

Glimel

contains the active ingredient *glibenclamide*

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Glimel.

It does not contain all of the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Glimel against the benefits they expect it will have for you.

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

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

What Glimel is used for

Glimel is used to control blood glucose in patients with type 2 diabetes mellitus.

This type of diabetes is also known as non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

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

Glimel is available only with a doctor's prescription.

There is no evidence that Glimel is addictive.

How Glimel works

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

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- tearfulness, crying or depression
- irritability
- hunger
- numbness around the lips and tongue
- restlessness or disturbed sleep.

If not treated quickly, these may progress to:

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

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 and more often
- blurred vision
- dry mouth or dry skin.

Hyperglycaemia can lead to serious problems with your heart, eyes, circulation or kidneys.

Before you take Glimel

When you must not take it

Do not take Glimel if you are allergic to medicines containing glibenclamide or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to this medicine may include itching or rash.

Do not take Glimel if you have any of the following medical conditions:

- type 1 diabetes mellitus, also known as insulin dependent diabetes
- unstable diabetes
- diabetic ketoacidosis
- diabetic coma or pre-coma
- severe kidney disease
- severe liver disease.

If you are not sure whether you should start taking Glimel, ask your doctor.

Do not take Glimel if you are pregnant or plan to become pregnant.

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

Do not take Glimel if you are breastfeeding or plan to breastfeed.

It is not known whether glibenclamide is excreted in milk or whether it has a harmful effect on

the newborn. Therefore Glimel is not recommended while you are breastfeeding unless the expected benefits outweigh any potential risks.

Do not give Glimel to children.

There is not enough experience with the use of Glimel in children.

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

Before you start to take it

Tell your doctor if you are allergic to any other sulfonylurea medicines or sulphonamide (sulphur) antibiotics.

You may have an increased chance of being allergic to Glimel if you are allergic to these medicines.

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

Tell your doctor if you have any medical conditions, especially the following:

- adrenal, pituitary (or thyroid) problems
- glucose-6-phosphate dehydrogenase (G6PD) deficiency
- kidney problems
- liver problems
- a history of diabetic coma
- heart failure.

Tell your doctor if:

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

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 about any of the above, tell them before you start taking Glimel.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Glimel, or may affect how well it works. These include:

- alcohol
- other medicines used to treat diabetes
- some medicines used to treat high blood pressure and heart conditions
- cimetidine and ranitidine, medicines commonly used to treat reflux and ulcers
- some medicines used to treat arthritis, pain and inflammation
- some antibiotics
- medicines used to prevent blood clots such as warfarin and heparin
- some medicines to lower blood fats and cholesterol
- disopyramide, a medicine used to treat irregular heart rhythms
- acetazolamide, a medicine used to treat glaucoma, epilepsy and oedema (swelling due to fluid)
- glucagon, a medicine used to treat low blood glucose
- bosentan, a medicine used to treat pulmonary hypertension
- some medicines to help prevent migraine headaches
- some medicines used for depression, mental illness or psychotic disorders
- oxpentifylline, a medicine used to treat blood vessel problems
- some medicines used to treat cancer
- steroids, including corticosteroids (such as prednisone, cortisone) and anabolic steroids
- oestrogens and oral contraceptives
- some medicines used to treat gout

- diuretics, also called fluid tablets
- phenytoin, a medicine used to treat epilepsy
- laxatives
- some cough and cold preparations and medicines used to treat a blocked nose
- some weight reducing preparations
- thyroid hormones
- some medicines used for asthma
- cyclosporin, a medicine used to prevent the rejection of transplanted organs
- some medicines used to treat tuberculosis
- (high dose) nicotinic acid used for the lowering of blood fats
- ritodrine, a medicine used to prevent premature labour
- indomethacin, a medicine used to treat arthritis (an inflammatory condition)
- barbiturates, medicines used for sedation.

Some medicines may hide the symptoms of low blood sugar (hypoglycaemia). These include:

- alcohol
- some medicines used to treat high blood pressure.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have more information on medicines to be careful with or avoid while taking Glimel.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

How to take Glimel

How much to take

The dose varies from patient to patient. Your doctor will decide the right dose for you.

Follow all directions given to you by your doctor and pharmacist carefully.

When to take it

Take your tablet immediately before breakfast. If you only eat a very light breakfast then this dose should be put off until lunchtime. Swallow the tablets with a glass of water.

Do not skip meals whilst using Glimel. Take your dose at the same time each day.

How long to take it for

Keep taking Glimel for as long as your doctor recommends.

