PROFESSIONAL INFORMATION FOR GLYTAB 30 mg

SCHEDULING STATUS
S3

PROPRIETARY NAME AND DOSAGE FORM
GLYTAB 30 mg modified release tablets

COMPOSITION
Each modified release tablet contains 30 mg gliclazide.
Inactive ingredients: calcium hydrogen phosphate anhydrous, hypromellose, magnesium stearate.
Sugar free.

PHARMACOLOGICAL CLASSIFICATION
A 21.2 Oral hypoglycaemics

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
Gliclazide is a sulphonylurea hypoglycaemic medicine, which reduces blood glucose levels by stimulating insulin secretion from the β-cells of the islets of Langerhans. In addition to this pancreatic action, it has been demonstrated that gliclazide administration may improve the metabolic utilisation of glucose at a peripheral level.

Pharmacokinetic properties
Plasma levels increase progressively until the sixth hour, resulting in a plateau-shaped curve from the sixth to the twelfth hour after administration. Gliclazide is completely absorbed. Food intake does not affect the rate or degree of absorption. The relationship between the dose administered and the area under the concentration curve, as a function of time, is linear up to 120 mg. Plasma protein binding is approximately 95 %.
Gliclazide is metabolised in the liver and excreted in the urine; less than 1 % of the unchanged form is found in the urine. No active metabolites have been detected in plasma. The elimination half-life of gliclazide varies between 12 and 20 hours.
No clinically significant modifications in the pharmacokinetic parameters have been observed in elderly patients.
A single daily dose of gliclazide maintains glucose lowering effects over 24 hours.

INDICATIONS
In Type 2 diabetic patients, in association with dietary measures, life-style changes and exercise, when dietary measures, life-style and exercise alone are not sufficient to control blood glucose.

CONTRAINDICATIONS
- Hypersensitivity to gliclazide, other sulphonylureas, sulphonamides, or to any of the ingredients of **GLYTAB 30 mg** (see **COMPOSITION**).
- Type 1 diabetes (juvenile insulin dependent diabetes mellitus), diabetic keto-acidosis or diabetic pre-coma.
- Children.
- Severe renal or hepatic insufficiency.
- **Pregnancy and lactation, as safety has not been established** (see **PREGNANCY AND LACTATION**)

WARNINGS AND SPECIAL PRECAUTIONS
The administration of oral hypoglycaemic medicines may be associated with increased cardiovascular mortality, as compared to treatment with diet alone or diet with insulin.

Factors favouring hypoglycaemia include:
- Patient refusing or (particularly elderly patients) being unable to co-operate.
- Malnutrition, irregular mealtimes, skipping meals, periods of fasting or dietary changes.
- Imbalance between physical exercise and carbohydrate intake.
- Overdose of **GLYTAB 30 mg** (see **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**).
- Certain endocrine disorders: thyroid disorders, hypopituitarism and adrenal insufficiency.
- Concomitant administration of certain other medicines (see **INTERACTIONS**).
- Deterioration in renal function.

The pharmacokinetic and pharmacodynamic properties of gliclazide may be altered in patients with hepatic or renal insufficiency. A hypoglycaemic episode occurring in these patients may be prolonged, thus appropriate management should be initiated and careful monitoring of blood-glucose concentration is essential during treatment with **GLYTAB 30 mg** (see **DOSAGE AND DIRECTIONS FOR USE**).

GLYTAB 30 mg should only be prescribed if the patient is likely to have a regular food intake (including breakfast). It is important to have a regular carbohydrate intake due to the increased risk of hypoglycaemia if a meal is taken late, if an inadequate amount of food is consumed or if the food is low in carbohydrates. Hypoglycaemia is more likely to occur during periods of low-calorie diet, irregular carbohydrate intake, following prolonged or strenuous exercise, following alcohol intake or during the administration of a combination of hypoglycaemic medicines. Symptoms of hypoglycaemia usually disappear after absorption of carbohydrates (sugar). However, despite initial effective measures, hypoglycaemia may occur. Artificial sweeteners have no effect on hypoglycaemia. In the case of severe prolonged hypoglycaemia, immediate medical treatment and even hospitalisation is necessary.
In an exceptional stress situation e.g. trauma, fever, infection or surgical intervention, or during the concomitant treatment with St. John's Wort (*Hypericum perforatum*) preparations (see **INTERACTIONS**), blood glucose regulation may deteriorate, and a temporary change to insulin may be necessary to maintain good metabolic control.

The hypoglycaemic efficacy of any oral antidiabetic medicine, including gliclazide, as in **GLYTAB 30 mg**, is attenuated over time in many patients. This may be due to progression in the severity of the diabetes, or to a reduced response to treatment. Adequate dose adjustment and dietary compliance should be considered.

Disturbances in blood glucose, including hypoglycaemia and hyperglycaemia, have been reported in diabetic patients receiving concomitant treatment with fluoroquinolones (especially in elderly patients). Careful monitoring of blood glucose is recommended during concomitant treatment (see **INTERACTIONS**).

The treatments of patients with glucose-6-phosphate dehydrogenase (G6DP) deficiency with sulfonylurea medicines, such as **GLYTAB 30 mg**, can lead to haemolytic anaemia. Caution is advised in patients with G6PD deficiency and a non-sulfonylurea alternative should be considered.

Laboratory tests:
Measurement of glycated haemoglobin levels (or fasting venous plasma glucose) is recommended in assessing blood glucose control. Self-monitoring of blood glucose levels may also be considered.

Effects on ability to drive and use machines
Patients should be made aware of the symptoms of hypoglycaemia, and should be careful when driving, or operating machinery.

INTERACTIONS
The following may increase the risk of hypoglycaemia:
- Antifungals, such as miconazole, fluconazole, ketoconazole.
- Barbiturates
- Beta-blockers.
- Cimetidine, ranitidine.
- Allopurinol.
- Angiotensin-converting enzyme (ACE) inhibitors, such as captopril and enalapril.
- Mono-amine oxidase (MOA) inhibitors, quinidine, quinine or salicylates.
- Nonsteroidal anti-inflammatory medicine (NSAIDs).
- Alcohol. Avoid intake of alcohol or medication containing alcohol.

The following may increase the risk of hyperglycaemia:
- Glucocorticoids, thiazide diuretics, lithium.
- Salbutamol, terbutaline I.V.
- Other beta-adrenergic agonists.
- Ephedrine, pseudoephedrine and common cold products.
- Chlorpromazine.
- Ritodrine.

