Consumer Medicine Information

What is in this leaflet

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.

What Minidiab is used for

What Minidiab does

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-insulindependent 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

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
- thirs
- 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.

Use in Children

Minidiab is not recommended for use in children.

Before you take Minidiab

When you must not take it Do not take Minidiab if you have an allergy to:

- · any medicines containing glipizide
- any of the ingredients listed at the end of this leaflet
- · other sulphonylureas
- sulfur antibiotics (e.g. sulphonamides) or thiazide diuretics (e.g. chlorothiazide).

Some of the symptoms of an allergic reaction may include:

- · shortness of breath
- · wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- · rash, itching or hives on the skin.

Do not take Minidiab if you have or have had 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.

Do 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.

Do not take Minidiab if 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 your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any other substances such as foods, preservatives or dyes.

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-6phosphate 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. Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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:

- · all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a 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-glucose-lowering effect of Minidiab.

These include:

- alcohol
- some medicines used to treat high blood pressure or other heart conditions (betablockers, 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)
- 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)
- 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
- · 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.

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

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.

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 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 (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 is 13 11 26 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.

While you are taking Minidiab

Things you must do

If you become pregnant while taking Minidiab, tell your doctor immediately.

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
- · 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

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

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.

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

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 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.

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

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

Tell your doctor if...

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

- 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.
- · diarrhoea or constipation
- 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.

 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. Tell your doctor as soon as possible if

Tell your doctor as soon as possible if you notice any of the following:

- 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.

Go to hospital if ...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- 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.

The above list includes serious side effects. You may need urgent medical attention or hospitalisation. 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 else that is making you feel unwell while you are taking Minidiab.

After taking Minidiab

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 30 $^{\circ}\mathrm{C}.$

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.

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.

Product description

What it 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.

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 monohydrate.

Supplier

Minidiab tablets are supplied in Australia by:

Pfizer Australia Pty Ltd Level 17, 151 Clarence Street Sydney NSW 2000 Toll Free Number: 1800 675 229 www.pfizer.com.au

Australian registration number AUST R 15421

Date of preparation

This leaflet was revised in October 2019.

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