

**APPROVED PATIENT INFORMATION LEAFLET for
DYNA GLICLAZIDE SR 30 mg (C1009)**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DYNA GLICLAZIDE SR 30 mg tablets

Read all of this leaflet carefully before you start taking DYNA GLICLAZIDE SR 30 mg.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **DYNA GLICLAZIDE SR 30 mg** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT DYNA GLICLAZIDE SR 30 mg CONTAINS:

The active substance is gliclazide.

Each **DYNA GLICLAZIDE SR 30 mg** tablet contains 30 mg gliclazide.

The other ingredients are calcium carbonate, colloidal silica dioxide, hypromellose, lactose monohydrate, magnesium stearate.

DYNA GLICLAZIDE SR 30 mg tablets contain sugar in the form of lactose monohydrate.

2. WHAT DYNA GLICLAZIDE SR 30 mg IS USED FOR:

The active substance, gliclazide, is a sulphonylurea antidiabetic medicine. It is used to treat a certain type of diabetes mellitus called type 2 diabetes.

Your doctor will only prescribe **DYNA GLICLAZIDE SR 30 mg** when your blood sugar level cannot be controlled with diet and exercise alone.

When you have type 2 diabetes, the amount of insulin your pancreas produces may not be enough, or your body may not be using it properly and you may still need more. **DYNA GLICLAZIDE SR 30 mg** works by causing your pancreas to release more insulin into the blood stream.

3. BEFORE YOU TAKE DYNA GLICLAZIDE SR 30 mg:

Do not take DYNA GLICLAZIDE SR 30 mg:

- if you are hypersensitive (allergic) to gliclazide, or to any of the other ingredients of **DYNA GLICLAZIDE SR 30 mg** (see **WHAT DYNA GLICLAZIDE SR 30 mg CONTAINS**).

- if you are hypersensitive (allergic) to any other sulphonylurea (medicine for diabetes) or sulphonamides (a type of antibiotic).
- if you have type 1 diabetes mellitus (Type 1 diabetes patients cannot produce or release insulin from their pancreas).
- if you have a liver disease.
- if you have severe kidney disease.
- if you have acid (acidosis) or ketones (diabetic ketoacidosis - a life-threatening problem that occurs when the body cannot use sugar (glucose) as a fuel source because there is no insulin or not enough insulin in your blood).
- if you have severe burns or injuries, a severe infection or had a major surgery.
- if you are pregnant or breastfeeding your baby.
- if you are taking a medicine to treat fungal infections called miconazole (see **Taking other medicines with DYNA GLICLAZIDE SR 30 mg**).

DYNA GLICLAZIDE SR 30 mg is contraindicated in children.

Take special care with DYNA GLICLAZIDE SR 30 mg:

The presence of other medical problems may affect the use of **DYNA GLICLAZIDE SR 30 mg**. Make sure you tell your doctor if you have any other medical problems, especially:

- if you have heart disease,
- if you have an overactive or underactive thyroid not properly controlled.
- if you have an underactive adrenal gland not properly controlled, as **DYNA GLICLAZIDE SR 30 mg** may worsen the condition.

- if you have an underactive pituitary gland not properly controlled.
- if you are undernourished or have a weakened physical condition.

In the initial weeks of treatment, the risk of low blood sugar may be increased and careful monitoring is necessary. Prolonged or serious episodes of hypoglycaemia (low blood sugar), even if controlled by sugar intake, require immediate medical treatment or even hospitalisation.

Symptoms of low blood sugar include aggression, apathy, behavioural changes that can mimic drunkenness, poor concentration, confusion, delirium, nightmares, sleepiness, sleep disorders, restlessness, depression, dizziness, seizures, blurred vision, slurred speech, excessive hunger, nausea, vomiting, shallow respiration, coma, slow heartbeat, anxiety, cold sweats, cool pale skin and shakiness.

It is important that you learn which symptoms of low blood sugar you usually have so that you can treat it quickly. You must also educate your family members about the symptoms of hypoglycaemia and how to treat them.

Symptoms of low blood sugar may develop quickly and may result from:

- i. Impaired (decreased) kidney function.
- ii. Patients refusing (especially the elderly) or unable to cooperate.
- iii. Delaying or missing a scheduled meal or snack, poor nutrition, if you are fasting, if you have changed your diet.
- iv. Exercising more than usual without increasing your carbohydrate intake.

- v. Drinking a significant amount of alcohol, especially when skipping meals
- vi. Severely impaired (decreased) liver function
- vii. Overdosage with **DYNA GLICLAZIDE SR 30 mg**.
- viii. If you suffer from problems with your thyroid, pituitary or adrenal glands
- ix. If you are or have been taking high doses of corticosteroids (used to treat inflammation)
- x. If you have a severe heart disease
- xi. If you take other medicines at the same time (see **Taking other medicines with DYNA GLICLAZIDE SR 30 mg**).