The concomitant use of **GLYTAB 30 mg** and danazol is not recommended. It is important to monitor urine and blood glucose levels if concurrent use cannot be avoided.
GLYTAB 30 mg may potentiate anticoagulation during concomitant treatment with anticoagulation therapy (i.e. warfarin). Adjustment of the anticoagulant dose may be required.
GLYTAB 30 mg may increase the plasma concentration of ciclosporin by reducing its metabolism. Dose reduction of ciclosporin may be necessary.
St. John's wort (Hypericum perforatum) decreases exposure to gliclazide and blood glucose levels should be monitored during concomitant administration with **GLYTAB 30 mg** (see **WARNINGS AND SPECIAL PRECAUTIONS**).
Dysglycaemia may occur during concomitant treatment of **GLYTAB 30 mg** and fluoroquinolones. Blood glucose levels should be monitored (see **WARNINGS AND SPECIAL PRECAUTIONS**).

PREGNANCY AND LACTATION
GLYTAB 30 mg is contraindicated in pregnancy and lactation (see **CONTRAINDICATIONS**).
Control of diabetes should be obtained before the time of conception to reduce the risk of congenital abnormalities linked to uncontrolled diabetes.
It is recommended that oral hypoglycaemic treatment is changed to insulin before a pregnancy is attempted, or as soon as pregnancy is discovered.

DOSAGE AND DIRECTIONS FOR USE
For adult use only
The daily dose may vary from 1 to 4 tablets a day, i.e. 30 to 120 mg taken as a single daily dose. It is recommended that the medication be taken with breakfast. If a dose is forgotten, the dose taken on the next day should not be increased. The dose should be adjusted according to the individual patient's metabolic response (blood glucose levels and/or glycosylated haemoglobin HbA1C).

Initial dose
The initial recommended dose is 30 mg once daily, taken with breakfast.

Dose adjustment
If fasting blood glucose levels have not decreased satisfactorily, the dosage can be increased progressively to 60, 90 or 120 mg per day, by successive increments, respecting an interval of at least one month between each increment, except in patients whose blood glucose levels have not decreased after 15 days of treatment. In this case, it is possible to propose a dosage increase at the end of the 2nd week of treatment. The daily dose should not exceed 120 mg. Previously untreated patients should commence with a dose of 30 mg.

Replacement of gliclazide 80 mg with GLYTAB 30 mg
In patients stabilised on gliclazide 80 mg, the replacement of gliclazide 80 mg by **GLYTAB 30 mg** may initially be based on: 1 tablet gliclazide 80 mg = 1 tablet of **GLYTAB 30 mg**.

Replacement of another sulphonylurea with GLYTAB 30 mg
GLYTAB 30 mg can replace another sulphonylurea treatment. For the transition to **GLYTAB 30 mg**, the dosage and the half-life of the previous oral hypoglycaemic medicine must be taken into account. If a patient is changed from another oral sulphonylurea with a prolonged half-life, a therapeutic window of a few days may prove to be necessary to avoid the additive effect of the two products and the subsequent risk of hypoglycaemia. During such a changeover, it is recommended to follow the same procedure as for the initiation of the treatment with **GLYTAB 30 mg**, i.e. to initiate treatment with a dose of 30 mg per day and then increase the dosage by increments, according to the metabolic evolution of each patient.

Association with other oral antidiabetic agents
GLYTAB 30 mg, can be given in combination with alpha glucosidase inhibitors or insulin, but in that case, diabetic control should be checked with blood sugar readings, because of the possibility of hypoglycaemia. In combined therapy with biguanides, there may be a greater risk of cardiovascular mortality than with the use of gliclazide alone.

Elderly patients and patients with renal failure
The efficacy and tolerance of **GLYTAB 30 mg**, prescribed using the same therapeutic regimen in subjects over 65 years and patients with mild to moderate renal failure (30 – 80 ml/min) has been confirmed in clinical trials. The dosage will therefore be identical to that recommended for adults under the age of 65 years, and for patients with normal renal function, with careful patient monitoring.

SIDE EFFECTS
Hypoglycaemia
Treatment with **GLYTAB 30 mg** modified release tablets can cause hypoglycaemia if meals are taken irregularly or if they are skipped. Possible symptoms of hypoglycaemia are: headache, intense hunger, nausea, vomiting, lassitude, sleep disorders, agitation, aggression, poor concentration, reduced awareness and slowed reactions, depression, confusion, visual and speech disorders, aphasia, tremor, paresis, sensory disorders, dizziness, feeling of powerlessness, loss of self-control, delirium, convulsions, shallow respiration, bradycardia, drowsiness and loss of consciousness, possibly resulting in coma and lethal outcome.
In addition, signs of adrenergic counter-regulation may be observed: sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris and cardiac dysrhythmia.
Usually, symptoms disappear after the intake of carbohydrates (sugar). However, artificial sweeteners have no effect. Experience with other sulphonylureas shows that hypoglycaemia can recur even when measures prove effective initially.
If a hypoglycaemic episode is severe or prolonged, and even if it is temporarily controlled by intake of sugar, immediate medical treatment or even hospitalisation is required.

Blood and the lymphatic system disorders
Less frequent: Anaemia (aplastic or haemolytic), leucopenia, thrombocytopenia, pancytopenia, eosinophilia.

Immune system disorders
Less frequent: Angioedema.

Metabolism and nutrition disorders
Frequent: Hypoglycaemia, nocturnal hypoglycaemia.
Less frequent: Severe hypoglycaemia.

Nervous system disorders
Frequent: Dizziness, drowsiness.

Eye disorders
Less frequent: Transient visual disturbances including blurred vision or changes in accommodation.

Gastrointestinal disorders
Frequent: Taste disturbances.
Less frequent: Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea, constipation.

Hepato-biliary disorders
Less frequent: Hepatitis, cholestasis, cholestatic jaundice, hepatic function impairment, hepatic porphyria, porphyria cutanea tarda.
Discontinue treatment if cholestatic jaundice occurs.

Skin and subcutaneous tissue disorders
Less frequent: Rash, pruritus, urticaria, erythema multiforme or exfoliative dermatitis, maculopapular rashes, photosensitivity, bullous reactions (including Stevens-Johnson syndrome and toxic epidermal necrolysis), drug rash with eosinophilia and systemic symptoms (DRESS) syndrome.

Renal and urinary disorders
Frequent: Polyuria.

General disorders and administrative site conditions
Frequent: Headache.

