SCHEDULING STATUS:

S3

PROPRIETARY NAME (and dosage form):
CONINSUL Tablets

COMPOSITION:
Each tablet contains: Gliclazide 80 mg.
Contains sugar: Lactose 40 mg

PHARMACOLOGICAL CLASSIFICATION:
A 21.2 Oral Hypoglycaemics

PHARMACOLOGICAL ACTION:
Gliclazide is a sulphonylurea with hypoglycaemic effect. It stimulates the secretion of insulin by the beta cells of the pancreas. Gliclazide is well absorbed, and peak plasma concentrations occur 2 to 8 hours after administration. Gliclazide is highly bound to plasma protein (85 to 97 %). Metabolism is extensive and all gliclazide metabolites are devoid of hypoglycaemic activity. Between 60 to 70 % of the dose is excreted in the urine, and 10 to 20 % in the faeces as metabolites. The elimination half-life of gliclazide is 10 to 12 hours.

INDICATIONS:
Maturity onset diabetics mellitus (non-insulin dependant of Type II) who do not respond satisfactorily on dietary modification alone.

CONTRAINDICATIONS:
Severe 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.
Severe renal dysfunction.
Patients with sulphonylurea intolerance.
Insulin-dependent diabetis mellitus.
Safety in pregnancy and lactation has not been established.

WARNINGS:
The administration of CONINSUL may be associated with increased cardiac mortality as compared to treatment with diet alone or diet plus insulin. A reduction in dosage may be necessary in patients with renal dysfunction.

DOSAGE AND DIRECTIONS FOR USE:
The final dosage regimen depends on the individual requirements of the patient. The usual dose in non-insulin dependant diabetes mellitus is 80 mg (1 tablet daily) for mild cases gradually increasing, if necessary, up to 4 tablets daily for severe cases 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 examination.

Important to note:
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.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Mild effects include nausea, vomiting, heartburn, anorexia, metallic taste, weight changes, epigastric pain, dizziness, weakness and paraesthesia. Sensitivity reactions with fever, eosinophilia, jaundice, skin rashes, pruritus, photosensitivity and blood disorders including leucopenia, thrombocytopenia, aplastic anaemia and agranulocytoses, haemolytic anaemia, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, erythema nodosum have occurred. Hypoglycaemic reactions may occur.

Interactions:
The hypoglycaemic effects 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 effects may be diminished by adrenalin, oestrogens, thiazide diuretics and corticosteroids. Propranolol and other beta-blockers may mask symptoms of hypoglycaemia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
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 drug has ceased. (This may take several days). Hypoglycaemic reactions should alert the physician to the possibility of renal dysfunction.

IDENTIFICATION:
8 mm Round flat bevelled edged white tablet

PRESENTATION:
Glass bottles of 60 and 100 tablets.
Polypropylene Containers of 30, 60, 100, 500 and 1000 tablets. Blister packs containing 30, 60,100, 500 and 1000 tablets.

STORAGE INSTRUCTIONS:
Store well closed in a dry place. Store below 25 °C and protect from light. KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
32/21.2/0653

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
TRINITY PHARMA (PTY) LTD
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DATE OF PUBLICATION OF THIS PACKAGE INSERT:
30 March 2000

SKEDULERINGSTATUS:

S3

EIENDOMSNAAM (EN DOSEERVORM):

CONINSUL Tablette

SAMESTELLING:
Elke tablet bevat: Gliklasied 80 mg
Contains sugar: Lactose 40 mg

FARMAKOLOGIESE KLASSIFIKASIE:
A 21.2 Orale hipoglukemie middels

FARMAKOLOGIESE WERKING:
Gliklasied is 'n sulfonielurea met 'n hipoglisemiese effek. Dit stimuleer die uitskeiding van insulien deur middel van die beta-selle van die pankreas.
Gliklasied word goed geabsorbeer en piek plasma konsentrasies kom 2 tot 8 ure na toediening voor. Gliklasied word tot 'n groot mate aan plasma proteïene gebind (85 tot 97 %). Gliklasied word ekstensief gemetaboliseer en nie een van die metaboliete het enige hipoglukemiese werking nie. Tussen 60 tot 70 % van 'n dosis word in die uriene uitgeskei en 10 tot 20 % in die fesies as metaboliete. Die halfleeftyd van gliklasied is 10 tot 12 ure.