The effects of **DYNA GLICLAZIDE SR 30 mg** may reduce over long periods of time and your doctor may increase your dose and request you increase the frequency of monitoring of your sugar levels.

In order to avoid gastrointestinal side effects (see **SIDE EFFECTS**) you should take your tablets with breakfast.

Should you experience side effects affecting the liver, your doctor may change your medication.

There is a potential for the occurrence of serious skin conditions to develop (toxic dermal necrolysis and allergic vasculitis). Symptoms include a painful, red area that spreads quickly, skin peeling without blistering, raw areas of skin, discomfort, fever, purple-coloured spots and patches on the skin, blisters, hives, open sores).

Do not eat chocolate because its fat slows down the sugar entering your bloodstream.

Know what to do if symptoms of low blood sugar occur. Eating some form of quick-acting sugar when symptoms of low blood sugar first appear will usually prevent them from getting worse.

Good sources of sugar include:

- Glucose tablets or gel.
- Fruit juice or non-diet soft drink (one-half cup) and sugar sweetened tea.
- Corn syrup or honey (1 tablespoon).
- Sugar cubes or table sugar dissolved in water.

If you have been diagnosed with, or have a family history of, a hereditary condition called G6PD (glucose-6-phosphate dehydrogenase) deficiency (abnormality of red blood cells), a side effect called haemolytic anaemia (abnormal breakdown of red blood cells) can occur when taking **DYNA GLICLAZIDE SR 30 mg**.

Your doctor may request tests to monitor your condition before or during treatment.

Taking DYNA GLICLAZIDE SR 30 mg with food and drink:

DYNA GLICLAZIDE SR 30 mg must be taken with food.

The tablet must be swallowed whole with half a glass of water and should be taken immediately before a substantial breakfast or the first main meal of the day. You should not miss a meal after you have taken the tablets.

Pregnancy and breastfeeding:

You should not take this medicine if you are pregnant or breastfeeding your baby (see **DO NOT TAKE DYNA GLICLAZIDE SR 30 mg**).

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **DYNA GLICLAZIDE SR 30 mg**.

Driving and using machinery:

You should be aware of the symptoms of hypoglycaemia (low blood sugar) which include dizziness, poor concentration, confusion, sleepiness and blurred vision.

Do not drive or operate machinery until you know how **DYNA GLICLAZIDE SR 30 mg** affects you.

Important information about some of the ingredients of DYNA GLICLAZIDE SR 30 mg:

DYNA GLICLAZIDE SR 30 mg contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **DYNA GLICLAZIDE SR 30 mg**.

DYNA GLICLAZIDE SR 30 mg contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with DYNA GLICLAZIDE SR 30 mg:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The following medicines or substances may cause your blood sugar levels to fall even lower than normal when taken together with **DYNA GLICLAZIDE SR 30 mg**:

- A medicine containing miconazole (used to treat fungal infections) increases the risk of hypoglycaemia or even coma and is therefore contraindicated (see **Do not take DYNA GLICLAZIDE SR 30 mg**).
- Alcohol increases the risk of hypoglycaemia (low blood sugar) and coma. Alcohol and medicines containing alcohol should be avoided.
- Allopurinol, probenecid, sulphinyprazole (anti-gout medicine).
- Anabolic steroids (a steroid hormone which promotes muscle growth) and androgens (male sex hormone).
- Certain medications used to treat high blood pressure and heart disease such as ACE-inhibitors, antidysrhythmics. (disopyramide), captopril, enalapril, quinidine, quinine and clonidine.
- Beta-blockers may increase the chance that high or low blood sugar can occur. Also, they can hide the symptoms of low blood sugar.

- Certain medications used to treat fungal and bacterial infections, such as ketoconazole, itraconazole, voriconazole, ciprofloxacin, chloramphenicol, sulphonamides, quinolones and tetracyclines.
- Anticoagulants (blood thinners).
- Certain antidepressants such as fluoxetine and monoamine-oxidase inhibitors.
- The appetite suppressant fenfluramine.
- Ranitidine and cimetidine (medicines used to treat heartburn).
- Fibrates (such as clofibrate) used to treat high cholesterol.
- Insulin and other oral antidiabetic medicines (such as acarbose, metformin, thiazolidinediones).
- Certain medicines used to treat pain and inflammation (NSAIDs and salicylates) such as aspirin, azapropazone and oxyphenbutazone.

Tell your doctor if you take any of the above mentioned medicines.

The following medicines may cause your blood sugar levels to rise when taken together with **DYNA GLICLAZIDE SR 30 mg**:

- Danazol used to treat endometriosis is not recommended for use with **DYNA GLICLAZIDE SR 30 mg**. If it cannot be avoided, regular urine and blood glucose monitoring must be done. Your dose of **DYNA GLICLAZIDE SR 30 mg** may need to be adjusted.
- Epinephrine (adrenaline), asthma medicines (salbutamol, terbutaline), cough and cold medicines, medicines containing ephedrine and pseudoephedrine.
- Corticosteroids (cortisone-like medicines used to treat inflammation).