Investigations
Frequent: Increased weight.
Less frequent: Raised hepatic enzyme levels (aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
An overdose of gliclazide may cause hypoglycaemia.
Moderate symptoms of hypoglycaemia, without any loss of consciousness or neurological signs, must be corrected by carbohydrate intake, dose adjustment and/or modification of diet.
Strict monitoring should be continued until the patient is out of danger.
Severe hypoglycaemic reactions, with coma, convulsions or other neurological disorders should be treated as a medical emergency, requiring immediate hospitalisation.
If hypoglycaemic coma is diagnosed or suspected, the patient should be given a rapid IV injection of 50 ml of concentrated glucose solution (50 %).
This should be followed by continuous infusion of a more dilute solution (10 %), at a rate necessary to maintain blood glucose levels above 5,5 mmol/l. Patients should be monitored closely, long enough to be sure that hypoglycaemia will not re-occur, and, depending on the patient's condition, the doctor will decide if further monitoring is necessary. Dialysis is of no use in these patients due to the strong binding of gliclazide to proteins.

IDENTIFICATION
White to off-white coloured, capsule shaped, uncoated tablets plain on both sides.

PRESENTATION
Clear PVC / aluminium or clear PVC/PVdC / aluminium blister strips containing 10 tablets. Each carton contains 60 or 100 tablets.

STORAGE INSTRUCTIONS
Store at or below 25 °C.
Keep in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
49/21.2/1207

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Forrester Pharma (Pty) Ltd
13 Pasita Street, Rosen Heights, Rosen Park, Bellville, 7530

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
20 March 2018

L0140/18A

PATIENT INFORMATION LEAFLET FOR GLYTAB 30 mg

SCHEDULING STATUS
Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
GLYTAB 30 mg modified release tablets

Read all of this leaflet carefully before you start taking **GLYTAB 30 mg**
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **GLYTAB 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 GLYTAB 30 mg CONTAINS
The active substance is 30 mg gliclazide.
The other ingredients are calcium hydrogen phosphate anhydrous, hypromellose, magnesium stearate.
Sugar free.

2. WHAT GLYTAB 30 mg IS USED FOR
GLYTAB 30 mg is a medicine that reduces blood sugar levels (oral antidiabetic medicine belonging to the sulphonylurea group).

GLYTAB 30 mg 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.

3. BEFORE YOU TAKE GLYTAB 30 mg
Do not take **GLYTAB 30 mg**:
- If you are hypersensitive (allergic) to gliclazide or any of the other ingredients of **GLYTAB 30 mg** (see **WHAT GLYTAB 30 mg CONTAINS**).
- If you have insulin-dependent diabetes (type 1).
- If you have a severe liver disease.
- If you have a severe kidney disease.
- If you are pregnant or breastfeeding your baby.

GLYTAB 30 mg is not recommended for use in children.

Take special care with GLYTAB 30 mg:
Follow the treatment plan prescribed by your doctor carefully to achieve proper blood sugar levels. This means, apart from regular tablet intake, you observe your dietary regimen, have physical exercise and, where necessary, reduce your weight.
During **GLYTAB 30 mg** treatment regular monitoring of your blood sugar level 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 **GLYTAB 30 mg**.
- 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.

If you have low blood sugar you may have the following symptoms:
headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness, and 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, 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 are not 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). If you are in stress-situations (such as accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia) may occur when **GLYTAB 30 mg** has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor 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.

Inform your doctor before taking **GLYTAB 30 mg** if you have a family history of, or you have been diagnosed with the hereditary condition glucose-6-phosphate dehydrogenase (G6DP) deficiency (abnormality of red blood cells), as lowering of the haemoglobin level in your body and breakdown of your red blood cells (haemolytic anaemia) can occur.

Taking GLYTAB 30 mg with food or drink:
It is recommended that **GLYTAB 30 mg** is taken with breakfast.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, please consult your doctor, pharmacist or healthcare professional before taking **GLYTAB 30 mg**.

Do not take **GLYTAB 30 mg** if you are pregnant, suspect that you are pregnant or breastfeeding your baby.

Driving and using machinery:
GLYTAB 30 mg may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that require your attention until you know how **GLYTAB 30 mg** affects you.

Taking other medicines with GLYTAB 30 mg:
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

The blood sugar lowering effect of **GLYTAB 30 mg** 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, ACE inhibitors such as captopril, or enalapril).
- Medicines to treat fungal infections (miconazole, fluconazole, ketoconazole).
- Medicines to treat ulcers in the stomach or duodenum (cimetidine, ranitidine).
- Medicines to treat depression (monoamine oxidase inhibitors).
- Medicines to treat pain (ibuprofen).
- Alcohol or medicines containing alcohol.

The blood glucose lowering effect of **GLYTAB 30 mg** 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 used to treat water retention and high blood pressure (thiazide diuretics).
- Lithium (used to treat depression).
- Medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline).
- Common cold products.

GLYTAB 30 mg may increase the effects of medicines which reduce blood clotting (such as warfarin).

GLYTAB 30 mg may increase the effect of medicines used after transplants (ciclosporin).

Blood glucose disturbances may occur when you take fluoroquinolones (antibiotic medicine used to treat bacterial infections), especially if you are elderly, or if you take St. John's wort (a herbal remedy used to treat depression) with **GLYTAB 30 mg**.

4. HOW TO TAKE GLYTAB 30 mg
Always take **GLYTAB 30 mg** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose is 1 to 4 tablets daily, taken once a day with breakfast. Your doctor may adjust your dose depending on your condition.

If you take more GLYTAB 30 mg than you should:
In event of overdosage, consult your doctor of pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take GLYTAB 30 mg:
If you have missed one 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.

5. POSSIBLE SIDE EFFECTS
GLYTAB 30 mg can have side effects.

Not all side effects reported for GLYTAB 30 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GLYTAB 30 mg, please consult your doctor, pharmacist or other healthcare professional.

If any of the following happens, stop taking **GLYTAB 30 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of your hands, feet, ankles, face, 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 allergic reaction to **GLYTAB 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:
- Blood disorders (including paleness of the skin, prolonged bleeding, bruising, sore throat and fever).
- Yellowing of the skin and eyes.
- Severe, painful skin rash causing blistering or peeling of your skin (erythema multiforme, exfoliative dermatitis, 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 as soon as possible if you notice any of the following:
- Hives.
- Dizziness or drowsiness.
- Blurred vision or difficulty to focus.
- Taste changes.
- Feeling sick (nausea), being sick (vomiting).
- Stomach pain.
- Heartburn.
- Constipation.
- Photosensitivity.
- Increased urination.
- Headache.
- Increased weight.
- Changes in blood results when tests are conducted.

