AYLIDE

Consumer Medication Information Leaflet (RiMUP)

Glimepiride (1mg, 2mg, 3mg, 4mg)

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What *Aylide* is used for

Aylide is used as an adjunct to diet and exercise in Non-Insuline Dependent (Typer II) Diabetes, *Aylide* may also be used in combination with an oral antidiabetic containing metformin or with insulin.

How *Aylide* works

Aylide, is a blood-sugar-lowering agent belonging to the sulfonylurea group. *Aylide* acts by stimulating insulin release from beta cells in pancrease.

Glimepiride increase the normal action of insulin on peripheral glucose uptake. A single dose of *Aylide* leads to good glucose control over 24 hours.

In patients with insufficient response to the maximum dose, combined use with an additional oral antidiabetic containing metformin or with insulin improves glucose control.

Before you use *Aylide*

- *When you must not use it*

To avoid risk of harm to the child, *Aylide* must not be taken during pregnancy; a changeover to insulin is necessary. Patients planning a pregnancy must inform their doctor, and should change over to insulin. Ingestion of glimepiride with the breast milk may harm the child. Therefore, *Aylide* must not be taken by breast-feeding women, and a changeover to insulin or discontinuation of breast-feeding is necessary.

Aylide is not suitable for the treatment of insulin-dependent (type 1) diabetes mellitus (e.g. for the treatment of diabetes with a history of ketoacidosis), of diabetic ketoacidosis, or of diabetic precoma or coma. *Aylide* must not be used in patients hypersensitive to glimepiride, other sulfonylureas, other sulfonamides, or to any of the excipients. No experience has been gained concerning the use of *Aylide* in patients with severe impairment of liver function and in dialysis patients. In patients with severe impairment of renal or hepatic function, a changeover to insulin is indicated, not least to achieve optimal glucose control.

- *Before you start to use it*

Some people will need special care before or while taking *Aylide*. For optimal control of blood sugar, a correct diet, regular and sufficient physical exercise and, if necessary, reduction of body weight are just as important as regular intake of *Aylide*.

- *Taking other medicines*

Hypoglycaemia may occur when one of the following medicines is taken:
- insulin,,
- oral antidiabetics,
- ACE inhibitors,
- allopurinol,
- anabolic steroids and male sex hormones,
- chloramphenicol,
- coumarin derivatives,
- cyclophosphamide,
- disopyramide,
- fenfluramine,
- fenyramidol,
- fibrates,
- fluoxetine,
- guanethidine,
- ifosfamide,
- MAO inhibitors,
- miconazole,
- para-aminosalicylic acid,
- pentoxifylline (high dose parenteral),
- phenylbutazone,
- azapropazone,
- oxyphenbutazone,
- probenecid,
- quinolones,
- salicylates,
- sulfinpyrazone,
- sulfonamides,
- tetracyclines,
- tritoqualine,
- trofosfamide,
- fluconazole.

Raised blood sugar levels may occur when one of the following medicines is taken:
- acetazolamide,
- barbiturates,
- corticosteroids,
- diazoxide,
- diuretics,
- epinephrine (adrenaline) and other sympathomimetic agents,
- glucagon,
- laxatives (after protracted use),
- nicotinic acid (in high doses),
- oestrogens and progestogens,
- phenothiazines,
- phenytoin,
- rifampicin,
- thyroid hormones.

Your doctor or pharmacist may have a more complete list of medication which interact with *Aylide*. Please refer to them if you are unsure.

How to use *Aylide*

- *How much to use*

Initial dose and dose titration:
The usual initial dose is 1 mg *Aylide* once daily. If necessary, the daily dose can be increased. Any increase should be based on regular blood sugar monitoring, and should be gradual, i.e., at intervals of one to two weeks, and carried out stepwise, as follows: 1 mg - 2 mg - 3 mg - 4 mg - 6 mg, and in exceptional cases - 8 mg.

