SCHEDULING STATUS: S3

1. NAME OF MEDICINE
GLICLAZIDE 80 KIARA (tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each GLICLAZIDE 80 KIARA tablet contains 80 mg gliclazide.
Contains sugar (lactose 40 mg).
For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM
White to off white, round, flat, bevelled edge tablets, scored on one side.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Maturity onset diabetics (non-insulin dependent or Type II) who do not respond satisfactorily on a dietary regimen.

4.2 Posology and method of administration
The usual initial dose in non-insulin dependent diabetes mellitus is 40 to 80 mg (half to one tablet) daily gradually increasing, if necessary, to up to 4 tablets daily given in divided doses with meals. The initial dose and the subsequent adjustments to the daily dosage should be determined by the results of medical and laboratory examinations.

Important:
In combination therapy with either insulin or another diabetic agent, diabetic control should be checked by blood sugar readings because of the possibility of hypoglycaemia.

In combined therapy with a biguanide there may be a greater risk of cardiovascular mortality than with the use of gliclazide alone.

4.3 CONTRAINDICATIONS
- Hypersensitivity to gliclazide or any of the other ingredients (see Section 6.1 *List of excipients*).
- Chronic liver disease including that caused by uncompensated cardiac failure or alcoholism.
- Metabolic decompensation with acidosis and ketosis.
- Precomatose states and diabetes mellitus complicated by fever, infection, febrile diseases, pancreatitis, trauma or gangrene, serious impairment of thyroid or adrenal function.

4.4 Special warnings and precautions for use
The administration of gliclazide may be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin.

A reduction in dosage may be necessary in patients with renal dysfunciton.

Lactose intolerance:
GLICLAZIDE 80 KIARA contains lactose. Patients with the rare hereditary conditions of galactose intolerance, e.g., galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance, should not take GLICLAZIDE 80 KIARA.

GLICLAZIDE 80 KIARA contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interactions with other medicines and other forms of interaction
The hypoglycaemic effect may be enhanced by the concomitant administration of sulphonamides, salicylates, phenylbutazone, beta-adrenoreceptor blocking agents, monoamine oxidase inhibitors, chloramphenicol, clofibrate or halofenate, ketoconazole and miconazole, cimetidine, dicoumarol and cyclophosphamide.
The hypoglycaemic effect may be diminished by adrenalin, oestrogens, thiazide diuretics and corticosteroids.
Propranolol and other beta-blockers may mask symptoms of hypoglycaemia.

4.6 Fertility, pregnancy and lactation
Safety and/or efficacy has not been established.

4.7 Effects on the ability to drive or use machinery
The effects of GLICLAZIDE 80 KIARA on the ability to drive and use machines have not been investigated.

4.8 Undesirable effects
Mild effects include nausea, vomiting, epigastric pain, dizziness, weakness and paraesthesia. Sensitivity reactions with fever, eosinophilia, jaundice, skin rashes and blood disorders including leukopenia, thrombocytopenia, aplastic anaemia and agranulocytosis have occurred.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose
Hypoglycaemic reactions should be treated by gastric lavage and correction of the hypoglycaemia by the administration of intravenous glucose. The patient's blood sugar should be continuously monitored until the effect of the medicine has ceased (this may take several days). Hypoglycaemic reactions should alert the physician to the possibility of renal dysfunction.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacological classification:
A 21.2 Oral Hypoglycaemics
ATC Code: A10BB09 - Sulfonylureas
Gliclazide is a sulphonylurea with hypoglycaemic effect. It stimulates the secretion of insulin by the beta cells of the pancreas.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Lactose, magnesium stearate, microcrystalline cellulose, povidone K30, purified talc and sodium starch glycolate.

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
24 months when stored in PVC foil or Tristar blisters, amber glass bottles or sealed aluminium bags.
48 months when stored in polypropylene securitainers.