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

6. STORING AND DISPOSING OF GLYTAB 30 mg
- Store at or below 25 °C.
- Keep 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 label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (such as toilets).

7. PRESENTATION OF GLYTAB 30 mg
Clear PVC/aluminium or clear PVC/PVdC/aluminium blister strips containing 10 tablets. Each carton contains 60 or 100 tablets.

8. IDENTIFICATION OF GLYTAB 30 mg
White to off-white coloured, capsule shaped, uncoated tablets plain on both sides.

9. REGISTRATION NUMBER
49/21.2/1207

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER
Forrester Pharma (Pty) Ltd
13 Pasita Street, Rosen Heights, Rosen Park, Bellville, 7530

11. DATE OF PUBLICATION
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PROFESSIONELE INLIGTING VIR GLYTAB 30 mg
SKEDULERINGSTATUS
S3

HANDELSNAAM EN DOSEERVORM
GLYTAB 30 mg gemodifiseerde vrystellings tablette

SAMESTELLING
Elke gemodifiseerde vrystellings tablet bevat 30 mg gliklasied.
Onaktiewe bestanddele: anhidriese kalsiumwaterstoffosfaat, hipromellose, magnesiumstearaat.
Suikervry.

FARMAKOLOGIESE KLASSIFIKASIE
A 21.2 Orale hipoglukemiese middels

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Gliklasied is 'n hipoglukemiese medisyne van die sulfonielureumgroep, wat bloedglukosevlakke verlaag deur insuliensekresie uit die β-selle van die eilande van Langerhans te stimuleer. Bykomend tot hierdie uitwerking op die pankreas, is aangetoon dat toediening van gliklasied die perifere metaboliese benutting van glukose verbeter.

Farmakokinetiese eienskappe
Plasmavlakke neem progressief toe tot en met die sesde uur, wat 'n plato-vormige kurwe veroorsaak vanaf die sesde tot die twaalfde uur na toediening. Gliklasied word volledig geabsorbeer. Inname van voedsel beïnvloed nie die tempo of mate van absorpsie nie. Die verwantskap tussen die toegediende dosis en die oppervlak onder die konsentrasie-kurwe, as 'n funksie van tyd, is lineër tot by 120 mg. Binding aan plasmaproteïene is ongeveer 95 %.
Gliklasied word in die lewer gemetaboliseer en in die urine uitgeskei; minder as 1 % word onverander in die urine aangetref. Geen aktiewe metaboliete is in die plasma waargeneem nie. Die eliminasie-halfleeftyd van gliklasied wissel tussen 12 en 20 uur.
Geen klinies beduidende modifikasies van die farmakokinetiese parameters is by bejaarde pasiënte waargeneem nie.
'n Enkele daaglikse dosis gliklasied handhaaf die glukoseverlagende effekte vir 24 uur.

INDIKASIES
By tipe 2 diabetiese pasiënte, in kombinasie met dieetmaatreëls, leefstylaanpassings en oefening, wanneer dieet, leefstylveranderings en oefening alleen onvoldoende is om bloedglukose te beheer.

KONTRA-INDIKASIES
- Hipersensitiwiteit vir gliklasied, ander sulfonielureums, sulfoonamiede, of vir enige van die bestanddele van **GLYTAB 30 mg** (sien **SAMESTELLING**).
- Tipe 1 diabetes (jeugdige insulien-afhanklike diabetes mellitus), diabetiese keto-asidose of diabetiese pre-koma.
- Kinders.
- Erge nier- of lewer-ontoereikendheid.
- **Swangerskap en borsvoeding, aangesien veiligheid nie bepaal is nie** (sien **SWANGERSKAP EN BORSVOEDING**).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Die toediening van orale hipoglukemiese medisynes kan geassosieer word met 'n toename in kardiovaskulêre mortaliteit, in vergelyking met behandeling met dieet alleen of dieet saam met insulien.

Faktore wat hipoglukemie aanhelp, sluit in:
- Pasiënt wat weier (veral bejaarde pasiënte) of nie in staat is om saam te werk nie.
- Wanvoeding, ongereelde maaltye, oorslaan van maaltye, tye van vas of dieetwysigings.
- Wanbalans tussen fisiese oefening en koolhidraat-inname.
- Oordosering met **GLYTAB 30 mg** (sien **BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN**).
- Sekere endokriene steurings: tiroïedsteurings, hipopituïtarisme en adrenale ontoereikendheid.
- Gepaardgaande toediening van sekere ander medisynes (sien **INTERAKSIES**).
- Verswakking van nierfunksie.

Die farmakokinetiese en farmakodinamiese eienskappe van gliklasied mag gewysig wees by pasiënte met lewer- of nierontoereikendheid. 'n Hipoglukemiese episode wat by hierdie pasiënte voorkom mag verleng wees, gevolglik moet dit toepaslik hanteer word en is noukeurige monitering van die bloedglukosekonsentrasie noodsaaklik tydens behandeling met **GLYTAB 30 mg** (sien **DOSIS EN GEBRUIKSAANWYSINGS**).

GLYTAB 30 mg moet slegs voorgeskryf word indien dit waarskynlik is dat die pasiënt gereeld voedsel sal inneem (insluitende ontbyt). Dit is belangrik dat koolhidrate gereeld ingeneem word weens die verhoogde risiko van hipoglukemie indien 'n maaltyd laat geneem word, indien 'n onvoldoende hoeveelheid voedsel ingeneem word of indien die voedsel min koolhidrate bevat. Hipoglukemie sal meer waarskynlik voorkom ten tye van 'n lae-kalorie dieet, ongereelde koolhidraatinname, na verlengde of intense oefening, na alkohol-inname of tydens die toediening van 'n kombinasie van hipoglukemiese medisynes. Simptome van hipoglukemie verdwyn gewoonlik na absorpsie van koolhidrate (suiker). Ten spyte van aanvanklike effektiewe maatreëls, mag hipoglukemie egter steeds voorkom. Kunsmatige versoeters het geen effek op hipoglukemie nie. In die geval van erg verlengde hipoglukemie, is onmiddellike mediese behandeling en selfs hospitalisasie nodig.
In uitsonderlike stressituasies bv. trouma, koors, infeksie of 'n chirurgiese ingreep, of tydens gepaardgaande behandeling met Johanneskruid (*Hypericum perforatum*) preparate (sien **INTERAKSIES**), mag bloedglukose beheer verswak en 'n tydelike omskakeling na insulien mag nodig wees om goeie metaboliese beheer te behou.

