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GLYADE[®] MR

Modified Release tablets containing gliclazide
(pronounced *gli-cla-zide*)

What is in this leaflet

This leaflet answers some common questions about GLYADE MR. It does not contain all the available information about this medicine. Reading this leaflet does not take the place of talking to your doctor, pharmacist, or diabetes educator.

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

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

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

What GLYADE MR is

The name of your medicine is GLYADE MR. The medicine releases the active ingredient gliclazide progressively over 24 hours. Gliclazide belongs to a group of medicines called sulphonylureas (sometimes spelled "sulfonlureas").

What GLYADE MR is used for

You have been prescribed GLYADE MR for Type 2 diabetes (also known as non-insulin-dependent diabetes (NIDDM), or maturity-onset diabetes).

GLYADE MR is available only with a doctor's prescription.

There is no evidence that GLYADE MR is addictive.

Why GLYADE MR is used for type 2 diabetes

Glucose is used by the body as fuel, and all people have glucose circulating in their blood. In diabetes, levels of blood glucose are higher than is needed, which is also known as **hyperglycaemia**.

A boxed section at the end of this leaflet contains advice about recognising and treating hypoglycaemia.

It is very important to control high blood glucose whether or not you feel unwell. This really helps to avoid serious long-term health problems, which can involve the heart, eyes, circulation, and/or kidneys.

GLYADE MR is used when diet and exercise are not enough to control your blood glucose properly. It lowers blood glucose by increasing the amount of

insulin (a hormone that controls blood glucose levels) produced by your pancreas.

As with many medicines used for the treatment of diabetes, there is a possibility that blood glucose levels may become very low during treatment with GLYADE MR. This is known as **hypoglycaemia**.

A boxed section at the end of this leaflet contains advice about recognising and treating hypoglycaemia.

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

Before you take GLYADE MR

There are some people who should not take GLYADE MR. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please consult your doctor, pharmacist, or diabetes educator.

Do not take GLYADE MR if:

- You are allergic to gliclazide or to any of the other ingredients of GLYADE MR listed at the end of this leaflet.
- You are allergic to other sulphonylurea medicines, to sulphonamide (sulpha) antibiotics, or to thiazide diuretics (a type of "fluid" or "water" tablet).
- You are pregnant or trying to become pregnant. Your doctor will usually replace GLYADE MR with insulin while you are pregnant.
- You are breastfeeding or plan to breast-feed.
- You have Type 1 diabetes mellitus (also known as insulin-dependent diabetes (NIDDM), or juvenile-onset diabetes).
- You have diabetic ketoacidosis (a problem which affects the acidity of your blood and can lead to coma – which is mainly associated with Type 1 diabetes).
- The packaging is torn or shows signs of tampering or the tablets do not look quite right.
- The expiry date (EXP) on the pack has passed.

Tell your doctor straight away if:

- You become pregnant while you are taking GLYADE MR.
- You are allergic to any other medicines or any foods, dyes, or preservatives.
- You have any other health problems including:
 - Kidney disease.
 - Liver disease.
 - A history of diabetic coma.
 - Adrenal, pituitary or thyroid problems.
 - Heart failure.
- You have any medical condition, or do anything, that may increase the risk of **hyperglycaemia** – for example:

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- You are ill or feeling unwell (especially with fever or infection).
- You are injured.
- You are having surgery.
- You are taking less GLYADE MR than prescribed.
- You are taking less exercise than normal.
- You are eating more carbohydrate than normal.
- You have any medical condition, or do anything, that may increase the risk of **hypoglycaemia** – for example:
 - Drinking alcoholic drinks.
 - Not eating regular meals.
 - Taking more exercise than usual.

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.

Taking GLYADE MR may change the effect of some medicines, and some medicines may affect how well GLYADE MR works. You may need different amounts of your medicine or to take different medicines. The medicines that may interact with GLYADE MR include the following:

- Other medicines used to treat diabetes (tablets and insulin).
- Some medicines used to treat high blood pressure and other heart conditions.
- Some hormones used in hormone replacement therapy and oral contraceptives.
- Some medicines for depression and other mental illness.
- Some medicines for epilepsy.
- Some medicines for high triglyceride levels.
- Some medicines used to treat arthritis, pain and inflammation.
- Some antibiotics.
- Some medicines used to treat fungal or yeast infections.
- Some medicines used to prevent blood clots (warfarin and similar medicines).
- Some medicines used to treat acid reflux and stomach ulcers.
- Some steroid medicines.
- Some medicines for hormonal disturbances (such as danazol).
- Some medicines for asthma.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking GLYADE MR.

For older people or children

- Elderly people can generally use GLYADE MR safely. There are no special instructions for older people taking GLYADE MR.

- **GLYADE MR is not recommended for use in children.**

How to take GLYADE MR

Follow all directions given to you by your doctor, pharmacist, and diabetes educator carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will select a dose when they prescribe GLYADE MR for you, and may adjust this later. The usual dose of GLYADE MR is between one and four tablets once daily.

Swallow your tablet(s) with a glass of water. Do not crush the tablets or break them.

It is important to take your GLYADE MR at the same time each day – usually with breakfast. Taking GLYADE MR with food can help to minimise the risk of hypoglycaemia.

Do not skip meals while taking GLYADE MR.

How long to take GLYADE MR for

GLYADE MR can help to control your blood glucose level, but it cannot cure your Type 2 diabetes.

GLYADE MR treatment is usually for a long period of time – so you should keep taking the tablets regularly unless advised otherwise by your doctor.