6.4 Special precautions for storage
Store at or below 25 °C and protect from light.

6.5 Nature and contents of container
28 tablets packed in PVC foil or Tristar blisters, polypropylene securitainers or sealed aluminium bags.
56 or 60 tablets packed in PVC foil or Tristar blisters, polypropylene securitainers, sealed aluminium bags or amber glass bottles.
250, 500 or 504 tablets packed in PVC foil or Tristar blisters, polypropylene securitainers or amber glass bottles.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Kiara Health (Pty) Ltd
72 Steel Road
Spartan
Kempton Park
1619
South Africa

8. REGISTRATION NUMBER
Z/21.2/197

9. DATE OF APPROVAL OF THE AUTHORISATION
25 May 1993

10. DATE OF REVISION OF THE TEXT
23 June 2021

Additional countries registration details:

Country	Product name	Scheduling status (or Category of distribution)	Registration number
Botswana	GLICLAZIDE 80 KIARA	S2	B9309055
Namibia	GLICLAZIDE 80 KIARA	NS2	05/21.2/0092
Mauritius	GLICLAZIDE 80 KIARA		R2992/02/14

Name and address of manufacturer:
Kiara Health (Pty) Ltd
72 Steel Road, Spartan,
Kempton Park, 1619
South Africa

51010339 V2 (17/02/2022)
02/22/GLIC007
Pro-Print

SKEDULERINGSTATUS: S3

1. NAAM VAN DIE MEDISYNE
GLICLAZIDE 80 KIARA (tablette)

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING
Elke GLICLAZIDE 80 KIARA tablet bevat 80 mg gliklasied.
Bevat suiker (laktose 40 mg).
Vir 'n volledige lys van eksipiënte, sien Afdeling 6.1.

3. FARMASEUTIESE VORM
Wit tot naaswit, ronde, plat tablette met afgeskuinsde rante, gekeep aan die een kant.

4. KLINIESE BESONDERHEDE
4.1 Terapeutiese indikasies
Volwasse-aanvang diabete (nie-insulienafhanklike of Tipe II) wat nie bevredigend op 'n dieetregimen reageer nie.

4.2 Posologie en metode van toediening
Die gewone aanvangsdosis in nie-insulienafhanklike diabetes mellitus is 40 tot 80 mg (halwe tot een tablet) daagliks wat geleidelik vermeerder kan word, indien nodig, tot en met 4 tablette daagliks toegedien in verdeelde dosisse met maaltye. Die aanvangsdosis en die daaropvolgende veranderinge aan die daaglikse dosis behoort deur die resultate van mediese en laboratoriumondersoeke bepaal te word.

Belangrik:
In kombinasieterapie met óf insulien óf 'n ander diabetiese middel, moet diabetiese beheer deur bloedsuikerlesings nagegaan word vanweë die moontlikheid van hipoglisemie.

In gekombineerde terapie met 'n biguanied mag daar 'n groter risiko vir kardiovaskulêre mortaliteit as met die gebruik van gliklasied alleen wees.

4.3 KONTRA-INDIKASIES
- Hipersensitiwiteit vir gliklasied of enige van die ander bestanddele (sien Afdeling 6.1 *Lys van eksipiënte*).
- Chroniese lewersiekte insluitende dié veroorsaak deur ongekompenseerde hartversaking of alkoholisme.
- Metaboliese dekompensasie met asidose en ketose.
- Prekomateuse toestande en diabetes mellitus gekompliseerd deur koors, infeksie, koorssiektes, pankreatitis, trauma of gangreen, ernstige inkorting van tiroïed- of bynierfunksie.

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik
Die toediening van gliklasied mag met verhoogde kardiovaskulêre mortaliteit geassosieer wees in vergelyking met behandeling met dieet alleen of dieet plus insulien.

'n Dosisverlaging mag in pasiënte met renale disfunksie nodig wees.

Laktose-intoleransie:
GLICLAZIDE 80 KIARA bevat laktose. Pasiënte met die raar oorerflikheidstoestande van galaktose-intoleransie, bv. galaktosemie, Lapp-laktasetekort, glukose-galaktose-wanabsorpsie of fruktose-intoleransie moenie GLICLAZIDE 80 KIARA neem nie.

GLICLAZIDE 80 KIARA bevat laktose wat 'n effek op die glisemiese beheer van pasiënte met diabetes mellitus mag hê.

4.5 Interaksie met ander medisyne en ander vorms van interaksie
Die hipoglisemiese effek mag deur die gesamentlike toediening van sulfonamiede, salisilate, fenielbutasoon, beta-adrenergiese blokkers, monoamienoksidase-inhibeerders, chlooramfenikol, klofibraat of halofenaat, ketokonasool of mikonasool, simetidien, dikumarol en siklofosfamied versterk word.
Die hipoglisemiese effek kan deur adrenalien, estrogene, tiasieddiuretika en kortikosteroïede verminder word.
Propranolol en ander beta-blokkers mag die simptome van hipoglisemie verberg.