Die hipoglukemiese effektiwiteit van enige orale antidiabetiese medisyne, insluitende gliklasied, soos in **GLYTAB 30 mg**, verswak oor tyd by baie pasiënte. Dit mag wees omdat die ernstigheidsgraad van die diabetes toeneem, of weens 'n verminderde respons op die behandeling. Voldoende aanpassing van die dosis en meewerking met dieetvoorskrifte moet in gedagte gehou word.

Versteurings in bloedglukose, insluitende hipoglukemie en hiperglukemie, is gerapporteer by diabetiese pasiënte wat gepaardgaande behandeling met fluorokinolone ontvang (veral by bejaarde pasiënte). Dit word aanbeveel dat bloedglukose noukeurig gemonitor word tydens gepaardgaande behandeling (sien **INTERAKSIES**).

Behandeling van pasiënte met glukose-6-fosfaatdehidrogenase (G6DP) tekort met sulfonielureummedisynes, soos **GLYTAB 30 mg**, kan tot hemolitiese anemie lei. Voorsorg moet getref word by pasiënte met G6PD-tekort en 'n nie-sulfonielureum alternatief moet oorweeg word.

Laboratoriumtoetse:
Bepaling van geglikosileerde hemoglobienvlakke (of vastende veneuse plasma glukose) word aanbeveel om bloedglukosebeheer te assesseer. Self-monitering van bloedglukosevlakke kan ook oorweeg word.

Uitwerking op die vermoë om te bestuur en masjiene te gebruik
Pasiënte moet bewus gemaak word van die simptome van hipoglukemie, en moet versigtig wees wanneer hulle bestuur of masjinerie hanteer.

INTERAKSIES
Die volgende mag die risiko vir hipoglukemie verhoog:
- Antifungusmiddels, soos mikonasool, flukonasool, ketokonasool.
- Barbiturate.
- Beta-blokkers.
- Simetidien, ranitidien.
- Allopurinol.
- Angiotensienomsettingsensiem (AOE) remmers, soos kaptopriel en enalapriel.
- Monoamienoksidase (MAO) inhibeerders, kinidien, kinien of salisilate.
- Sulfoonamiede, klaritromisien.
- Niesteroïdale anti-inflammatoriese medisyne (NSAIM's).
- Alkohol. Vermy die inname van alkohol of medikasie wat alkohol bevat.

Die volgende mag die risiko vir hiperglukemie verhoog:
- Glukokortikoïede, tiasieddiuretika, litium.
- Salbutamol, terbutalien IV.
- Ander beta-adrenergiese agoniste.
- Efedrien, pseudoëfedrien en verkoueprodukte.
- Chloorpromasien.
- Ritodrien.

Die gepaardgaande gebruik van **GLYTAB 30 mg** en danasol word nie aanbeveel nie. Dit is belangrik om urien- en bloedglukosevlakke te monitor indien gelyktydige gebruik onvermydelik is.

GLYTAB 30 mg mag antikoagulasie versterk tydens gepaardgaande behandeling met antikoagulasiemiddels (bv. warfarien). Dit mag nodig wees om die dosis van die antikoagulant aan te pas.
GLYTAB 30 mg kan die plasmakonsentrasie van siklosporien verhoog deur die metabolisme daarvan te verlaag. Dit mag nodig wees om die dosis van siklosporien te verlaag.
Johanneskruid (*Hypericum perforatum*) verminder die blootstelling aan gliklasied en bloedglukosevlakke moet tydens gepaardgaande toediening met **GLYTAB 30 mg** gemonitor word (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).
Disglukemie kan tydens gepaardgaande behandeling met **GLYTAB 30 mg** en fluorokinolone voorkom. Bloedglukosevlakke moet gemonitor word (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).

SWANGERSKAP EN BORSVOEDING
GLYTAB 30 mg word teenaangedui tydens swangerskap en borsvoeding (sien **KONTRA-INDIKASIES**).
Diabetes moet onder beheer gebring word voor bevrugting om die risiko te verlaag van aangebore abnormaliteite wat verband hou met ongekontroleerde diabetes.
Dit word aanbeveel dat orale hipoglukemiese behandeling vervang word met insulien voordat gepoog word om swanger te raak, of so gou as wat swangerskap waargeneem word.

DOSIS EN GEBRUIKSAANWYSINGS
Vir volwasse gebruik alleenlik
Die daaglikse dosis kan wissel van 1 tot 4 tablette per dag, d.i. 30 tot 120 mg wat as 'n enkel daaglikse dosis geneem word. Dit word aanbeveel dat die medikasie met ontbyt geneem word. Indien 'n dosis oorgeslaan word, moet die dosis wat die volgende dag geneem word, nie verhoog word nie. Die dosis behoort by die individuele pasiënt se metaboliese respons aangepas te word (bloedglukosevlakke en/of geglikosileerde hemoglobien HbA1C).

Aanvanklike dosis
Die aanbevole aanvanklike dosis is 30 mg een keer daagliks, met ontbyt geneem.

Dosisaanpassing
Indien vastende bloedglukosevlakke nie bevredigend verlaag het nie, kan die dosis progressief verhoog word tot 60, 90 of 120 mg per dag, met opeenvolgende verhogings, met 'n tussenpose van ten minste een maand tussen elke verhoging, behalwe by pasiënte wie se bloedglukosevlakke nie verlaag het na 15 dae van behandeling nie. In sodanige geval kan voorgestel word dat die dosis aan die einde van die 2de week van behandeling verhoog word. Die daaglikse dosis moenie 120 mg oorskry nie. Voorheen onbehandelde pasiënte moet met 'n dosis van 30 mg begin.

Vervanging van gliklasied 80 mg met GLYTAB 30 mg
By pasiënte wat op gliklasied 80 mg gestabiliseer is, kan die vervanging van gliklasied 80 mg met **GLYTAB 30 mg** aanvanklik gebaseer word op: 1 tablet gliklasied 80 mg = 1 tablet GLYTAB 30 mg.

Vervanging van 'n ander sulfonielureum met GLYTAB 30 mg
GLYTAB 30 mg kan ander sulfonielureum behandeling vervang. Vir die oorgang na GLYTAB 30 mg, moet die dosis en halfleeftyd van die vorige orale hipoglukemiese medisyne in berekening gebring word. Indien 'n pasiënt van 'n ander orale sulfonielureum met 'n verlengde halfleeftyd oorgeskakel word kan 'n terapeutiese venster van 'n paar dae nodig wees om die versterkende effek van die twee produkte en die gevolglike risiko van hipoglukemie te vermy. Tydens so 'n omskakeling word aanbeveel dat dieselfde prosedure gevolg word soos met die aanvang van die behandeling met **GLYTAB 30 mg**, d.i. om behandeling te begin 'n dosis van 30 mg per dag en dan die dosis met inkremente te verhoog, in ooreenstemming met die metaboliese vordering van elke pasiënt.

