

# GLIZID TABLET

*Gliclazide 80mg*

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## **What is in this leaflet**

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## **What *Glizid* is used for**

For non-insulin dependant diabetes mellitus, where dietary management alone is insufficient.

## **How *Glizid* work**

Gliclazide is a sulphonylurea blood sugar lowering agent. It stimulates the secretion of insulin by functioning islet beta cells of the pancreas. However, when the insulin secretion falls again, the blood sugar lowering effect persists and maybe due to inhibition of production glucose in liver and increased sensitivity to any available insulin. Gliclazide is only effective for patients whose pancreas is capable of producing insulin. In addition to this pancreatic action, it has been demonstrated that gliclazide administration may improve the utilization of glucose at a peripheral level.

## **Before you use *Glizid***

*When you must not take it*

It should not be taken in the presence of insulin dependant diabetes mellitus (e.g. juvenile diabetes), ketoacidosis, severe infections, stress, trauma, severe renal & hepatic impairment, adrenal or thyroid dysfunction, patients with sulphonylurea intolerance, pregnancy, unstable diabetes, diabetic pre-coma and coma.

*Before you start to take it*

Dosage adjustments may be required in patients suffering from infections, injury, shock or after anaesthesia. Reduction of dosage may be necessary in elderly patients and patients with renal dysfunction because of decreased metabolism and excretion. Care is necessary during excessive exercise as low blood sugar may be

provoked. Gliclazide is unlikely to impair a patient's ability to drive or use machinery.

*Taking other medications*

Compounds that may diminish the hypoglycaemia effect and requires an increase in dosage adjustment – rifampicin, thiazide diuretics, adrenaline, chlorpromazine, corticosteroids, cyclophosphamide, diazoxide, gemfibrozil, isoniazid, oestrogens oral contraceptives, phenytoin and thyroid hormones. Compounds that may increase the hypoglycaemic effect and requires a reduction in their dosage adjustment – anti-infective agents such as chloramphenicol, fluconazole, miconazole and sulphonamides, azapropazone, indobufen, phenylbutazone and salicylates, coumarin anticoagulants and heparin, lipid regulating agents such as clofibrate and halofenate; and monoamine oxidase inhibitors, captopril, cimetidine, doxepin, enalapril, fenfluramine, methyldopa, nortriptyline and sulphinyprazine, anabolic steroids, isoniazid, mebendazole and tetracycline.

Beta blockers may mask symptoms of hypoglycaemia and may inhibit normal physiological response to hypoglycaemia.

## **How to take *Glizid***

*How much to take*

The dosage is determined by the physician according to the severity of the diabetic state. 40-80mg daily with meals, gradually increased, if necessary, up to 320mg daily. Doses of more than 160mg daily should be given in 2 divided doses. Use in elderly and children : To consult the doctor.

*When to take it*

Take gliclazide exactly as your doctor has told you.

*How long to take it*

You should check with your doctor or pharmacist.

*If you forget to take it*

Do not take a double dose to make up for a forgotten tablet.

*If you take too much (overdose)*

Confusion, coma, seizures, cerebral oedema, tachycardia, sweating, tremor and chest pains may occur. For treatment of overdose, consult doctor immediately if symptoms exist.

## **While you are using *Glizid***

*Things you must do*

Inform doctor of medications you are taking. Check with doctor before discontinuing medication, gradual dosage reduction may be necessary.

*Things you must not do*

You must take your medication as directed.

*Things to be careful of*

Inform the doctor if you are pregnant or lactating as it is not known whether gliclazide is excreted in the breast milk as of other sulphonylureas.

## **Side effects**

Nausea, vomiting, headache, loss of appetite, diarrhea, metallic taste usually mild and dose-dependent, rashes, itchiness, sensitivity to light, confusion, coma, seizures, brain edema, faster heart rate, sweating, shaking and chest pains, yellowing of the skin or whites of the eyes caused by liver or blood problems, blood disorders, serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome), itchy red swollen skin, skin inflammation that results in reddish, painful, tender lumps, syndrome of Inappropriate Secretion of antidiuretic hormone (SIADH) characterized by water retention, low sodium levels in blood and central nervous system (CNS) effects may infrequently occur.