- Calcium channel blockers, clonidine, diazoxide (cardiovascular medicines used to treat heart problems).
- Lithium (used to treat certain types of depression).
- Thiazide diuretics (water tablets).
- Anti-epileptic medication such as phenytoin.
- Glucagon (a hormone that assists with the breakdown of glucogen to glucose).
- Female hormones oestrogen and progesterone.
- Antibacterial medicines rifampicin and isoniazid.
- Thyroid hormones.
- Barbiturates (sleeping tablets and sedatives).
- Chlorpromazine (tranquiliser or sedative also used for nausea or vomiting).
- Glucocorticoids (used to assist the body to break down carbohydrates, proteins and fats).
- Ritrodrene (used to stop premature labour).

Tell your doctor if you are taking any of the above mentioned medicines.

4. HOW TO TAKE DYNA GLICLAZIDE SR 30 mg:

Do not share medicines prescribed for you with any other person.

Always take **DYNA GLICLAZIDE SR 30 mg** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of **DYNA GLICLAZIDE SR 30 mg** is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will decide on the correct dose based on your metabolic response and blood sugar level. The tablet must be swallowed whole with half a glass of water and should be taken immediately before a substantial breakfast or the first main meal of the day. You should not miss a meal after you have taken the tablets. Take **DYNA GLICLAZIDE SR 30 mg** at the same time each day.

The usual initial dose is 30 mg (one tablet) once daily, taken with breakfast.

Dose adjustments:

If your fasting blood glucose levels have not decreased satisfactorily, your doctor may increase the dosage progressively to 60, 90 or 120 mg per day (2 to 4 tablets). Your doctor will instruct you how to increase your dosage, but usually you should increase the number of tablets at an interval of at least one month between each increment.

If you take more DYNA GLICLAZIDE SR 30 mg than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Too much **DYNA GLICLAZIDE SR 30 mg** can cause low blood sugar (also called hypoglycaemia). (The side effects of low blood sugar are detailed in **Take special care with DYNA GLICLAZIDE SR 30 mg** and are listed under **POSSIBLE SIDE EFFECTS**).

Symptoms of low blood sugar must be treated before they lead to unconsciousness (passing out). It is important that you learn which symptoms of low blood sugar you usually have so that you can treat it quickly.

Severe or persistent hypoglycaemia will need immediate treatment, follow-up by a medical doctor and may even require urgent hospital admission. If hypoglycaemia has persisted for a protracted (lengthy) period of time, neurological (nervous system) damage may not be reversible.

If you forget to take a dose of DYNA GLICLAZIDE SR 30 mg:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

DYNA GLICLAZIDE SR 30 mg can have side effects.

Not all side effects reported for **DYNA GLICLAZIDE SR 30 mg** are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while taking **DYNA GLICLAZIDE SR 30 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **DYNA GLICLAZIDE SR 30 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- skin rash including purple or red spots, hives or blisters
- serious skin conditions such as Stevens-Johnson syndrome and toxic epidermal necrolysis with symptoms such as blistering of the skin, mouth eyes or genitals).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **DYNA GLICLAZIDE SR 30 mg**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- low blood sugar levels (you may experience a number of the following side effects at the same time: headache, excessive hunger, nausea, vomiting, lack of energy, restlessness, trouble sleeping, sleepiness or drowsiness, nightmares, agitation, aggression, poor concentration, decreased awareness, slowed reactions, depression, delirium, lack of interest, confusion, trouble with vision or speech, slurring, seizures (fits), tremor, muscle weakness, dizziness, feeling of powerlessness, drunken behaviour, losing self control, shallow breathing, abnormally slow or fast heartrate, unconsciousness, coma, sweating, cold sweats, clammy skin, anxiety, high blood pressure, fast heartbeat, chest pain)
- abnormally slow or fast heart-rate, palpitations, high blood pressure, heart attack, chest pain
- liver failure (signs include yellow discolouration of the skin and eyes (jaundice) and pain in the upper right abdomen)
- kidney problems (passing more urine than is normal for you or more frequently).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness, drowsiness
- constipation, diarrhoea, stomach pain or discomfort, stomach spasms, decreased or increased appetite, heartburn, bloating, flatulence (gas), weight gain, nausea, vomiting, changes in sense of taste
- increased frequency to urinate

Less frequent side effects:

- abnormal blood test results including anaemia
- anorexia
- blurred vision, worsening eyesight
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin)
- hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, blistering or peeling of the skin, thinning of the skin, pale skin, unusual bruising.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF DYNA GLICLAZIDE SR 30 mg:

Store at or below 25 °C in a dry place.

Keep well closed for HDPE containers.

Keep the tablets in the original packaging until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

8. IDENTIFICATION OF DYNA GLICLAZIDE SR 30 mg:

White to almost white, oval, slightly biconvex tablets.