Assosiasie met ander orale antidiabetiese medisynes
GLYTAB 30 mg kan in kombinasie met alfa-glukosidase inhibeerders of insulien gegee word, maar in so 'n geval behoort diabetiese beheer met bloedsuikerbepalings gekontroleer te word, weens die moontlikheid van hipoglukemie. In kombinasieterapie met biguaniede, mag daar 'n groter risiko vir kardiovaskulêre mortaliteit wees as met die gebruik van gliklasied alleen.

Bejaarde pasiënte en pasiënte met nierversaking
Die effektiwiteit en toleransie van **GLYTAB 30 mg**, wat met dieselfde terapeutiese regimen by pasiënte oor 65 jaar en pasiënte met geringe tot matige nierversaking (30 – 80 ml/min) voorgeskryf is, is in kliniese proewe bevestig. Die dosis sal dus identies wees aan die aanbevole dosis vir volwassenes onder die ouderdom van 65 jaar, en vir pasiënte met normale nierfunksie, en hierdie pasiënte moet noukeurig gemonitor word.

NEWE-EFFEKTE
Hipoglukemie
Behandeling met **GLYTAB 30 mg** gemodifiseerde vrystellings tablette kan hipoglukemie veroorsaak indien maaltye ongereeld geneem word of oorgeslaan word. Moontlike simptome van hipoglukemie is: hoofpyn, intense honger, naarheid, braking, lusteloosheid, slaapsteurings, agitasie, aggressie, swak konsentrasie, verminderde bewustheid en verstadigde reaksies, depressie, verwardheid, sig- en spraaksteurings, afasie, tremor, parese, sensoriese steurings, duiseligheid, gevoel van magteloosheid, verlies aan selfbeheersing, delirium, konvulsies, vlak asemhaling, bradikardie, lomerigheid en bewussynsverlies, wat moontlik lei tot koma en sterfte.
Daarby mag tekens van adrenergiese teen-regulering waargeneem word: sweting, klam vel, angstigheid, tagikardie, hipertensie, hartkloppings, angina pectoris en kardiale disritmie.
Simptome verdwyn gewoonlik nadat koolhidrate (suiker) ingeneem is. Kunsmatige versoeters het egter geen effek nie. Ondervinding met ander sulfonielureums wys dat hipoglukemie weer kan voorkom, selfs wanneer die maatreëls aanvanklik effektief was.
Indien 'n hipoglukemiese episode erg of verleng is, en selfs indien dit tydelik beheer word deur die inname van suiker, is onmiddellike mediese behandeling of selfs hospitalisasie nodig.

Bloed- en limfstelselversteurings
Minder dikwels: Anemie (aplasties of hemolities), leukopenie, trombositopenie, pansitopenie, eosinofilie.

Immuunstelselversteurings
Minder dikwels: Angio-edeem.

Metabolisme- en voedingsteurings
Dikwels: Hipoglukemie, nagtelike hipoglukemie.
Minder dikwels: Erge hipoglukemie.

Senuweestelselversteurings
Dikwels: Duiseligheid, lomerigheid.

Oogversteurings
Minder dikwels: Vlietende visuele steurings, insluitende dowwe visie of veranderings in akkommodasie.

Gastro-intestinale versteurings
Dikwels: Smaaksteurings.
Minder dikwels: Abdominale pyn, naarheid, braking, slegte spysvertering, diarree, hardlywigheid.

Hepatobilière versteurings
Minder dikwels: Hepatitis, cholestase, cholestatiese geelsug, belemmering van lewerfunksie, hepatiese porfirie, simptomatiese porfirie. Staak behandeling indien cholestatiese geelsug voorkom.

Vel- en subkutaneweefselversteurings
Minder dikwels: Uitslag, pruritus, urtikaria, multivorme eriteem of eksfoliatiewe dermatitis, makulopapulêre uitslag, fotosensitiwiteit, blaasvormende reaksies (insluitende Stevens-Johnsonsindroom en toksiese epidermale nekrolise), geneesmiddeluitslag met eosinofilie en sistemiese simptome (DRESS) sindroom.

Nier- en urienwegversteurings
Dikwels: Poliurie.

Algemene versteurings en toestande by die plek van toediening
Dikwels: Hoofpyn.

Ondersoeke
Dikwels: Gewigstoename.
Minder dikwels: Verhoogde lewerensiemvlakke (aspartaataminotransferase (AST), alanienaminotransferase (ALT), alkaliese fosfatase).

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
'n Oordosis gliklasied mag hipoglukemie veroorsaak.
Matige simptome van hipoglukemie, sonder enige verlies van bewussyn of neurologiese tekens, moet reggestel word deur die inname van koolhidrate, aanpassing van die dosis en/of aanpassing van die dieet.
Noukeurige monitering moet volgehou word totdat die pasiënt buite gevaar is.
Hewige hipoglukemiese reaksies, met koma, konvulsies of ander neurologiese versteurings moet as 'n mediese noodgeval behandel word en vereis onmiddellike hospitalisering.
Indien 'n hipoglukemiese koma gediagnoseer of vermoed word, moet die pasiënt 'n vinnige binneaarse inspuiting van 50 ml gekonsentreerde glukose-oplossing (50 %) gegee word. Dit behoort opgevolg te word met aaneenlopende infusie van 'n meer verdunde oplossing (10 %), teen 'n tempo wat bloedglukosevlakke bo 5,5 mmol/l handhaaf. Pasiënte moet noukeurig gemonitor word, lank genoeg om seker te maak dat hipoglukemie nie weer sal intree nie, en, afhangende van die pasiënt se toestand, sal die dokter besluit of verdere monitering nodig is. Dialise is van geen waarde by hierdie pasiënte nie, weens die sterk binding van gliklasied aan proteïene.

IDENTIFIKASIE
Wit tot naaswit, kapsulevormige, onbedekte tablette, glad aan albei kante.

AANBIEDING
Helder PVC/aluminium of helder PVC/PVdC/aluminium stulpstroke wat 10 tablette bevat. Elke karton bevat 60 of 100 tablette.