## **After using *Glizid***

*Storage*

Store in cool, dry place below 30°C. Protect from light. Keep out of reach of children.

*Disposal*

Do not dispose via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

## **Product description**

*What it looks like*

White, round, flat bevel-edged top double-scored tablet

*Ingredients*

microcrystalline cellulose, polyvinylpyrrolidone, magnesium stearate and tricalcium phosphate.

*MAL NO:* MAL20002267A

## **Manufacturer**

Prime Pharmaceutical Sdn. Bhd.  
1505, Lorong Perusahaan Utama 1  
Taman Perindustrian Bukit Tengah  
14000 Bukit Mertajam, Penang, Malaysia.

## **Date of revision**

27-10-2011

## **Marketing Authorization Holder**

Prime Pharmaceutical Sdn. Bhd.  
Penang, Malaysia.

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## **Apakah yang ada pada risalah ini**

- Apakah kegunaan *Glizid*
- Bagaimana *Glizid* berfungsi
- Sebelum mengambil *Glizid*
- Cara menggunakan *Glizid*
- Semasa menggunakan *Glizid*
- Kesan-kesan sampingan
- Cara penyimpanan dan pelupusan *Glizid*
- Maklumat lanjut
- Pengilang
- Tarikh kemaskini RiMUP

## **Apakah kegunaan *Glizid***

Untuk penyakit kencing manis yang bukan akibat insulin, di mana pengurusan pemakanan sahaja tidak berkesan.

## **Bagaimana *Glizid* berfungsi**

Gliclazide ialah agen penurun paras gula darah. Ia merangsangkan pengeluaran insulin oleh sel beta islet dari pankreas. Bagaimanapun, kesan penurunan paras gula darah berterusan selepas pengeluaran insulin berkurangan mungkin akibat rencatan pengeluaran glukos dalam hati dan tambahan sensitiviti kepada insulin. Gliclazide hanya berkesan kepada pesakit dengan pankreas yang masih berupaya mengeluarkan insulin. Selain itu, gliclazide mungkin meningkatkan penggunaan glukos di tahap pinggir.

## **Sebelum mengambil *Glizid***

*Bila tidak boleh mengambil*

Tidak boleh diambil oleh pesakit kencing manis akibat insulin (seperti kencing manis juvana), ketoasidosis, jangkitan serius, tekanan, trauma, ketidaksempurnaan serius ginjal dan hati, disfungsi serius adrenal dan tiroid, pesakit yang intolerans ubat sulfonilurea, kehamilan, penyakit kencing manis tak stabil, pra-koma dan koma penyakit kencing manis. *Sebelum mula mengambil*

Pengubahsuaian dos diperlukan untuk pesakit dengan jangkitan, kecederaan, kejutan atau lepas pembiusan. Pengurangan dos perlu untuk pesakit tua dan pesakit ginjal kerana pengurangan metabolisma dan perkumuhan. Perlu berhati-hati semasa senaman berlebihan yang mungkin mengakibatkan paras gula dalam darah rendah. Gliclazide sepatutnya tidak mengganggu keupayaan memandu dan mengendalikan mesin.

## **Tarikh kemaskini RiMUP**

27-10-2011

*Jika mengambil ubat-ubat lain*

Bahan yang mengurangkan kesan hipoglisemia memerlukan peningkatan dos – rifampicin, diuretic thiazid, adrenalin, chlorpromazin, kortikosteroid, siklofosamid, diazolid, gemfibrozil, isoniazid, kontraseptif estrogen, fenitoin dan hormon tiroid. Bahan yang meningkatkan kesan hipoglisemia memerlukan pengurangan dos – agen anti-jangkitan seperti kloramfenicol, flukonazol, mikonazol dan sulfonamid, azapropazon, indobufen, fenilbutazon dan salisilat, anti-bekuan koumarin dan heparin, agen regulasi lipid seperti klofibrat dan halofenat; dan agen rencatan monoamin oxidase, kaptopril, cimetidin, dosepin, enalapril, fenfluramine, metildopa, nortriptilin dan sulfipirazin, steroid anabolik, isoniazid, mebendazol dan tetrasiklin. Ubat penghalang beta mungkin mengaburi tanda hipoglisemia dan rencatan kesan fisiologi normal kepada hipoglisemia.