INDIKASIES:
Volwasse aanvang diabetes mellitus (nie-insulien-afhanklike òf Tipe II) wat nie voldoende gekontroleer kan word deur dieët modifikasie alleen nie.

KONTRA-INDIKASIES:
Ernstige lewersiektetoestande insluitende dié veroorsaak deur nie-gekompenseerde hartversaking en alkoholisme. Metaboliese dekompensasie met asidose en ketose.
Prekomatose toestande en diabetes mellitus wat gekompliseerd is deur koors, infeksies, febriele siektes, pankreatitis, trouma of gangreen, ernstige ingekorte skildklier of adrenale funksies.
Ernstige nierdisfunksie.
Pasiënte met sulfonielureum intoleransie.
Insulien-afhanklike diabetes mellitus.
Die veiligheid tydens swangerskap en borsvoeding is nog nie vasgestel nie.

WAARSKUWINGS:
Die toediening van CONINSUL kan gepaard gaan met 'n toename in kardiovaskulêre mortaliteit in vergelyking met dieët alleen of dieët plus insulien. 'n Verlaging in dosis mag nodig wees by pasiënte met nierdisfunksie.

DOSIS EN GEBRUIKSAANWYSINGS:
Die finale dosering hang af van die individuele vereistes van die pasiënt. Die gewone dosis in nie-insulien-afhanklike diabetes mellitus is 80 mg (1 tablet) daagliks vir geringe gevalle wat geleidelik vermeerder kan word, indien nodig, tot 4 tablette daagliks vir meer ernstige gevalle, in verdeelde dosisse tydens maaltye. Die aanvangsdosis sowel as die daaropvolgende aanpassing moet gebasseer wees op mediese en laboratoriumondersoeke.

Belangrik:
In kombinasie-terapie met óf insulien, óf ander diabetiese middels, moet diabetiese kontrole gedoen word deur middel van bloedsuikertellings as gevolg van die moontlikheid van hipoglisemie.
In kombinasie-terapie met 'n biguaniede mag daar 'n groter risiko wees van kardiovaskulêre mortaliteit as wat die geval sou wees met die gebruik van gliklasied alleen.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Ligte newe-effekte sluit in naarheid, braking, sooibrand, anoreksie, metaalsmaak, verandering in liggaamsmassa, epigastriese pyn, duiseligheid, swakheid en parastesie. Sensitiwiteitsreaksies met koors, eosinofilie, geelsug, veluitslag, pruritus, liggevoeligheid en bloedsiektes soos leukopenie, trombositopenie, aplastiese anemie en agranulositose, hemolitiese anemie, veelvuldige eriteem, Stevens-Johnson se sindroom, afskilferende dermatitis en erythema nodosum het voorgekom. Hipoglisemiese reaksies kan voorkom.

Interaksies:
Die hipoglisemiese effek kan verhoog word deur die gelyktydige toediening van sulfonamiede, salisilate, fenielbutasoon, beta-adrenoreseptor-blokkeerders, monoamienoksidase-inhibeerders, chlooramfenikol, klofibrate, of halofenaat, ketokonasool en mikonasool, simetidien, dikoumarol en siklofosfamied.
Die hipoglisemiese effek kan verminder word deur adrenalien, estrogeen, tiasied diuretika en kortikosteroïede.
Propranolol en ander beta-blokkeerders mag dalk die simptome van hipoglisemie maskeer.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Hipoglukemiese reaksies behoort deur middel van maaglediging behandel te word en die herstel van die hipoglukemie met die toediening and binneaarse glukosevoeding. Die pasiënt se bloedsuiker moet deurlopend gemonitor word totdat die geneesmiddel se uitwerking verdwyn het. (Dit mag 'n paar dae neem). Hipoglukemiese reaksies behoort die geneesheer teen die moontlikheid van nierdisfunksie te waarsku.

IDENTIFIKASIE:
8 mm ronde plat gekeepte kante wit tablet.

AANBIEDING:
Glas bottels bevattende 60 en 100 tablette
Polipropilieenhouers met 30, 60, 100, 500 en 1000 tablette.
Stolpverpakkings wat 30, 60, 100, 500 en 1000 tablette bevat.

BERGINGSINSTRUKSIES:
Bewaar diggesluit in 'n droë plek. Berg benede 25 °C en beskerm teen lig. HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
32/21.2/0653

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
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