Dose range in patients with well controlled diabetes:
The usual dose range in patients with well controlled diabetes is 1 to 4 mg *Aylide* daily. Only some patients benefit from daily doses of more than 6 mg.

Secondary dosage adjustment:
As the control of diabetes improves, sensitivity to insulin increases;

therefore, glimepiride requirements may fall as treatment proceeds. To avoid an excessive reduction in blood sugar (hypoglycaemia), a timely dose reduction or cessation of *Aylide* therapy must be considered. A dose adjustment must also be considered whenever the patient's weight or lifestyle changes, or other factors causing an increased susceptibility to hypoglycaemia or to an excessive increase in blood sugar levels (hyperglycaemia) arise

- *When to use it*

Timing and distribution of doses are to be decided by the doctor, taking into consideration the patient's current lifestyle. Normally, a single daily dose of *Aylide* is sufficient. This dose should be taken immediately before a substantial breakfast or – if none is taken – immediately before the first main meal. It is very important not to skip meals after taking *Aylide.*

- *How long to use it*

Treatment with *Aylide* is normally a long-term therapy. In principle, the dosage of *Aylide* is governed by the desired blood sugar level. The dosage of glimepiride must be the lowest which is sufficient to achieve the desired metabolic control.

Treatment with *Aylide* must be initiated and monitored by a doctor.

Aylide must be taken at the times and in the doses prescribed.

- *If you forget to use it*

Treatment with *Aylide* must be initiated and monitored by a doctor. *Aylide* must be taken at the times and in the doses prescribed. Mistakes, e.g. forgetting to take a dose, must never be corrected by subsequently taking a larger dose. Measures for dealing with such mistakes (in particular forgetting a dose or skipping a meal) or situations where a dose cannot be taken at the prescribed time must be discussed and agreed between doctor and patient beforehand. A doctor must be notified immediately if the dose taken is too high, or an extra dose has been taken.

- *If you use too much (overdose)*

Aylide overdose may lead to severe and sometimes life-threatening hypoglycaemia and may require hospitalisation even as a precautionary measure.

Significant overdose with severe reactions is a medical emergency and will necessitate immediate treatment and hospitalisation. Mild episodes of hypoglycaemia can usually be treated with oral carbohydrates. Adjustments in dosage, meal patterns or physical activity may be necessary.

More severe episodes with coma, seizure or neurologic impairment may be treated with glucagon (intramuscular or subcutaneous) or concentrated glucose solution (intravenous). If life-threatening amounts have been ingested, detoxification (by, e.g., gastric lavage, activated charcoal) will be necessary. Sustained administration of carbohydrates and observation may be necessary because hypoglycaemia may recur after apparent clinical recovery.

While you are using it

- *Things you must do*

To achieve optimal control of blood sugar, a correct diet, regular and sufficient physical exercise and, if necessary, reduction of body weight are just as important as regular intake of *Aylide*.

In the initial weeks of treatment, the risk of hypoglycaemia may be increased and necessitates especially careful monitoring.

Hypoglycaemia can almost always be promptly controlled by immediate intake of sugar, e.g., in the form of glucose, sugar cubes or sugar-sweetened beverages. Patients should always carry at least 20 grams of glucose with them for this purpose (food or beverages containing artificial sweeteners – such as diet foods or drinks - are ineffective in controlling hypoglycaemia). They may require the assistance of other persons to avoid complications.

- *Things you must not do*

Since some adverse effects (e.g., severe hypoglycaemia, certain changes in the blood picture, severe allergic or pseudoallergic reactions, or liver failure) may under certain circumstances become life threatening, it is essential that, if sudden or severe reactions do occur, you inform a doctor at once, and on no account continue taking the drug without a doctor's express guidance.

- *Things to be careful of*

To avoid risk of harm to the child, *Aylide* must not be taken during pregnancy; a changeover to insulin is necessary. Patients planning a pregnancy must inform their doctor, and should change over to insulin.

Ingestion of glimepiride with the breast milk may harm the child. Therefore, *Aylide* must not be taken by breast-feeding women, and a changeover to insulin or discontinuation of breast-feeding is necessary.