BEWARINGSINSTRUKSIES
Bêre by of onder 25 °C.
Hou in die buitenste karton tot benodig vir gebruik.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
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PASIËNTINLIGTINGSBLAD VIR GLYTAB 30 mg

SKEDULERINGSTATUS
Skedule 3

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM
GLYTAB 30 mg gemodifiseerde vrystellings tablette

Lees hierdie hele inligtingsblad aandagtig deur, voordat u begin om GLYTAB 30 mg te neem.
- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Indien u enige verdere vrae het, vra asseblief u dokter of apteker.
- **GLYTAB 30 mg** is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al het hulle dieselfde simptome as u.

1. WAT GLYTAB 30 mg BEVAT

Die aktiewe bestanddeel is 30 mg gliklasied.
Die ander bestanddele is anhidriese kalsiumwaterstoffosfaat, hipromellose en magnesiumstearaat
Suikervry.

2. WAARVOOR GLYTAB 30 mg GEBRUIK WORD
GLYTAB 30 mg is 'n medisyne wat bloedsuikervlakke verlaag (mondelikse antidiabetiese medisyne wat behoort aan die sulfonielureumgroep).
GLYTAB 30 mg word by 'n sekere vorm van diabetes (tipe 2 diabetes mellitus) by volwassenes gebruik, wanneer dieet, oefening en gewigsverlies alleen nie voldoende is om bloedsuiker op die korrekte vlak te hou nie.

3. VOORDAT U GLYTAB 30 mg NEEM
Moenie **GLYTAB 30 mg** neem nie:
- Indien u hipersensitief (allergies) is vir gliklasied of vir enige van die ander bestanddele van **GLYTAB 30 mg** (sien **WAT GLYTAB 30 mg BEVAT**).
- Indien u insulien-afhanklike diabetes (tipe 1) het.
- Indien u 'n erge lewersiekte het.
- Indien u aan 'n erge niersiekte ly.
- Indien u swanger is of u baba borsvoed.

GLYTAB 30 mg word nie aanbeveel vir gebruik by kinders nie.

Neem spesiale sorg met GLYTAB 30 mg:
Volg die behandelingsplan wat deur u dokter voorgeskryf is noukeurig om bloedsuikervlakke behoorlik in stand te hou. Dit beteken dat u, bo en behalwe gereelde tablet inname, u dieetplan moet nakom, fisiese oefening doen en, waar nodig, u liggaamsgewig verminder.
Tydens **GLYTAB 30 mg** behandeling is gereelde monitering van u bloedsuikervlak nodig.
In die eerste paar weke van behandeling mag die risiko groter wees dat u verlaagde bloedsuikervlakke (hipoglukemie) kan hê.
Lae bloedsuiker (hipoglukemie) mag voorkom:
- Indien u ongereeld eet of maaltye heeltemal oorslaan.
- Indien u vas.
- Indien u wangevoed is.
- Indien u dieet verander.
- Indien u fisies meer aktief raak en koolhidraatinname nie ooreenstemmend toeneem nie.
- Indien u alkohol drink, veral in kombinasie met oorgeslane maaltye.
- Indien u ander medisynes of natuurlike geneesmiddels terselfdertyd neem.
- Indien u te hoë dosisse **GLYTAB 30 mg** neem.
- Indien u aan bepaalde hormoon-geïnduseerde versteurings ly (funksionele versteurings van die skildklier, pituïtêre klier of bynierkorteks).
- Indien u nier- of lewerfunksie erg belemmer is.

U kan die volgende simptome hê indien u bloedsuiker laag is: hoofpyn, intense honger, naarheid, braking, moegheid, slaapsteurings, rusteloosheid, aggressiwiteit, swak konsentrasie, verminderde wakkerheid en reaksietyd, depressie, verwardheid, spraak- of visuele afwykings, tremor, sensoriese versteurings, duiseligheid en hulpeloosheid.
Die volgende tekens en simptome mag ook voorkom: sweting, klam vel, angstigheid, vinnige of onreëlmatige hartklop, hoë bloeddruk, skielike erge pyn in die borskas wat kan uitstraal na omliggende areas (angina pectoris).
Indien bloedsuikervlakke aanhou om te daal mag u aansienlike verwardheid (delirium) ondervind, konvulsies ontwikkel, selfbeheer verloor, u asemhaling kan vlak en u hartklop stadiger wees, u kan u bewussyn verloor.
In die meeste gevalle verdwyn die simptome van lae bloedsuiker baie vinnig indien u 'n vorm van suiker inneem, soos glukosetablette, suikerblokkies, soet vrugtesap of versoete tee. Om hierdie rede behoort u altyd 'n vorm van suiker (glukosetablette, lekkergoed of suikerblokkies) by u te hê. Onthou dat kunsmatige versoeters of produkte wat slegs kunsmatige versoeters bevat nie effektief is om bloedsuikervlakke te herstel nie. Kontak asseblief u dokter of die naaste hospitaal indien dit nie gehelp het wanneer u suiker ingeneem het nie of indien die simptome weer terugkom.
Simptome van lae bloedsuiker kan afwesig wees, minder opsigtelik wees of baie stadig ontwikkel sodat u nie betyds agterkom dat u bloedsuikervlak gedaal het nie. Dit kan gebeur indien u 'n bejaarde pasiënt is wat sekere medisynes neem (soos dié wat op die sentrale senuweestelsel inwerk en beta-blokkers). Indien u in 'n stressituasie is (soos 'n ongeluk, chirurgie ondergaan, koors ens.) mag u dokter u tydelik omskakel na insulienterapie.
Simptome van hoë bloedsuiker (hiperglukemie) kan voorkom wanneer **GLYTAB 30 mg** nog nie die bloedsuiker voldoende verlaag het nie, wanneer u nie gehou het by die behandelingsplan wat deur u dokter voorgeskryf is nie, of in spesiale stressituasies. Dit mag dors, dikwelse urinering, droë mond, droë jeukende vel, velinfeksies en verminderde prestasie insluit.
Kontak u dokter of apteker indien hierdie simptome voorkom.

Lig u dokter in voordat u **GLYTAB 30 mg** neem indien u 'n familiegeskiedenis het van, of indien u gediagnoseer is met, die oorerflike toestand glukose-6-fosfaatdehidrogenase (G6DP) tekort (abnormaliteit van rooibloedselle), aangesien die hemoglobienvlakke in u liggaam kan verlaag en afbraak van u rooibloedselle kan voorkom (hemolitiese anemie).

Die neem van GLYTAB 30 mg met kos en drinkgoed:
Dit word aanbeveel dat **GLYTAB 30 mg** met ontbyt geneem word.

Swangerskap en borsvoeding:
Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgdeskundige voordat u **GLYTAB 30 mg** neem.
Moenie **GLYTAB 30 mg** neem indien u swanger is, vermoed dat u swanger kan wees of u baba borsvoed nie.

