

Aylide

contains the active ingredient *glimepiride*

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Aylide.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Aylide against the benefits expected for you.

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

Please read this leaflet carefully and keep this leaflet with your medicine.

You may need to read it again.

What Aylide is used for

Aylide is used to control high blood sugar levels in people with type 2 diabetes mellitus.

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

Aylide is used when diet and exercise are not enough to control your condition. However, as Aylide does not replace these, your doctor will suggest that you continue with your diet and exercise programs, while you are taking Aylide.

Aylide contains the active ingredient glimepiride, which belongs to a group of medicines called sulfonylureas.

These medicines work to lower blood sugar levels by causing your

pancreas to release more insulin into the blood stream.

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

Your doctor may have prescribed Aylide for another reason.

Aylide is not recommended for use in children, as its safety and effectiveness in this age group has not been established.

Aylide is available only with a doctor's prescription.

There is no evidence that Aylide is addictive.

Before you take Aylide

When you must not take it

Do not take Aylide if you are allergic to:

- medicines containing glimepiride (e.g. Amaryl)
- any other sulfonylureas
- related medicines such as sulfur antibiotics (e.g. sulfonamides) or thiazide diuretics
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Aylide if you have:

- severe kidney problems or require dialysis
- severe liver failure

- type 1 diabetes mellitus, also known as insulin-dependent diabetes mellitus (IDDM)
- unstable diabetes
- diabetic ketoacidosis
- diabetic coma or pre-coma
- glucose-6-phosphate dehydrogenase (G6PD) deficiency.

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

Aylide is not recommended for use during pregnancy. Your doctor may replace Aylide with insulin, as insulin is more suitable for controlling blood sugar during pregnancy.

Do not take Aylide if you are breastfeeding.

Aylide is not recommended for use during breastfeeding as it passes into breast milk and therefore may affect breastfed baby. Your doctor will advise you on what to do if you are breastfeeding.

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 whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

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

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

- kidney problems
- liver problems
- a history of diabetic coma
- adrenal or pituitary problems
- heart failure.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you:

- are taking any other anti-diabetic treatment
- drink alcohol in any amount
- do not eat regular meals
- do a lot of exercise or you do heavy exercise or work
- are ill or feeling unwell.

Alcohol, diet, exercise, and your general health all strongly affect the control of your diabetes. Discuss these things with your doctor.

Tell your doctor if you plan to have surgery.

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

Taking other medicines

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

Some medicines may be affected by Aylide, or may affect how well it works.

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

- alcohol
- other medicines used to treat diabetes
- anabolic steroids
- some antibiotics
- some antidepressants

- some anti-inflammatory agents, such as ibuprofen and naproxen
- some medicines used to treat arthritis and gout
- some blood pressure lowering medicines, such as beta-blockers and ACE inhibitors
- some medicines used to treat blood clots, blood vessel problems and irregular heart rhythms
- some cholesterol-lowering and weight reduction medicines
- some cancer and organ transplant treatments

Some medicines may lead to loss of control of your diabetes by weakening the blood glucose-lowering effect of Aylide. These include:

- alcohol
- some antibiotics, such as rifampicin
- some blood pressure, cholesterol and heart medications
- corticosteroids, glucagon and other hormonal therapies
- oral contraceptives
- some asthma medicines, preparations for coughs and colds, and weight reduction medicines
- some fluid and glaucoma medications
- large doses of laxatives
- some psychiatric and sedating medications

Aylide may change the effects of other medicines. These include:

- coumarin derivatives, which are used to prevent blood clots

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

- alcohol
- certain heart medications, such as beta-blockers

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.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Aylide.

How to take Aylide

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

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

The usual adult starting dose is 1 mg once a day. Your doctor may then increase this dose depending on how you respond to the medicine.

Aylide is not recommended for use in children.

People with kidney problems may need smaller doses.

How to take it

Swallow the tablets whole with at least half a glass of water.

Aylide tablets can be divided in half along the breakline, if advised by your doctor or pharmacist.

When to take it

You must make sure that you take Aylide just before or with a meal.

