PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ZICLAGID MR 30 mg modified-release tablets

ZICLAGID MR 60 mg modified-release tablets

Gliclazide

Contains sugar.

ZICLAGID MR 30 mg: Each modified-release tablet contains 59,4 mg lactose monohydrate.

ZICLAGID MR 60 mg: Each modified-release tablet contains 118,8 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking ZICLAGID MR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZICLAGID MR 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.

What is in this leaflet

1. What ZICLAGID MR is and what it is used for
2. What you need to know before you take ZICLAGID MR
3. How to take ZICLAGID MR
4. Possible side effects
5. How to store ZICLAGID MR
6. Contents of the pack and other information.

1. What ZICLAGID MR is and what it is used for

ZICLAGID MR is an oral antidiabetic medicine belonging to the sulphonylurea group that reduces blood sugar levels.

ZICLAGID MR is used in a certain form of diabetes (type 2 diabetes mellitus) in adults, when diet, exercise and weight loss alone do not have an adequate effect on keeping blood sugar at the correct level.

2. What you need to know before you take ZICLAGID MR

Do not take ZICLAGID MR

- If you are hypersensitive (allergic) to gliclazide, other sulphonylureas, sulphonamides, or to any of the other ingredients of ZICLAGID MR listed in section 6 of this leaflet.
- If you have insulin-dependent diabetes (type 1).
- If you have ketone bodies and sugar in your urine (this may mean you have diabetic ketoacidosis), a diabetic pre-coma or coma.
- If you have a severe liver or kidney disease.
- If you are taking miconazole (a medicine used to treat fungal infections).
- If you are pregnant or breastfeeding your baby.

Do not give ZICLAGID MR to children.

Warnings and precautions

Talk to your doctor before taking ZICLAGID MR.

Follow the treatment plan prescribed by your doctor carefully to achieve proper blood sugar levels. This means, apart from regularly taking ZICLAGID MR, you should observe your dietary regimen, do physical exercise and, where necessary, reduce your weight. During ZICLAGID MR treatment regular monitoring of your blood (and possibly urine) sugar level and also your glycosylated haemoglobin (HbA1c) is necessary.

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased.

Low blood sugar (hypoglycaemia) may occur:

- if you take meals irregularly or skip meals altogether,
- if you are fasting,

- if you are malnourished,
- if you change your diet,
- if you increase your physical activity and carbohydrate intake does not match this increase,
- if you drink alcohol, especially in combination with skipped meals,
- if you take other medicines or natural remedies at the same time,
- if you take too high doses of ZICLAGID MR,
- if you suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex),
- if your kidney function or liver function is severely decreased.

Symptoms of low blood sugar (hypoglycaemia)

If you have low blood sugar you may have the following symptoms: headache, intense hunger, nausea (feeling sick), vomiting (being sick), weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness and feeling of helplessness. The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heartbeat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).
If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions (fits), lose self-control, your breathing may be shallow and your heartbeat slowed down, you may become unconscious.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, such as glucose tablets, sugar cubes, sweet juice or sweetened tea. You should therefore always carry some form of sugar with you (glucose tablets, sweets or sugar cubes). Remember that artificial sweeteners or products containing only artificial sweeteners are not effective. Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.
Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you may not

be aware in time that your blood sugar level has dropped. This may happen if you are an elderly patient taking certain medicines (such as those acting on the central nervous system and beta-blockers) or if you are in stressful situations (such as accidents, undergoing surgery, fever etc.). Your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia)

Symptoms of high blood sugar (hyperglycaemia) may occur when ZICLAGID MR has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor, if you take St John's wort (*Hypericum perforatum*) preparations (see section **Other medicines and ZICLAGID MR**) or in special stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.
If these symptoms occur, you must contact your doctor or pharmacist.

Glucose-6-phosphate dehydrogenase (G6DP)

If you have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells); lowering of the haemoglobin level and breakdown or red blood cells (haemolytic anaemia) can occur. Contact your doctor before taking ZICLAGID MR.

Children and adolescents

ZICLAGID MR is not recommended for use in children due to a lack of data (see section **Do not take ZICLAGID MR**).

Other medicines and ZICLAGID MR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
The blood sugar-lowering effect of ZICLAGID MR may be increased and signs of low blood sugar levels may occur when one of the following medicines is taken:

- Other medicines used to treat high blood sugar (oral antidiabetics or insulin).

- Antibiotics (such as sulphonamides, clarithromycin).
- Medicines to treat high blood pressure or heart failure (beta-blockers, such as propranolol, bisoprolol or ACE inhibitors, such as captopril or enalapril).
- Medicines to treat fungal infections (miconazole, fluconazole or ketoconazole).
- Medicines to treat ulcers in the stomach or duodenum (cimetidine, ranitidine).
- Medicines to treat depression (monoamine oxidase inhibitors).
- Medicines to treat pain (phenylbutazone, ibuprofen).
- Alcohol or medicines containing alcohol.

The blood glucose-lowering effect of ZICLAGID MR may be decreased and raised blood sugar levels may occur when one of the following medicines is taken:

- Medicines to treat disorders of the central nervous system (chlorpromazine).
- Medicines reducing inflammation (corticosteroids).
- Medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline).
- Danazol (medicine to treat breast disorders and endometriosis).
- St John’s wort (herbal remedy used to treat depression).

ZICLAGID MR may increase the effects of medicines which reduce blood clotting (such as warfarin).