Bestuur en die gebruik van masjinerie:
GLYTAB 30 mg mag u vermoë om te bestuur en masjinerie te gebruik belemmer. Moenie bestuur, masjinerie hanteer of enigiets anders doen wat u aandag vereis nie, totdat u weet hoe **GLYTAB 30 mg** u affekteer.

Die gebruik van ander medisynes saam met GLYTAB 30 mg:
Sê altyd vir u gesondheidsorgdeskundige indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisynes in).

Die bloedsuikerverlagende effek van **GLYTAB 30 mg** mag versterk word en tekens van lae bloedsuikervlakke mag verskyn wanneer een van die volgende medisynes geneem word:
- Ander medisynes wat gebruik word om hoë bloedsuiker te behandel (mondelikse antidiabetiese middels of insulien).
- Antibiotika (soos sulfoonamiede, klaritromisien).
- Medisynes wat gebruik word om hoë bloeddruk of hartversaking te behandel (beta-blokkers, ACE-inhibeerders soos kaptopriel of enalapriel).
- Medisynes om swaminfeksies te behandel (mikonasool, flukonasool, ketokonasool).
- Medisynes om ulkusse in die maag of duodenum te behandel (simetidien, ranitidien).
- Medisynes om depressie te behandel (monoamienoksidase-inhibeerders).
- Medisynes om pyn te behandel (ibuprofeen).
- Alkohol of medisynes wat alkohol bevat.

Die bloedglukoseverlagende effek van **GLYTAB 30 mg** mag verswak word en verhoogde bloedsuikervlakke kan voorkom wanneer een van die volgende medisynes geneem word:
- Medisynes om versteurings van die sentrale senuweestelsel te behandel (chloorpromasien).
- Medisynes wat inflammasie verminder (kortikosteroïede).
- Medisynes wat gebruik word om waterterughouding en hoë bloeddruk te behandel (tiasiedddiuretika).
- Litium (gebruik om depressie te behandel).
- Medisynes om asma te behandel of wat tydens kraam gebruik word (binneaarse salbutamol, ritodrien en terbutalien).
- Verkouemiddels.

GLYTAB 30 mg mag die uitwerking versterk van medisynes wat bloedstolling verminder (soos warfarien).
GLYTAB 30 mg mag die uitwerking versterk van medisynes wat na oorplantings gebruik word (siklosporien).
Versteurings van bloedglukose mag voorkom wanneer u fluorokinolone neem (antibiotiese medisyne wat gebruik word om bakteriese infeksies te behandel), veral indien u bejaard is, of indien u Johanneskruid ('n kruiekuur wat gebruik word om depressie te behandel) saam met **GLYTAB 30 mg** neem.

4. HOE OM GLYTAB 30 mg TE NEEM
Neem **GLYTAB 30 mg** altyd presies soos wat u dokter vir u voorgeskryf het. Kontroleer met u dokter of apteker indien u onseker is.
Die gewone dosis is 1 tot 4 tablette daagliks, een keer per dag met ontbyt geneem.
U dokter kan u dosis aanpas afhangende van u toestand.

Indien u meer GLYTAB 30 mg geneem het as wat u behoort:
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien u vergeet om GLYTAB 30 mg te neem:
Indien u een dosis gemis het, moet daardie dosis oorgeslaan word en die volgende dosis moet op die gewone tyd met 'n maaltyd geneem word. Moenie 'n dubbele dosis neem om te vergoed vir die dosis wat oorgeslaan is nie.

5. MOONTLIKE NEWE-EFFEKTE
GLYTAB 30 mg kan newe-effekte hê.
Nie alle newe-effekte wat vir GLYTAB 30 mg gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien u algemene gesondheid agteruitgaan of indien u enige ongewenste effekte ervaar terwyl GLYTAB 30 mg geneem word, konsulteer asseblief u dokter, apteker of ander gesondheidsorgdeskundige.

Indien enige van die volgende gebeur, hou op om **GLYTAB 30 mg** te neem en sê onmiddellik vir u dokter of gaan na die ongevalle-afdeling by u naaste hospitaal:
- Swelling van u hande, voete, enkels, gesig, mond of keel, wat dit moeilik kan maak om te sluk of asem te haal.
- Uitslag of gejeuk.
- Floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie op **GLYTAB 30 mg** gehad het. U mag dringende mediese bystand of hospitalisasie nodig hê.

Sê onmiddellik vir u dokter of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- Bloedafwykings (insluitende 'n bleek vel, langdurige bloeding, kneusing, seer keel en koors).
- Vergeling van die vel en oë.
- Hewige, pynlike veluitslag wat blaasvorming of afskilfering van u vel veroorsaak (multivorme eriteem, eksfoliatiewe dermatitis, Stevens-Johnsonsindroom of toksiese epidermale nekrolise).
- DRESS-sindroom (veluitslag op u gesig wat uitbrei na u liggaam, koors en griepagtige simptome).

Hierdie is alles ernstige newe-effekte. U mag dringende mediese bystand nodig hê.

Sê so gou as moontlik vir u dokter indien u enige van die volgende opmerk:
- Galbulte.
- Duiseligheid of lomerigheid.
- Dowwe visie of probleme om te fokus.
- Smaakveranderings.
- Naarheid, braking.
- Maagpyn.
- Sooibrand.
- Hardlywigheid.
- Fotosensitiwiteit.
- 'n Toename in urienafskeiding.
- Hoofpyn.
- Toename in gewig.
- Veranderings in resultate van bloedtoetse.

Indien u enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter of apteker in.

6. BERGING EN WEGDOENING VAN GLYTAB 30 mg
- Bêre by of onder 25 °C.
- Hou in die buitenste karton tot nodig vir gebruik.
- STOOR ALLE MEDISYNES BUITE BEREIK VAN KINDERS.
- Moenie gebruik ná die vervaldatum wat op die etiket of karton gedruk is nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

7. AANBIEDING VAN GLYTAB 30 mg
Helder PVC/aluminium of helder PVC/PVdC/aluminium stulpstroke wat 10 tablette bevat. Elke karton bevat 60 of 100 tablette.

8. IDENTIFIKASIE VAN GLYTAB 30 mg
Wit tot naaswit, kapsulevormige, onbedekte tablette, glad aan albei kante.

9. REGISTRASIENOMMER
49/21.2/1207

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
Forrester Pharma (Edms.) Bpk.
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11. PUBLIKASIEDATUM
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