

MINIDIAB^{*} TABLETS

Glipizide

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking MINIDIAB. This leaflet answers some common questions about MINIDIAB. It does not contain all the available information and 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 MINIDIAB against the benefits they expect it will have for you.

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

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

1. What MINIDIAB is used for

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) or maturity onset diabetes.

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.

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

There is no evidence that MINIDIAB is addictive.

How MINIDIAB works

MINIDIAB belongs to a group of medicines called sulphonylureas. These medicines lower high 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). 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

2. Before you take MINIDIAB

Some information is provided below. However, always talk to your doctor if you have concerns or questions about your treatment.

When MINIDIAB must not be taken

Do not take MINIDIAB if you have an allergy to:

- MINIDIAB and other medicines containing glipizide
- other sulphonylureas
- sulfur antibiotics (eg. sulphonamides) or thiazide diuretics (eg. chlorothiazide)
- any of the ingredients listed under 7 (b) at the end of this leaflet.

Symptoms of an allergic reaction to MINIDIAB may include skin

rash and itching. If you are not sure if you have or have had an allergic reaction to MINIDIAB, check with your doctor.

Do not take MINIDIAB if:

1. you have any of the following conditions:

- Type I diabetes mellitus (insulin dependent diabetes mellitus)
- diabetes ketoacidosis with or without coma
- severe kidney disease
- severe liver disease
- severe thyroid disease
- severe or unstable diabetes
- infection or high temperature
- gangrene
- severe trauma
- major surgery

If you are not sure about any of the above, ask your doctor.

2. you are pregnant or intend becoming pregnant.

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

3. you are breast-feeding or plan to breast-feed.

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

4. the packaging is torn or shows signs of tampering or the tablets do not look quite right.

5. the expiry date (Exp.) on the carton has passed.

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

Do not give MINIDIAB to children. There is not enough evidence to recommend the use of MINIDIAB in children.

If you are not sure if you should start taking MINIDIAB, talk to your doctor.

Before you start taking MINIDIAB

Tell your doctor if:

1. you are allergic to any other medicines or any other substances such as foods, preservatives or dyes.

2. you have or have had any of the following conditions:

- kidney problems
- liver problems
- adrenal or pituitary or thyroid problems
- hemolytic 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. If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you start taking MINIDIAB.

Taking other medicines

Tell your doctor, pharmacist or diabetes educator if you are

taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines and MINIDIAB may interfere with each other.

a. Some medicines may lead to low blood glucose (hypoglycaemia) by increasing the blood-glucose-lowering 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 eg. aspirin; non-steroidal anti-inflammatory drugs)
- some antibiotics (sulphonamides, chloramphenicol)
- medicines used to prevent blood clots (coumarin derivatives)
- some medicines used to treat fungal infections (miconazole, fluconazole)
- 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 eg. cimetidine)
- some medicines used to treat cancer (cyclophosphamide)

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

These include:

- alcohol
- 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)
- oestrogens, progestogens, oral contraceptives and certain other hormonal treatments such as danazol. These medicines are used for example in birth control, Hormone Replacement Therapy (HRT), 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 (sympathomimetics)
- thyroid hormones
- some medicines used to treat cancer (cyclophosphamide)

c. MINIDIAB may change the effect of some other medicines.

These include:

- barbiturates (used for sedation)

Tetracycline, a type of antibiotic, can interfere with the

measurement of glucose in the urine.

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

3. How to take MINIDIAB

(a) How to 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.

(b) 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.

(c) When to take it

Swallow your tablets whole with a glass of water.

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 given more than once a day.

Do not skip meals while taking MINIDIAB.

(d) How long to take MINIDIAB

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.

(e) 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 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.

(f) If you take too much (overdose)

If you think that you or anyone else may have taken too much MINIDIAB, immediately telephone your doctor or Poisons Information Centre for

advice – the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 0800 764 766 – or go to Accident and Emergency (Casualty) at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

If you take too much MINIDIAB, you may experience symptoms of 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.

4. While taking MINIDIAB

Things you must do

If you become pregnant while taking MINIDIAB, tell your doctor.

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

Tell all doctors, dentists and pharmacists who are treating you 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
- certain other medicines (refer Section 2, Taking other medicines, part (b))
- too little exercise
- eating more carbohydrate than normal

If you become ill, or experience extra stress, injury, fever, injection 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 dietitian'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 must 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 15+ sunscreen. If your skin does appear to be burning, tell your doctor immediately. Exposure to sunlight may cause a skin rash, itching, redness or a severe sunburn.

Be careful driving or operating machinery until you know how MINIDIAB affects you. Also, 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.

Make sure you know how you react to MINIDIAB before you drive a car or operate machinery.

If you drink alcohol while taking MINIDIAB, you may feel sick, have a headache, stomach pains, flushing, breathing difficulties or rapid heartbeat.

Emergencies

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

Sick days

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 dietitian can give you a list of foods to use for sick days.

5. Side effects

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

MINIDIAB 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.

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.

Tell your doctor if you notice any of the following and they worry you:

- signs of hypoglycaemia which may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, 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.
- diarrhoea or constipation
- dizziness, sleepiness or headache. These may be experienced but are usually mild and transient. However, they may also be symptoms of hypoglycaemia.
- rashes, sores, redness, itching, or eczema. Sometimes these effects may disappear following continued treatment but you should ask your doctor for advice if you experience skin problems while taking MINIDIAB.
- unusual weight gain
- 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.

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

- symptoms of sunburn such as redness, itching and blistering which may occur more quickly than normal.
- 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 and looking pale.
- 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.

This is not a complete list of all possible side effects. Some people may get other side effects while taking MINIDIAB.

Tell your doctor if you notice anything that is making you feel unwell while you are taking MINIDIAB.

6. After treatment with MINIDIAB

(a) Storage

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

Keep your tablets in the blister pack until it is time to take them. The blister packaging will help protect the tablets.

Keep the pack in a cool, dry place where it stays below 25°C. Do not store MINIDIAB or any other

medicine, in a bathroom or near a sink. Do not leave MINIDIAB in the car or on window sills. Heat and dampness can destroy some medicines.

(b) Disposal

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

7. Product Description

(a) What MINIDIAB tablets look like

MINIDIAB tablets are white, round, convex and scored so that they can be broken in half. Each pack contains 100 tablets in blister strips.

(b) Ingredients

The active ingredient in MINIDIAB is glipizide. Each MINIDIAB tablet contains 5 milligrams of glipizide.

Each tablet also contains: cellulose, maize starch, stearic acid and lactose.

(c) Manufacturer and Supplier

MINIDIAB tablets are supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll Free Number: 1800 675 229

MINIDIAB tablets are supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland, New Zealand

Toll Free number: 0800 736 363

Australian Registration Number:

AUST R 15421

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