If you forget to take GLYADE MR

Take your next planned dose at the usual time and continue as normal.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much GLYADE MR

Taking too much GLYADE MR (overdose) may cause very low blood sugar (hypoglycaemia) - which may require urgent medical attention. **If you think that you or anyone else may have taken too much GLYADE MR then act immediately:**

- Treat the hypoglycaemia by following the boxed instructions at the end of this leaflet.
- Telephone your doctor, the Poisons Information Centre (telephone 13 11 26 in Australia), or go to the Accident and Emergency department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are taking GLYADE MR

Things you must do

Take GLYADE MR exactly as your doctor has prescribed. Otherwise you may not get the full benefits from treatment.

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Tell all doctors, dentists, pharmacists and diabetes educators who are involved with your treatment that you are taking GLYADE MR.

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.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of **hypoglycaemia** and **hyperglycaemia** and know what to do. Boxed instructions at the end of this leaflet can help you with this.

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

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

Tell your doctor immediately if you notice the return of any symptoms of hyperglycaemia that you had before starting GLYADE MR, or if your blood sugar levels are high. These may be signs that GLYADE MR is no longer working, even though you may have been taking it successfully for some time.

Things you must not do

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

Do not use GLYADE MR to treat other complaints unless your doctor tells you to.

Do not stop taking GLYADE MR, or change the dosage, without checking with your doctor.

Do not skip meals while taking GLYADE MR.

Things to be careful of

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

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

GLYADE MR may cause dizziness and drowsiness in some people. Drinking alcohol can make this worse. If either of these occurs, 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. **A boxed section at the end of this leaflet contains advice about recognising and treating hypoglycaemia.**

Side Effects

If you do not feel well while you are taking GLYADE MR then tell your doctor, pharmacist, or diabetes educator as soon as possible.

All medicines can have side effects. Most of the time they are not serious but sometimes they can be.

GLYADE MR helps most people with Type 2 diabetes, but it may sometimes have unwanted side effects. These can include:

- **Hypoglycaemia. A boxed section at the end of this leaflet contains advice about recognising and treating hypoglycaemia.**
- Stomach upset with symptoms like feeling sick, heartburn, diarrhoea or constipation.

Hypoglycaemia requires prompt attention (see boxed section at the end of this leaflet).

Other side effects are usually mild when they occur. Do not be alarmed by this list of possible side effects. You may not experience any of them. However if you do – or if you notice anything else that is making you feel unwell – you should consult your doctor or pharmacist. Other uncommon side effects have been reported and you may wish to discuss this issue with your doctor, pharmacist, or diabetes educator.

If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- Skin rash, itching and/or hives.

These side effects are very rare but can become serious.

After taking GLYADE MR

Storage

Keep GLYADE MR tablets where children cannot reach them. 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. GLYADE MR will not keep as well outside its blister packaging.

Heat and dampness can destroy some medicines. Keep them in a cool dry place where the temperature stays below 30°C. Do not store medicines in the bathroom or near a sink. Do not leave them in a car or on a windowsill.


Disposal

If your doctor tells you to stop taking GLYADE MR, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

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What GLYADE MR looks like

GLYADE MR tablets are white oblong tablets with "DIA 30" engraved on one face and Servier logo  on the other.

GLYADE MR tablets come in a blister strip. Each box contains 100 tablets.

Ingredients

Each tablet of GLYADE MR contains 30 mg of gliclazide as the active ingredient and a number of inactive ingredients.

The inactive ingredients in GLYADE MR tablets include calcium hydrogen phosphate, maltodextrin, hypromellose, magnesium stearate, colloidal anhydrous silica.

The tablets are gluten free and lactose free.

Distributor

GLYADE MR is distributed in Australia by:
Alphapharm Pty Limited
Chase Building 2
Wentworth Park Road
Glebe NSW 2037
ABN 93 002 359 739

GLYADE MR is registered on the Australian Register of Therapeutic Goods. Australian Register Number: AUST R

This leaflet was prepared July 2007

Recognising and treating hypoglycaemia (very low blood sugar levels)

Hypoglycaemia may occur during GLYADE MR treatment.

The first signs of hypoglycaemia are usually weakness, trembling or shaking, sweating, lightheadedness, dizziness, headache or lack of concentration, irritability, tearfulness, hunger, and/ or numbness around the lips and tongue.

At the first signs of hypoglycaemia take some sugar to raise your blood sugar level quickly. Do this by eating 5 to 7 jelly beans, 3 teaspoons of sugar or honey, drinking half a can of non-diet soft drink, taking 2-3 glucose tablets or a tube of glucose gel.

Then take some extra carbohydrates - such as plain biscuits, fruit or milk - unless you are within 10-15 minutes of your next meal. Taking this extra carbohydrate will help to prevent a second drop in your blood glucose level.

If not treated quickly, hypoglycaemia symptoms may progress to loss of co-ordination, slurred speech, confusion, fits or loss of consciousness.

If hypoglycaemia symptoms do not get better straight away after taking sugar then go to the Accident and Emergency department at your nearest hospital – if necessary by calling an ambulance.

Contact your doctor or diabetes educator for advice if you are concerned about hypoglycaemia.

Recognising and treating hyperglycaemia (high blood sugar levels)

Some people may feel fine when their glucose levels are high. Others notice symptoms of hyperglycaemia like tiredness, lack of energy, thirst, passing large amounts of urine, headache, and/or blurred vision.

If you notice symptoms of hyperglycaemia, or your blood sugar levels are high, tell your doctor immediately. You may need adjustments of the dose or type of medicines you are taking.

It is very important to control high blood glucose whether or not you feel unwell. This really helps to avoid serious long-term health problems, which can involve the heart, eyes, circulation, and/or kidneys.

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