

MIARYL TABLET

Glimepiride (2mg)

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What Miaryl is used for

Miaryl is a 3rd Generation Oral Hypoglycaemic Agent or an oral diabetes medicine that helps to control blood sugar levels.

Miaryl is used to treat Type II diabetes (non-insulin dependent diabetes mellitus) whenever blood sugar levels cannot be controlled adequately by diet, physical exercise and weight reduction alone.

Miaryl may be used in combination with an oral antidiabetic containing metformin or with insulin.

A single dose of Miaryl could control or regulate well the glucose level in blood for almost 24hours.

How Miaryl works

Glimepiride, the active ingredient of Miaryl is a blood sugar lowering agent belonging to the sulphonylurea group. Miaryl stimulates the release of insulin from functioning pancreatic beta cells. The insulin then reduces your blood sugar level.

Before you use Miaryl

When you must not use it

- Miaryl must not be used if you are hypersensitive or

allergic to glimepiride or other sulfonylureas (medicines used to lower your blood sugar such as glibenclamide) or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or any of the excipients.

- Miaryl is not suitable for the treatment of insulin dependent (Type I) Diabetes mellitus.

- If you have diabetic ketoacidosis (a complication of diabetes when your acid level is raised in your body and you may have some of the following signs: fatigue, feeling sick (nausea), frequent urination and muscular stiffness)

- If you are in a diabetic coma.

- If you have severe kidney disease.

- If you have severe impairment of liver function .

- Miaryl **must not** be used during pregnancy , by breast-feeding women or by those planning a pregnancy. Ingestion of Miaryl with breast milk can harm the child ; a changeover to insulin is necessary.

Before you start to use it

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 Miaryl.

Clinical signs of hyperglycaemia (raised blood sugar levels) include intense thirst, dryness of the mouth , an increased urinary frequency, and dry skin. Inform your doctor if you experience any of these signs.

During treatment with Miaryl , glucose levels in blood and urine must be checked regularly. Alertness and

reactions may be impaired due to hypo or hyperglycaemia, especially when beginning or after altering treatment, or when Miaryl is not taken regularly.

Taking other medicines

Ask your doctor or pharmacist before taking, taking or recently taken any other medicine, including over-the-counter products.

- Avoid drinking alcohol while you are taking this medicine.

- There are various drugs that can interact with Miaryl and change the way the medicine works. Some of these drugs are acetylsalicylic acid such as Aspirin, "sulfa" drugs, warfarin and betablockers.

- Some medicines can make it harder for you to control your diabetes. These include ACE inhibitors (i.e. drugs used to treat high blood pressure - hypertension), diuretics (water pills), corticosteroids (such as prednisone), birth control pills, and some kinds of cold and allergy drugs.

Make sure your doctor and pharmacist knows if you are taking these or any other medicines.

How to use Miaryl

How much to use

The dose of Miaryl depends on your needs, condition and results of blood and urine sugar tests and is determined by your doctor.

Your doctor will tell you how many tablets to take each day. If you take the wrong dose, Miaryl may not work as well and your condition may not improve.

Depending on your blood glucose levels, your doctor may increase or decrease the dose. The usual starting dose is

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half the Miaryl tablet, 1mg once a day. The usual dose range is 1-4mg daily.

When to use it

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.

Take this medicine just before or with the first main meal of the day (usually breakfast). If your breakfast is very light, you may wait until lunch to take the tablet.

Do not skip meals while taking Miaryl.

How long to use it

Keep taking Miaryl exactly as prescribed until your doctor tells you to stop. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well. Use Miaryl regularly to get the most benefit. Get your prescription refilled before you run out of medicine completely.

If you forget to use it

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

If you use too much (overdose)

Miaryl overdose may lead to severe and sometimes life-threatening hypoglycaemia and may require hospitalization.

Symptoms of an overdose may include symptoms of hypoglycaemia (low blood glucose), such as:

- Weakness, trembling or shaking sweating
- Light headedness, dizziness, headache or lack of concentration
- Tearfulness, crying, irritability
- Hunger
- Numbness around the lips and tongue
- Loss of coordination or confusion
- Loss of consciousness or seizures
- Slurred speech

Significant overdose with severe reactions is a medical emergency which necessitates immediate treatment and hospitalization.

Severe episodes may be treated with glucagons (intramuscular or subcutaneous) or concentrated glucose solution (intravenous). If life-threatening amounts are ingested, detoxification (by gastric lavage, activated charcoal) will be necessary.

Persons in a state of unconsciousness must not be given food or drink.

In most cases the signs of mild reduced blood sugar (hypoglycaemia) vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, sweetened tea. Adjustments in dosage, meal patterns or physical activity may be necessary.

While using Miaryl

Things you must do

Inform your doctor if you have

Low blood sugar (hypoglycaemia):

- If your blood sugar gets too low, you may feel shaky, weak, drowsy, confused, or very hungry. You may sweat or

have blurred vision, trouble concentrating, a fast heartbeat or a headache that doesn't go away. Signs of severe hypoglycaemia include disorientation, loss of consciousness and seizures.

You may have low blood sugar while you are taking Miaryl, especially if you miss a meal, exercise for a long time, drink alcohol or use another anti-diabetic medication.

You should therefore always take some form of sugar with you (e.g. sugar cubes).

Remember that artificial sweeteners are not effective. Please contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.

Things you must not do

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not change the dosage or stop taking your medicine without checking with your doctor.
- Do not chew or crush the Miaryl tablet. It must be swallowed whole with at least half a glass of water.
- Do not skip meals.
- Do not consume alcohol as alcohol intake may increase or decrease the blood sugar lowering action of Miaryl in an unpredictable way.

Things to be careful of

Your ability to concentrate or react may be reduced if your blood sugar is lowered (hypoglycaemia), or raised (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could

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endanger yourself or others when driving a car or using machines.

Please ask your doctor whether you can drive a car if you :

- Have frequent episodes of hypoglycaemia.
- Have fewer or no warning signals of hypoglycaemia.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Miaryl. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

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

- Stomach upset including nausea (feeling sick) and vomiting
- Abdominal pain or discomfort, diarrhoea
- Eye problems, including blurred or double vision.

Mostly, these are mild side effects of the medicine and are short-lived.

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

- Yellowing of your skin or eyes, also called jaundice
- Signs of anemia such as tiredness, being short of breath and looking pale.
- Signs of frequent or worrying infections, such as fever,

severe chills, sore throat or mouth ulcers

- Bleeding or bruising more easily than normal, or reddish or purplish blotches under the skin
- Symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal.

The above list includes some serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Skin reactions such as itching, redness or itchy hives like rash or spots
- Shortness of breath
- wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body.

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

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

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 Miaryl

Storage Store in airtight containers at room temperature of not more than 25°C.

Keep out of the reach and sight of children.

Do not use the tablets after the expiry date.

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

Miaryl is a grayish green coloured, rectangular shaped tablet.

Active Ingredient(s)

Glimepiride 2mg

Inactive Ingredients

Sodium starch glycollate, Lactose, Povidone, Magnesium stearate, Microcrystalline cellulose.

Colouring agents

Ferric Oxide (Yellow)
Blue No.1 (Brilliant Blue FCF)

MAL number

MAL06041483A

Manufacturer

Jin Yang Pharmaceutical Co., Ltd.
649 -3, Choji-dong, Ansan-Si, Kyunggi-do, Korea.

Importer / Distributor / Product Registration Holder

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640-A, 4th Mile Ipoh Road, 51200, Kuala Lumpur.

Date of revision

29th October 2013