## **Cara menggunakan *Glizid***

*Berapa banyak harus diambil*

Dos dicadangkan oleh doktor berdasarkan keadaan penyakit kencing manis. 40-80mg setiap hari selepas makan, ditingkatkan beransuran, jika perlu kepada 320mg setiap hari. Dos yang lebih daripada 160mg setiap hari harus dibahagikan kepada 2 dos berasingan. Penggunaan untuk pesakit tua dan kanak-kanak perlu atas nasihat doktor.

*Bila perlu diambil*

Ambil gliclazide mengikut arahan oleh doktor.

*Berapa lama perlu diambil*

Perlu mengikut nasihat doktor atau ahli farmasi.

*Jika terlupa mengambil*

Jangan mengambil dos berganda sebagai gantian dos yang terlepas.

*Jika mengambil berlebihan(terlebih dos)*

Mungkin mengalami kekeliruan, koma, kekejangan, edema otak, denyutan jantung cepat, peluh, gigil dan sakit dada. Perlu rawatan segera doktor jika terdapat tanda-tanda terlebih dos.

## **Cara menggunakan *Glizid***

*Perkara yang perlu dilakukan*

Beritahu doktor ubat yang sedang diambil. Dapatkan nasihat doktor

sebelum hentikan pengambilan ubat, pengurangan dos perlu dilakukan secara beransuran.

*Perkara yang tidak boleh dilakukan*  
Pengambilan ubat mestilah seperti yang diarahkan.

*Perkara yang perlu diberi perhatian*  
Beritahu doktor jikalau hamil atau penyusuan kerana tiada maklumat tentang perkumuhan gliclazide dalam susu ibu seperti ubat sulfonilurea lain.

## **Kesan-kesan sampingan**

Loya, muntah, sakit kepala, tiada selera makan, cirit-birit, rasa metalik ringan dan bergantung kepada dos, ruam, kegatalan, sensitif cahaya, kekeliruan, koma, kekejangan, edema otak, denyutan jantung cepat, peluh, gigil dan sakit dada, demam kuning, gangguan darah, penyakit serius dengan lepuh kulit, mulut, mata dan alat kelamin(sindrom Stevens-Johnson), kulit merah dan gatal, inflamasi kulit dengan sakit bengkak, sindrom gangguan sekresi hormon anti-diuretik(SiADH) dengan sifat retensi air, paras natium darah rendah dan kesan sistem saraf pusat mungkin berlaku.

## **Cara penyimpanan dan pelupusan *Glizid***

*Penyimpanan*

Simpan di tempat yang dingin dan kering, bawah 30°C. Jauhkan dari cahaya. Jauhkan dari kanak-kanak

*Pelupusan*

Jangan dibuang dalam air sisa atau sisa buangan. Dapatkan nasihat ahli farmasi cara pelupusan ubat yang ingin dibuang.

## **Maklumat lanjut**

*Rupa dan warna produk*

Tablet putih, bulat, rata tepi serong dengan permukaan atas skor silang.

*Bahan-bahan kandungan*

selulos mikrokristalin, polivinilpirolidon, magnesium stearat dan trikalsium fosfat.

*MAL NO:* MAL20002267A

## **Pengilang**

Prime Pharmaceutical Sdn. Bhd.  
1505, Lorong Perusahaan Utama 1  
Taman Perindustrian Bukit Tengah  
14000 Bukit Mertajam, Pulau Pinang,  
Malaysia.

## **Pemegang pendaftaran keluaran**

Prime Pharmaceutical Sdn. Bhd.  
Pulau Pinang, Malaysia.