Aylide tablets are usually taken once a day, immediately before

breakfast. If you eat only a light breakfast, you should delay taking the tablet until after the first main meal of the day (e.g. lunch).

Do not skip meals while taking Aylide.

How long to take it for

To properly control your condition, Aylide must be taken every day.

Keep taking Aylide for as long as your doctor tells you to.

Aylide will help control your diabetes but will not cure it. Aylide is usually taken on a long-term basis. It is important to keep taking your medicine even if you feel well.

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 (with food) 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 are not sure what to do or have any questions, 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 Aylide. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Taking too much Aylide may cause severe hypoglycaemia or very low

blood sugar levels. This is very serious and, if not treated quickly, can lead to loss of coordination, slurred speech, confusion, fitting, unconsciousness and coma.

At the first signs of hypoglycaemia, immediately raise your blood sugar levels quickly by taking one of the following:

- 5-7 jelly beans,
- 3 teaspoons of sugar or honey
- Half can of a sugar-containing (non-diet) soft drink
- 2-3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal, follow up with extra carbohydrates, e.g. plain biscuits, fruit or milk, when over the initial symptoms.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and seizures.

While you are taking Aylide

Things you must do

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

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

Keep a continuous supply so you don't run out, especially over weekends or during holidays.

If you become pregnant while taking Aylide, stop taking it and tell your doctor immediately.

If you plan to have surgery (that requires a general anaesthetic), including dental surgery, tell your doctor or dentist that you are taking Aylide.

Make sure you, your friends, family and work colleagues can recognise the symptoms of

hyperglycaemia and hypoglycaemia and know how to treat them. Provide them with the telephone number for your doctor, the Poison information Centre (13 11 26 in Australia) and Emergency Services.

See "Controlling blood sugar".

Always carry some sugary food or drink with you.

If you experience any of the symptoms of low blood glucose (hypoglycaemia), immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Diet and low calorie soft drinks do NOT contain sugar and are unsuitable to take for hypoglycaemia.

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

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

- too much Aylide
- too much or unexpected exercise
- delayed meal or snack
- too little food

If you experience any signs of high blood sugar (hyperglycaemia), contact your doctor immediately.

The risk of hyperglycaemia is increased in the following:

- undiagnosed or uncontrolled diabetes
- illness, infection or stress
- too little Aylide
- certain other medicines
- too little exercise
- sudden immobilisation, e.g. after an accident
- eating more carbohydrate than normal.

Tell your doctor if you become ill, experience extra stress, have an injury, fever, infection, or need surgery.

Your blood sugar levels may become difficult to control during these times, and your doctor may

decide to change your treatment to insulin.

Make sure you check your blood sugar levels regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor, pharmacist or diabetes educator will show you how and when to do this.

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

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

Drinking alcohol while taking Aylide may increase your chances of getting hypoglycaemia.

You may get flushing, headache, breathing difficulties, rapid heart beat, stomach pains or feel sick and vomit. Your doctor may suggest you avoid alcohol while taking Aylide.

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

These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision.

These may be signs that your treatment with Aylide may need to be reviewed.

Things you must not do

Do not skip meals while taking Aylide.

Do not use Aylide to treat any other conditions unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition, or if their symptoms seem similar to yours.

Things to be careful of

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

Aylide 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 15+ sunscreen. If your skin does appear to be burning, tell your doctor immediately.

If you have to be alert, e.g. when driving, be especially 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. Drinking alcohol can make this worse. However, Aylide by itself is unlikely to affect how you drive or operate machinery.

Make sure you know how you react to Aylide before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded. If this occurs, do not drive.

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 Aylide readily available

If you become sick with a cold, fever or flu, it is very important to continue taking Aylide, even if you feel unable to eat your normal meal. If you have trouble eating solid foods, 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 food to use for sick days.

Controlling blood sugar

Your blood sugar levels may change if you:

- do not take your tablets regularly

- do not eat proper meals or skip meals
- drink alcohol
- exercise more than usual
- are sick, under an unusual amount of stress or have an infection, or
- if your dose of Aylide is not right.

If your blood sugar is not properly controlled, you may experience either:

- hyperglycaemia, high blood sugar
- hypoglycaemia, low blood sugar.