Blood glucose disturbances may occur when you take fluoroquinolones (antibiotic medicines used to treat bacterial infections) with ZICLAGID MR.

ZICLAGID MR with food and drink

ZICLAGID MR can be taken with food and non-alcoholic drinks.

Drinking alcohol is not recommended as it can alter the control of your diabetes in an unpredictable manner.

Gastrointestinal symptoms, such as stomach pain, discomfort, nausea (feeling sick) or vomiting

(being sick), heartburn, diarrhoea or constipation can be reduced when ZICLAGID MR is taken with food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ZICLAGID MR.

ZICLAGID MR should not be used during pregnancy and breastfeeding.

Driving and using machines

If your diabetes is not well controlled by ZICLAGID MR, your ability to concentrate or to react may be impaired if, for example, your blood sugar is too low (hypoglycaemia) or too high (hyperglycaemia). It is not always possible to predict to what extent ZICLAGID MR may interfere with your daily activities. You should ensure that you do not engage in activities, e.g. driving a vehicle, operating machinery or do anything else that require your attention until you are aware of the measure to which ZICLAGID MR affects you.

ZICLAGID MR contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZICLAGID MR.

3. How to take ZICLAGID MR

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

Always take ZICLAGID MR exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 30 mg to 120 mg, taken once a day with breakfast.

Your doctor may adjust your dose depending on blood sugar levels. Changes in external factors (such as weight loss, change in lifestyle, stress) or improvements in blood sugar control, may also require your dose of ZICLAGID MR to change.

Method of administration

Swallow your tablets whole. Do not chew them.

Take your tablet(s) with a glass of water at breakfast time (and preferably at the same time each day). You must always eat a meal after taking your tablet(s).

Your doctor will tell you how long your treatment with ZICLAGID MR will last.

If you have the impression that the effect of ZICLAGID MR is too strong or too weak, or if you notice that your blood sugar levels are high even though you are taking ZICLAGID MR as prescribed, you should tell your doctor or pharmacist.

If you take more ZICLAGID MR than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You may require medical attention.

The signs of overdose are those of low blood sugar (hypoglycaemia). The symptoms can be helped by taking sugar or sugary drinks straight away, followed by a substantial snack or meal. If the patient is unconscious immediately inform a doctor and call the emergency services. The same should be done if somebody, e.g. a child, has taken ZICLAGID MR unintentionally. Unconscious patients must not be given food or drink.

It should be ensured that there is always a pre-informed person that can call a doctor in case of emergency.

If you forget to take ZICLAGID MR

If you forget a dose, this dose should be skipped, and the next dose should be taken at the usual time with a meal. Do not take a double dose to make up for a forgotten dose.

If you stop taking ZICLAGID MR

As the treatment for diabetes is usually life long, you should discuss it with your doctor before stopping ZICLAGID MR. Stopping could cause high blood sugar (hyperglycaemia), which

increases the risk of developing complications of diabetes.

4. Possible side effects

ZICLAGID MR can have side effects.

Not all side effects reported for ZICLAGID MR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZICLAGID MR, please consult your health care provider for advice.

If any of the following happens, stop taking ZICLAGID MR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZICLAGID MR. 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 (hypoglycaemia). For signs and symptoms of hypoglycaemia, please refer to the section **Take special care with ZICLAGID MR** – Signs of low blood sugar (hypoglycaemia). If left untreated, these symptoms can progress to drowsiness, loss of consciousness or possible coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention.
- blood disorders (including paleness of the skin, prolonged bleeding, bruising, sore throat and fever),
- yellowing of the skin and eyes, also called hepatitis or jaundice,
- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis,

- DRESS syndrome (skin rash on your face that extends to your body, fever and flu-like symptoms).

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:

- stomach pain, feeling sick (nausea), being sick (vomiting), heartburn, diarrhoea, constipation,
- rash, itching.

Less frequent side effects:

- visual difficulties,
- abnormal liver function test results,
- skin reactions, such as hives, redness, blisters or swelling.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZICLAGID MR.

5. How to store ZICLAGID MR

- Store at or below 25 °C, in a dry place.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or blister strip.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZICLAGID MR contains

The active substance in ZICLAGID MR is gliclazide.

ZICLAGID MR 30 mg: Each modified-release tablet contains 30 mg gliclazide.

ZICLAGID MR 60 mg: Each modified-release tablet contains 60 mg gliclazide.

The other ingredients are lactose monohydrate, magnesium stearate (E572), anhydrous sodium carbonate, hypromellose and anhydrous colloidal silica.

What ZICLAGID MR looks like and contents of the pack

ZICLAGID MR 30 mg: White to cream white, oblong, uncoated tablets, engraved with “30” on one side and plain on the other side.

ZICLAGID MR 60 mg: White to cream white, oblong, uncoated tablets, engraved with “60” on one side and plain on the other side.

Clear PVC/PVDC/silver aluminium blister strips packed into an outer carton.

Pack sizes:

ZICLAGID MR 30 mg: 60 tablets.

ZICLAGID MR 60 mg: 30 tablets.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

Centurion, Pretoria

0157

This leaflet was last revised

HCR: Zydus Healthcare SA (Pty) Ltd

Date of registration: 26 November 2024

Date of revision: Not revised yet.

Registration numbers

ZICLAGID MR 30 mg: 53/21.2/0551

ZICLAGID MR 60 mg: 53/21.2/0552