packaging will help protect the tablets.

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 take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take 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.

Side effects

| Side effects | What to do |
|---|--|
| signs of low blood glucose (hypoglycaemia) which may include weakness, trembling or shaking, sweating, light- headedness, headache, dizziness, sleepiness, irritability, tearfulness or crying, hunger and lack of concentration confusion, shaking and feeling generally unwell. These may be experienced but are usually mild and transient. However, they may also be symptoms of hypoglycaemia stomach upset including nausea (feeling sick), vomiting and stomach cramps or pain | Speak to your doctor if you have any of these side effects and they worry you. |

| Side effects | What to do |
|--|--|
| diarrhoea or constipation rashes, sores, redness, itching, or eczema Sometimes these effects may disappear following continued | Speak to your doctor if you have any of these side effects and |

| Side effects | What to do |
|---|--------------------|
| treatment but you should ask your doctor for advice if you experience skin problems while taking MINIDIAB. | they worry you. |
| visual disturbances which may include blurred vision, double vision and abnormal vision | |
| These may be experienced but are usually mild and transient. However, they may also be symptoms of hypoglycaemia. | |
| symptoms of sunburn such as redness, itching and blistering which may occur more quickly than normal. | |

Side effects

| Side effects | What to do |
|---|--|
| yellowing of the skin or eyes (also called jaundice) bleeding or bruising more easily than normal, reddish or purplish blotches under the skin signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers signs of anaemia such as tiredness, being short of breath, looking pale and having seizures (or fits) signs of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin or eyes, and dark coloured urine signs of allergic reaction such as shortness of breath, wheezing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, skin rash including hives, raised red, itchy spots. | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects. |

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 <u>www.tga.gov.au/reporting-problems</u>. 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 MINIDIAB contains

| Active ingredient | glipizide |
|-------------------|---------------------|
| (main ingredient) | |
| Other ingredients | cellulose |
| (inactive | maize starch |
| ingredients) | stearic acid |
| | lactose monohydrate |

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

What MINIDIAB looks like

MINIDIAB tablets are white, round, biconvex and scored so that they can be broken in half. Each pack contains 100 tablets in blister strips (AUST R 15421).

Who distributes MINIDIAB

Pfizer Australia Pty Ltd Sydney NSW Toll Free Number: 1800 675 229 www.pfizermedinfo.com.au

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