1.NAMEOFTHEFINISHED PRODUCT

Glimicron80mg Tablet

2.QUALITATIVEANDQUANTITATIVECOMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Gliclazide	80 mg

Kindlyrefer to Section 6.1 for excipient.

3.PHARMACEUTICALFORM

Round,whiteuncoatedtablet,flatfaces,bevel-edged,crossscoreembossed ononeface.

4.CLINICALPARTICULARS

4.1 Therapeuticindication

Noninsulindependentdiabetes(type2)inadultswhendietarymeasures,physicalexercise and weight loss alone are not sufficient to control blood glucose.

4.2 PosologyandMethodofadministration

The total daily dose may vary from 40 to 320 mg taken orally. The dose should be adjusted accordingtotheindividualpatient's response,commencingwith40-80mgdaily(½-1tablet) andincreasinguntiladequatecontrolisachieved. Asingledoseshouldnot exceed160mg(2 tablets). When higher doses are required, Glimicron 80 mg Tablets should be taken twice daily and according to the main meals of the day.

InobesepatientsorthosenotshowingadequateresponsetoGlimicron80mgTablets alone, additional therapy may be required.

Glimicron80mgcanbegivenincombinationwithbiguanides,alphaglucosidaseinhibitors or insulin.

InpatientsnotadequatelycontrolledwithGlimicron80mg,concomitantinsulintherapycan be initiated under close medical supervision.

4.3Contraindication

Except under special circumstances, this medication should not be used when the following medical problems exist: Acidosis, burns, diabetic coma, infection, ketoacidosis, ketosis, surgery and trauma.

Risk-benefit should be considered when the following medical problems exist: Adrenal insufficiency, pituitary insufficiency, fever, nausea, vomiting, thyroid function impairment, debilitatedphysicalcondition,hepaticfunctionimpairment,malnourishment,renalfunction impairment,sensitivitytooralantidiabeticagentsandpatientswithacuteporphyria.

Warningsandprecautions

- Patients sensitive to one of the oral antidiabetic agents may be sensitive to the others also.
- Oral antidiabetic agents must not be used during pregnancy. Abnormal blood glucose levels have been associated with a higher incidence of congenital abnormalities during earlypregnancy, andwithincreased perinatalmorbidityandmortalitylaterinpregnancy.
- Itshould not beusedin insulin-dependentdiabetesmellitus.
- It should not be given in severe impairment of renal or hepatic function because of an increased risk of hypoglycaemia or severe impairment of thyroid function.
- Its antidiuretic effect may cause problems in patients with conditions associated with fluid retention.
- It is not known whether gliclazide is excreted in breast milk. However other sulphonylureas have been found in breast milk and there is no evidence to suggest that gliclazide differs from the group in this respect.
- Geriatric patients and patients with renal insufficiency may be more sensitive to the effects of this medication because of reduced metabolism and excretion. Dosage should therefore be initiated at a lower level and adjusted cautiously. In the elderly, hypoglycaemia may be more difficult to recognize and may cause more neurological symptoms. These symptoms include anxiety, confusion, and difficulty in concentrating, drowsiness, nervousness or unusual tiredness.
- Dental: The leukopenic and thrombocytopenic effects of sulfonylureas may result in an increased incidence of microbial infection, delayed healing and gingival bleeding. If leukopenia or cytopenia occurs, dental work should be deferred until blood counts have returned to normal. Patients should be instructed in the proper oral hygiene required during this period. This includes cautious use of regular toothbrushes, dental floss and toothpicks.
- Cross-sensitivityto othersulfonamideorthiazide-typemedicationsmayalso occur.

Drug Interactions

- An odd interaction involves alcohol intolerance which is similar to disulfiram-alcohol interaction. There is also an increased risk of hypoglycaemia with alcohol.
- Compounds that may diminish the hypoglycaemic effect and thus necessitate an increase in the dosage requirement of the sulfonylurea include rifampicin and thiazide diuretics, corticosteroids and estrogens.
- Compounds that may increase the hypoglycaemic effect of sulfonylureas and necessitate a reduction in their dosage requirement include anti-infective agents such as chloramphenicol, guanetidine, monoamine oxidase inhibitors, salicylates, sulfonamides, trimethoprim, phenylbutazone, ketoconazole, miconazole, fluconazole, sulphinpyrazone and azapropazone.
- A reversible decrease in thrombocyte count in patients receiving ketotifen concomitantlywith oral antidiabetic agents has been observed in a few cases. Concurrent administration of ketotifen should therefore be avoided.
- Beta-blockers may mask some of the symptoms of hypoglycaemia. Also, beta-blockers may have hypoglycaemic or hyperglycaemic actions of their own.

- Thehypoglycaemic effectmaybe enhancedwhenadministeredconcurrentlywithinsulin.
- Ifadministered concurrentlywithanticoagulants, increasedplasmaconcentrationsofboththe anticoagulant and sulfonylurea may occur initially; with continued therapy, decreased anticoagulant plasma concentrations and increased hepatic metabolism of the sulphonylurea may occur; dosage adjustments of one or both medications may be required.