Glimel will help control diabetes but will not cure it. Most people will need to take Glimel for a long period of 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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Missed doses can cause high blood sugar (hyperglycaemia).

Do not take a double dose to make up for the dose you missed. If you double a dose this may cause low blood sugar (hypoglycaemia).

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

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Glimel. Do this even if there

are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Glimel, you may experience symptoms of hypoglycaemia (low blood glucose). If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, fits or loss of consciousness.

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

While you are taking Glimel

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Glimel.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Glimel.

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

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 experience any of the symptoms of hypoglycaemia (low blood glucose), you need to raise your blood glucose immediately. You can do this by doing one of the following:

- eating 5-7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2-3 concentrated glucose tablets.

Make sure that you have a full breakfast immediately after your first dose. If you usually have a light breakfast, hold off the first dose until lunch.

Due to the hypoglycaemic effect of Glimel, it is recommended that you have a full meal immediately after a dose, to avoid a drop in your blood glucose level.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk. Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

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

The risk of hypoglycaemia is also increased in the following situations:

- Taking too much Glimel
- Too much or unexpected exercise
- Delayed meal or snack
- Too little food

If you experience any of the symptoms of hyperglycaemia (high blood glucose), contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- Undiagnosed or uncontrolled diabetes
- illness, infection or stress
- taking less Glimel than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if any of the following happen:

- you become ill
- you are injured
- you have a fever
- you have an infection
- you are having surgery.

Your blood glucose may become difficult to control at these times. Your doctor may replace Glimel with insulin.

Visit your doctor regularly so that they can check on your progress.

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.

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

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

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

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

Things you must not do

Do not skip meals while taking Glimel.

You are more at risk of developing hypoglycaemia if you skip meals.

Do not stop taking Glimel or change the dose without checking with your doctor.

Do not give Glimel to anyone else, even if they have the same condition as you.

Things to be careful of

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

Glimel may cause dizziness and drowsiness in some people. Drinking alcohol can make this worse. If any of these occur, do not drive, operate machinery or do

anything else that could be dangerous.

Be careful not to let your blood glucose levels fall too low.

Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery.

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a 15+ sunscreen. If your skin does appear to be burning, tell your doctor immediately.

Glimel may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause skin rash, itching, redness or severe sunburn.

If outdoors, wear protective clothing and use a highly effective sunscreen. If you experience sunburn, tell your doctor immediately.

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., sugar sachets or jelly beans
- carry emergency food rations in case of a delay e.g. dried fruit, biscuits or muesli bars
- keep some Glimel readily available.

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

Glimel helps most people with type 2 diabetes, but it may have unwanted side effects in some 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.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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, lightheadedness, headache, dizziness, irritability and tearfulness
- stomach upset including cramps, nausea (feeling sick), vomiting
- heartburn, indigestion
- pressure on the stomach or feeling of fullness
- diarrhoea or constipation
- loss of appetite
- transient visual disturbances due to a decrease of blood glucose levels
- headache
- weakness
- eye problems including blurred or double vision
- hypersensitivity reactions, allergic or pseudoallergic reactions
- unusual weight gain.

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

- skin reactions including skin rash, itching or hives
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing

- symptoms of sunburn such as redness, itching or blistering, which may occur more quickly than normal
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- symptoms of lactic acidosis (too much acid in the blood) which may include loss of appetite, unexplained weight loss, nausea, vomiting, stomach pain, trouble breathing, feeling weak, tired or uncomfortable, unusual muscle pain, slow heart beat
- yellowing of the eyes or skin (jaundice)
- a change in the colour or amount of urine passed, blood in the urine
- severe upper stomach pain with nausea and vomiting
- signs of anaemia such as tiredness, being short of breath when exercising and looking pale
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- tremors, convulsions
- sudden onset of abnormal thoughts or delusions
- deafness
- blindness.

In very rare cases, intolerance to alcohol may occur. Drinking large amounts of alcohol may interfere with the way Glimel works. It may not work at all or it may take much longer than usual to work.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Glimel

Storage

Keep Glimel where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

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

Do not leave Glimel in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Glimel is a round, white, flat bevelled edged tablet marked GE/5 on one side and a Greek Alpha symbol on the reverse.

Each bottle contains 100 tablets.

Ingredients

The active ingredient in Glimel is glibenclamide. Each Glimel tablet contains 5 mg of glibenclamide.

The tablets also contain:

- microcrystalline cellulose
- purified talc
- colloidal anhydrous silica
- pregelatinised maize starch
- magnesium stearate.

The tablets are gluten free.

Manufacturer

Glimel is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

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