

# Aylide

contains the active ingredient *glimepiride*

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## CONSUMER MEDICINE INFORMATION

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### 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.

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### What Aylide is used for

Aylide together with diet and exercise, is used to lower 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 alone 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.

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### Before you take Aylide

#### **When you must not take it**

**Do not take Aylide if you are allergic to:**

- \* medicines containing glimepiride (eg. Amaryl) or any other sulfonylureas or sulfonamides
- \* 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 problems
- \* type 1 diabetes mellitus, also known as insulin-dependent diabetes mellitus (IDDM)
- \* diabetic ketoacidosis.

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

Aylide is not recommended for use during pregnancy. Your doctor will 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 unwanted effects have been caused by this medicine in nursing animals. 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
- \* glucose-6-phosphate dehydrogenase (G6PD) deficiency, a condition in which the body does not have enough of the enzyme G6PD
- \* adrenal or pituitary problems.

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

**Tell your doctor if you:**

- \* drink alcohol in any amount
- \* do not eat regular meals
- \* do a lot of exercise
- \* 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 about any of the above, tell him/her before you start taking Aylide.**

**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 Aylide, or may affect how well it works.**

**Medicines that may increase the effects of Aylide include:**

- \* other medicines used to treat diabetes
- \* some medicines used to lower blood pressure (eg. ACE inhibitors, beta-blockers)
- \* anabolic steroids and male sex hormones
- \* aspirin
- \* clofibrate, a cholesterol-lowering medicine

- \* coumarin derivatives (eg. warfarin), medicines used to prevent blood clots
- \* some antibiotics (eg. quinolones, sulfonamides, chloramphenicol, tetracyclines)
- \* some antifungals (eg. fluconazole, miconazole)
- \* some medicines used to treat depression (eg. fluoxetine, MAOIs)
- \* disopyramide, a medicine used to treat irregular heart rhythms
- \* oxpentifylline, a medicine used to treat blood vessel problems
- \* some medicines used to treat cancer (eg. phosphamides)
- \* some medicines used to treat reflux and ulcers (eg. cimetidine and ranitidine).

**Medicines that may reduce the effects of Aylide include:**

- \* acetazolamide, a medicine used to treat glaucoma
- \* some medicines used to lower blood pressure (eg. beta-blockers, calcium channel blockers)
- \* corticosteroids such as prednisone and cortisone
- \* glucagon, a medicine used to treat low blood glucose
- \* some medicines used to treat tuberculosis (eg. isoniazid, rifampicin)
- \* nicotinic acid (high dose), used for the lowering of blood fats
- \* oestrogens and progestagens, hormones used in oral contraceptives and hormone replacement therapy
- \* some medicines used to treat mental illness or psychotic disorders (eg. phenothiazines)
- \* phenytoin, a medicine used to treat epilepsy (convulsions)
- \* diuretics, also known as fluid tablets
- \* sympathomimetics, used in some asthma medicines, preparations for coughs and colds and weight-reduction

- \* thyroid hormones (eg. thyroxine)
- \* large doses of laxatives
- \* barbiturates, medicines used for sedation
- \* some medicines used to treat reflux and ulcers, (eg. cimetidine and ranitidine).

**Medicines that may hide the symptoms of low blood sugar include:**

- \* some medicines used to lower blood pressure (eg. beta-blockers, clonidine)
- \* guanethidine and reserpine, medicines used in anaesthesia.

Your doctor can tell you what to do if you are taking any of these medicines.

**Medicines that are affected by Aylide include:**

- \* rifampicin, a medicine used to treat tuberculosis
- \* fluconazole, a medicine used to treat fungal infections
- \* amiodarone, a medicine used to treat irregular heart beats
- \* some anti-inflammatory agents, medicines used to treat arthritis, pain and swelling (eg. ibuprofen, naproxen, diclofenac).

**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.

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**How to take Aylide**

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**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.

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**

**Take Aylide immediately before breakfast, or the first main meal of the day.**

**Do not skip meals while taking Aylide.**

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

## **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 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 by taking the following:**

- \* jelly beans, sugar or honey
- \* (non-diet) soft drink
- \* glucose tablets.

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## **While you are taking Aylide**

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### **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, 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.**

See "Controlling blood sugar".

**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
- \* 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***

**Alertness and reaction time may be impaired due to changes in blood sugar levels.**

Know how this affects you before you do anything that requires alertness, such as driving or operating machinery, particularly at the start of treatment, at a change of dose or when you have not taken your Aylide tablets regularly.

### ***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.

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## **Side effects**

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**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:**

- \* nausea (feeling sick) or vomiting
- \* loss of appetite

- \* diarrhoea or a feeling of fullness in the stomach
- \* blurred vision, particularly at the start of treatment or with a change in dosage.

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

- \* weakness, trembling or shaking
- \* sweating
- \* lightheadedness, headache, dizziness, lack of concentration
- \* confusion, tearfulness or crying, irritability
- \* extreme hunger
- \* slurred speech
- \* confusion, anxiety
- \* bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- \* yellowing of the skin or eyes
- \* signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- \* symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal.

The above list includes serious side effects, which may require medical attention.

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

- \* convulsions or fits
- \* chest pain
- \* swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- \* rash, redness or itching of the skin/itchy hives-like rash or spots.

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.

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## After taking Aylide

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### 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 degrees 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.**

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## Product description

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### 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
- \* povidone
- \* microcrystalline cellulose
- \* magnesium stearate
- \* sodium starch glycollate
- \* viron 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 (eg. sunset yellow, allura red AC, brilliant scarlet).

### Supplier

Aylide is supplied in Australia by:

**Alphapharm Pty Limited**

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

- \* Aylide 1 - AUST R 116858
- \* Aylide 2 - AUST R 116859
- \* Aylide 3 - AUST R 116860
- \* Aylide 4 - AUST R 116862

This leaflet was prepared on  
18 November 2008.