4.6 Fertiliteit, swangerskap en laktasie
Veiligheid en/of effektiwiteit is nog nie vasgestel nie.

4.7 Effekte op die vermoë om te bestuur en masjiene te gebruik
The effek van GLICLAZIDE 80 KIARA op die vermoë om te bestuur en masjiene te gebruik is nog nie ondersoek nie.

4.8 Ongewenste effekte
Geringe effekte sluit naarheid, braking, epigastriese pyn, duiseligheid, swakheid en parestesie in.
Sensitiwiteitsreaksies met koors, eosinofilie, geelsug, veluitslae en bloedafwykings, insluitende leukopenie, trombositopenie, aplastiese anemie en agranulositose, het voorgekom.

Aanmelding van vermoedelike nadelige reaksies
Dit is belangrik om vermoedelike nadelige reaksies na goedkeuring van die medisyne aan te meld. Dit laat voortgesette monitering van die voordeel/risiko-balans van die medisyne toe. Gesondheidsorgverskaffers word versoek om enige vermoedelike nadelige reaksies aan die SARGP via die "**6.04 Nadelige Middelreaksie-Aanmeldingsvorm**" te rapporteer; dit kan aanlyn onder die SARGP se publikasies by https://www.sahpra.org.za/Publications/Index/8 gevind word.

4.9 Oordosis
Hipoglisemiese reaksies moet met maagspoeling en die korrigering van die hipoglisemie deur die toediening van intraveneuse glukose behandel word. Die pasiënt se bloedsuiker moet deurlopend gemonitor word totdat die uitwerking van die medisyne opgehou het (dit mag etlike dae duur). Hipoglisemiese reaksies moet die geneesheer op die moontlikheid van nierdisfunksie bedag maak.

5. FARMAKOLOGIESE EIENSKAPPE
5.1 Farmakodinamiese eienskappe
Farmakologiese klassifikasie:
A 21.2 Orale Hipoglisemiese Middels
ATC-Kode: A10BB09 – Sulfonielureums
Gliklasied is 'n sulfonielureum met hipoglisemiese effek. Dit stimuleer die afskeiding van insulien deur die beta-selle van die pankreas.

6. FARMASEUTIESE BESONDERHEDE
6.1 Lys van eksipiënte
Laktose, magnesiumstearaat, mikrokristallyne sellulose, povidoon K30, gesuiwerde talk en natriumstyselglikolaat.

6.2 Onverenigbaarhede
Nie van toepassing nie.

6.3 Raklewe
24 maande wanneer dit in PVC-foelie- of Tristar-stulpstroke, amber glasbottels of geseëlde aluminiumsakkies gestoor word.
48 maande wanneer dit in polipropileensekuriteitsbewaarders gestoor word.

6.4 Spesiale voorsorgmaatreëls vir berging
Bewaar teen of onder 25 °C en beskerm teen lig.

6.5 Aard en inhoud van die pakkie
28 tablette verpak in PVC-foelie- of Tristar-stulpstroke, polipropileensekuriteitsbewaarders of geseëlde aluminiumsakkies.
56 of 60 tablette verpak in PVC-foelie- of Tristar-stulpstroke, polipropileen-sekuriteitsbewaarders of geseëlde aluminiumsakkies of amber glasbottels.
250, 500 of 504 tablette verpak in PVC-foelie- of Tristar-stulpstroke, polipropileensekuriteitsbewaarders of amber glasbottels.

7. HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
Kiara Health (Pty) Ltd
72 Steel Road
Spartan
Kempton Park
1619
South Africa

8. REGISTRASIENOMMER
Z/21.2/197

9. DATUM VAN GOEDKEURING VAN DIE MAGTIGING
25 Mei 1993

10. DATUM VAN HERSIENING VAN DIE TEKS
23 Junie 2021

Bykomende lande se registrasiebesonderhede:

Land	Produknaam	Skeduleringstatus (of Kategorie van verspreiding)	Registrasie-nommer
Botswana	GLICLAZIDE 80 KIARA	S2	B9309055
Namibië	GLICLAZIDE 80 KIARA	NS2	05/21.2/0092
Mauritius	GLICLAZIDE 80 KIARA		R2992/02/14

Naam en adres van vervaardiger:
Kiara Health (Pty) Ltd
72 Steel Road, Spartan,
Kempton Park, 1619
South Africa

KIARA