4.6 Pregnancyandlactation

Noneknown

4.7 Effectsonabilitytodriveanduse machines

Not applicable

MainSide/AdverseEffects

- Gastro-intestinaldisturbancessuchasnausea,vomiting,heartburn,anorexia,diarrhoea and a metallic taste are usually mild and dose-dependant.
- Skinrashesandpruritus.
- Severe,prolongedandsometimesfatalhypoglycaemia.
- Othersevereeffectsmaybemanifestationsofahypersensitivityreactionwhichincludes cholestatic jaundice, leucopenia, thrombocytopenia, aplastic anaemia, agranulocytosis, haemolytic anaemia, erythema multiforme or Stevens-Johnson syndrome, exfoliative dermatitis and erythema nodosum.

4.9 Overdose

Clinical features:

- Nauseaandvomiting.
- Abdominalpain,(rarely)haematemesisandmelaena.Drowsiness,coma,twitching, convulsions.
- Depressedlimbreflexeswithextensorplantarresponses.
- Hyperapnoea,acutepulmonaryoedema.
- Sinustachycardia,hypotension,circulatoryfailure.
- Absenceof sweating.
- Hypoglycaemia,hyperkalaemia,metabolic(lactic)acidosis, leucocytosis.
- Latecomplicationcholestasisjaundice

Treatmentof overdose:

- Emesisorgastriclavage,ifappropriate.Administrationofrepeateddosesoforal activated charcoal with appropriate cathartic may also be used.
- Supportive measures.
- 50mlof50%glucose IVrepeatedasnecessaryand/orglucagon1-2mgIVtocorrect hypoglycaemia, followed by an IV infusion of 5 - 10% dextrose for 24 to 72 hours as necessary.
- Treatmildhypoglycaemiawithimmediateingestionofasourceof sugar.

5.PHARMACOLOGICAL PROPERTIES

5.1Pharmacodynamicproperties

Gliclazide, a sulphonylurea, acts by promoting release of insulin from the beta cells of pancreatic islet tissue by an unknown process. Insulin production is not increased. Hepatic glycogenolysisand gluconeognesisaredecreased. Insulinsensitivityisincreasedatperipheral targetsites.Therefore,sulfonylureasareeffectiveonlyinpatientswhose pancreas arecapable of producing insulin.

Pharmacokineticproperties

- Absorption
  Itisreadilyabsorbedfromthegastro-intestinaltract.
- Protein Binding
  Gliclazideisveryextensivelybound to plasma proteins.
- MetabolicReactions
  It is extensively metabolized in the liver to metabolites without significant hypoglycaemic activity.
- Half-life
  Plasmahalf-lifeisabout10 to12 hours.
- Excretion
  Bothunchangeddrugandmetabolitesareexcretedintheurine.

5.3 PreclinicalSafetyData

NOT APPLICABLE

6. PHARMACEUTICALPARTICULARS

List ofexcipients

Lactose Monohydrate
Polyvinylpyrrolidone K-25
MicrocrystallineCellulosepH101
Sodium Starch Glycolate
Magnesium Stearate
Purifiedwater

6.2 Incompatibilities

NOT APPLICABLE

6.3 Shelflife

3 yearsfromdateofmanufacture

6.4 Specialprecautionforstorage

Storebelow30°C.Protectfrommoisture.

Natureandcontentsof container

PrimaryPackaging	
1	Materialdescription :RigidPVDCfilm Width :106 mm Thickness :0.25 mm Colouroffilm :Glasscleartransparent
2	Material description :Glimicronaluminiumfoil Width : 106 mm Specification :Foilproperty:Silverplainhardtempered20micron aluminium foil with 6276 primer on bright and heat seal on dull surface, 3-4 gsm.
SecondaryPackaging	
3	Materialdescription :Glimicron80mgTablet Insert Dimension : 160mm(W) x165mm(L)
4	Materialdescription :Glimicron80mgTablet(10x10)UnitBox Dimension :47.5mm(L)x43.5mm(W)x101.0mm(H)
5	Materialdescription :PVCshrink-wrapGlimicron80mgUnitBox Dimension :340mm(W) x157mm(L)
6	Materialdescription :PlaincartonforGlimicron80mgTablet Dimension :458mm(L)x410mm(W) x224mm(H)

Instructionsforuseandhandling<and disposal>

NOT APPLICABLE

7.MARKETINGAUTHORISATION HOLDER

Hovid Berhad
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8.NUMBER(S)INTHENATIONALREGISTEROFFINISHEDPHARMACEUTICAL PRODUCTS

HOV/MAL/029

9.DATE OFFIRSTAUTHORISATION

2016

10.DATEOFREVISIONOFTHETEXT

April2021