These conditions can be very serious.

Make sure, you and your family and friends are aware of the signs and symptoms of hyperglycaemia and hypoglycaemia, and what to do.

Hyperglycaemia

Hyperglycaemia means high blood sugar levels. If it is not treated, it can lead to serious problems with your heart, eyes, circulation or kidneys. Signs of hyperglycaemia include:

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

Aylide is used to control this.

Hypoglycaemia

Hypoglycaemia means low blood sugar levels. If you are elderly, immobilised, drink alcohol or take more than one medicine for your diabetes, you may be more susceptible to hypoglycaemia.

Hypoglycaemia can be very serious and can occur suddenly.

Signs of hypoglycaemia include:

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

- irritability
- extreme hunger
- numbness around the lips and tongue.

If hypoglycaemia is not treated promptly, these may progress to:

- loss of coordination
- slurred speech
- confusion
- unconsciousness or fitting
- coma.

If you experience any of these symptoms, immediately take one of the following:

- 5 to 7 jelly beans
- 3 teaspoons of sugar or honey
- half a can of non-diet soft drink
- 2 to 3 concentrated glucose/sugar tablets or sugar cubes.

This helps to raise the sugar levels in your blood. Carry some of these with you in case of such as event.

Contact your doctor or go to Accident and Emergency at the nearest the hospital immediately if:

- symptoms do not improve
- hypoglycaemia is severe.

You may feel dizzy and shaky so do not drive.

Side effects

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

Aylide is generally well tolerated.

However, like all other medicines, it may have unwanted side effects in some people.

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, lightheadedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers
- eye problems, including blurred or double vision
- stomach upset including nausea (feeling sick) and vomiting
- diarrhoea, abdominal pain or a feeling of fullness in the stomach
- change in or loss of taste
- hair loss
- weight gain

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

- rash, sores, redness or itching of the skin, itchy hives-like rash or spots
- symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal
- bleeding or bruising more easily than normal, or reddish or purplish blotches under the skin
- yellowing of the skin or eyes, also called jaundice
- signs of frequent or worrying infections, such as fever, severe chills, sore throat or mouth ulcers
- signs of anaemia, such as tiredness, being short of breath and looking pale.

The side effects listed above are serious and require urgent medical attention or hospitalisation.

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

This is not a complete list of all possible side effects.

Other side effects not listed above may also occur in some people, and some side effects (eg. changes in liver function) can only be found when your doctor does tests from time to time to check your progress.

After taking Aylide

Storage

Keep Aylide 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 the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Aylide, 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

Aylide is available in 4 strengths:

- Aylide 1 - pink, capsule-shaped tablet with a breakline, marked "GM" over "1" on one side, and "G" over "G" on the other
- Aylide 2 - green, capsule-shaped tablet with a breakline, marked

"GM" over "2" on one side, and "G" over "G" on the other

- Aylide 3 - yellow, capsule-shaped tablet with a breakline, marked "GM" over "3" on one side, and "G" over "G" on the other
- Aylide 4 - blue, capsule-shaped tablet with a breakline, marked "GM" over "4" on one side and "G" over "G" on the other.

Each pack contains 30 tablets.

Ingredients

The active ingredient in Aylide is glimepiride.

Each Aylide 1, 2, 3 and 4 tablet contains 1, 2, 3 or 4 mg of glimepiride, respectively.

The tablets also contain the following inactive ingredients:

- Lactose monohydrate
- povidone
- microcrystalline cellulose
- magnesium stearate
- sodium starch glycollate
- iron oxide red CI77491
[1 mg tablet only]
- iron oxide yellow CI77492
[2 mg and 3 mg tablets only]
- indigo carmine CI73015
[2 mg and 4 mg tablets only].

The tablets do not contain sucrose, gluten, tartrazine or any other azo dyes (e.g. sunset yellow, allura red AC, brilliant scarlet).

Supplier

Aylide is supplied 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:

Aylide 1 - AUST R 116858

Aylide 2 - AUST R 116859

Aylide 3 - AUST R 116860

Aylide 4 - AUST R 116862

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