Side effects

Based on experience with *Aylide* and on what is known of other sulfonylureas, the following adverse effects must be considered:

Hypoglycaemia: As a result of the blood-sugar-lowering action of *Aylide*, hypoglycaemia may occur and may also be prolonged. Possible symptoms of hypoglycaemia include headache, ravenous hunger, nausea, vomiting, tiredness, sleepiness, disordered sleep, restlessness, aggressiveness, impaired concentration, alertness and reactions, depression, confusion, difficulty in speaking and even speech loss, visual disorders, tremor, sensory disturbances, dizziness, helplessness, loss of self-control, cerebral convulsions, drowsiness and loss of consciousness up to and including

coma, shallow respiration and slow heart rate (bradycardia). In addition, signs of adrenergic counter-regulation may be present such as sweating, clammy skin, anxiety, rapid heart rate (tachycardia), angina pectoris, and cardiac arrhythmias. The clinical picture of a severe hypoglycaemic attack may resemble that of a stroke. The symptoms of hypoglycaemia nearly always subside when hypoglycaemia is corrected.

Eyes: Especially at the start of treatment, temporary visual impairment may occur due to the change in blood sugar levels.

Digestive tract: Occasionally, gastrointestinal symptoms such as the following may occur: nausea, vomiting, sensations of pressure or fullness in the upper abdomen, abdominal pain and diarrhoea.
In rare cases, liver enzyme levels may increase. In isolated cases, impairment of liver function (e.g. with cholestasis and jaundice) and hepatitis may develop, possibly leading to liver failure.

Blood: Severe changes in the blood may occur: Rarely, decrease of platelets in blood. and, in isolated cases, decrease in the number of white blood cells (leukocytes) found in the blood, or, e.g. Deficiency in the number of red blood cells, abnormally low number of granular white blood cells in the blood, an acute condition involving a severe and dangerous lowered white blood cell, and reduction in the number of red and white blood cells may develop.

Other adverse reactions: Occasionally, allergic or pseudoallergic reactions may occur, e.g. in the form of itching, urticaria or rashes. Such reactions may be mild, but also may become more serious and may be accompanied by , shortness of breath and a fall in blood pressure, sometimes progressing to shock. If urticaria occurs, a doctor must be notified immediately. In isolated cases, a decrease in serum sodium, inflammation of blood vessels (allergic vasculitis) and hypersensitivity of the skin to light may occur.

Please speak with your doctor if you notice any of the adverse effects listed in this package insert or any other undesired effects or unexpected changes.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting).

Storage and Disposal of *Aylide*

- *Storage*

Do not store above 25°C.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Aylide 1 - Pink, capsule-shaped, flat faced tablets marked “GM” breakline “1” on one side and “G” breakline “G” on the other.
Aylide 2 - Green, capsule-shaped, flat faced tablets marked “GM” breakline “2” on one side and “G” breakline “G” on the other.
Aylide 3 – yellow capsule shaped, flat faced tablets marked “GM” breakline “3” on one side and “G” breakline “G” on the other.
Aylide 4 – blue capsule shaped, flat faced tablet marked “GM” breakline “4” on one side and “G” breakline “G” on the other.

- *Ingredients*
  - Active ingredient

Glimepiride

  - *Inactive ingredients*

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

- *MAL numbers :*

Aylide 1mg - MAL08091395A
Aylide 2mg - MAL08111776A
Aylide 3mg - MAL08091396A
Aylide 4mg - MAL08091397A

Manufacturer
Merck Farma y Quimica SA
Manufacturer ID: 24641
Ctra. Nacional 152,
Km 19 (Poligon Industrial Merck),
08100 Mollet del Valles,
Barcelona, Spain.

Product Registration Holder
Pahang Pharmacy Sdn. Bhd
Lot 5979, Jalan Teratai,
5 1/2 Mile Off Jalan Meru
41050 Klang
Selangor, MALAYSIA.

Date of revision
21/08/2014