

**GLICLAZIDE 80MG TABLETS
PL 21880/0070**

UKPAR

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**GLICLAZIDE 80MG TABLETS
PL 21880/0070**

LAY SUMMARY

The MHRA granted Medreich Plc a Marketing Authorisation (licence) for the medicinal product Gliclazide 80mg Tablets on 03 December 2010.

This medicine is only available on prescription from your doctor.

Gliclazide 80mg Tablets are used to treat diabetes mellitus in adults when this is not controlled by diet, physical exercise or weight loss alone. You get diabetes mellitus if your body does not produce enough insulin to control blood sugar levels.

The product contains the active ingredient gliclazide, which is a blood sugar lowering sulphonylurea. Sulphonylureas act by increasing the release of the hormone insulin from the pancreas and thereby lower high blood sugar levels.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Gliclazide 80mg tablets outweigh the risks; hence a Marketing Authorisation has been granted.

**GLICLAZIDE 80MG TABLETS
PL 21880/0070**

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a Marketing Authorisation for the medicinal product Gliclazide 80mg Tablets (PL 21880/0070) to Medreich Plc on 03 December 2010. The product is available as a prescription-only medicine (POM) and is indicated for the treatment of maturity onset diabetes mellitus.

The application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Glimil Tablets (PL 16363/0006), first approved on 10 June 1999 to Milpharm Limited.

No new data were submitted nor were they necessary for this simple application, as the data are identical to those of the previously granted cross-reference product.

The product contains the active ingredient gliclazide. Gliclazide is a hypoglycaemic sulphonylurea differing from other related compounds by the addition of an azabicyclo octane ring. Oral sulphonylureas act by stimulating the release of insulin from beta cells, but they may also have long-term extrapancreatic effects that reduce hepatic glucose production and increase the number of peripheral insulin receptors. Sulphonylureas are effective only in individuals with functional beta cells.

In man, apart from having a similar hypoglycaemic effect to the other sulphonylureas, gliclazide has been shown to reduce platelet adhesiveness and aggregation, and increase fibrinolytic activity. These factors are thought to be implicated in the pathogenesis of long-term complications of diabetes mellitus.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 21880/0070
PROPRIETARY NAME: Gliclazide 80mg Tablets
ACTIVE(S): Gliclazide
COMPANY NAME: Medreich Plc
E.C. ARTICLE: Article 10c of Directive 2001/83/EC
LEGAL STATUS: POM

1. INTRODUCTION

This is a simple, piggyback application for Gliclazide 80mg Tablets submitted under Article 10c of Directive 2001/83/EC, as amended. The proposed Marketing Authorisation Holder is Medreich Plc, 9 Royal Parade, Kew Gardens, Surrey, TW9 3QD, United Kingdom.

The application cross-refers to Glimil Tablets (PL 16363/0006), approved on 10 June 1999 to Milpharm Limited. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Gliclazide 80mg Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Each tablet contains 80mg gliclazide. The product is packaged in polyvinylchloride/aluminium blisters. Gliclazide 80mg Tablets are available in pack sizes of 28 and 60 tablets.

The proposed shelf-life (36 months) and storage conditions (Do not store above 25°C) are consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the product will be available as a prescription-only medicine (POM).

2.4 Marketing Authorisation Holder/Contact Persons/Company

Medreich Plc, 9 Royal Parade, Kew Gardens, Surrey, TW9 3QD, England.

The Qualified Person (QP) responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

With the exception of lactose monohydrate, none of the excipients contain materials of animal or human origin. The supplier of lactose monohydrate has confirmed that the lactose is sourced from healthy animals under the same conditions as milk for human consumption and prepared without the use of other ruminant materials, except calf rennet. This is consistent with the cross-reference product.

2.11 Bioequivalence

No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula and utilising the same process as the reference product Glimil Tablets (PL 16363/0006).

3. EXPERT REPORTS

The applicant cross-refers to the data for Glimil Tablets (PL 16363/0006), to which it claims identity. This is acceptable.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The proposed Summary of Product Characteristics is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

Milpharm Limited has previously submitted results of consultations with target patient groups (“user testing”), in accordance with Article 59 of Council Directive 2001/83/EC, for the reference product Glimil Tablets (PL 16363/0006). The results indicate that the leaflet is well-structured and organised, easy to understand, and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

As the leaflets for Glimil Tablets (PL 16363/0006) and this product are considered the same, no further user testing of the leaflet for this product is necessary.

Carton and blister

The proposed artwork is consistent with the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSION

The data submitted with the application are acceptable. The grant of a marketing authorisation is recommended.

NON-CLINICAL ASSESSMENT

As this is an abridged simple application, no new non-clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As the application is for an identical version of an already authorised product, it is not expected that environmental exposure will increase following approval of the marketing authorisation for the proposed product.

The grant of a marketing authorisation is recommended.

CLINICAL ASSESSMENT

As this is an abridged simple application, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The Marketing Authorisation Holder has not submitted a Risk Management Plan (RMP). As the application is for an identical version of an already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active ingredient is well-established.

The grant of a marketing authorisation is recommended.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the cross-reference product and as such have been judged to be satisfactory.

NON-CLINICAL

No new non-clinical data were submitted and none are required for an application of this type.

EFFICACY

This application is identical to a previously granted application for Glimil Tablets (PL 16363/0006). No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

BENEFIT/RISK ASSESSMENT

The quality of the product is acceptable, and no new non-reclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with gliclazide is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

**GLICLAZIDE 80 MG TABLETS
PL 21880/0070**

STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the marketing authorisation application on 03 June 2010.
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 10 June 2010.
- 3 Following assessment of the application the MHRA requested further information relating to the dossier on 24 September 2010 and 05 October 2010.
- 4 The applicant responded to the MHRA's request, providing further information on 01 October and 29 October 2010.
- 5 The application was determined on 03 December 2010.

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gliclazide 80mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 80mg Gliclazide

3 PHARMACEUTICAL FORM

Gliclazide 80mg Tablets are presented as white round tablets with 'G 80' on one side and score line on other side.

4 CLINICAL PARTICULARS

4.1 *Therapeutic indications*

For the treatment of maturity onset diabetes mellitus.

4.2 *Posology and method of administration*

Adults: The total daily dose may vary from 40 to 320mg taken orally. The dose should be adjusted according to the individual patient's response, commencing with 40 - 80mg daily (½ to 1 tablets) and increasing until adequate control is achieved. A single dose should not exceed 160mg (2 tablets). When higher dose is required, Gliclazide should be taken twice daily and according to the main meals of the day.

In obese patients or those not showing adequate response to Gliclazide alone, additional therapy may be required.

Elderly: Plasma clearance of gliclazide is not altered in the elderly and steady state plasma levels can therefore be expected to be similar to those in adults under 65 years. Clinical experience in the elderly to date shows that gliclazide is effective and well tolerated. Care should be exercised, however, when prescribing sulphonylureas in the elderly due to possible age-related increased risk of hypoglycaemia.

Children: Gliclazide, as with other sulphonylureas, is not indicated for the treatment of juvenile onset diabetes mellitus.

4.3 *Contraindications*

Gliclazide is contra indicated in:

- Juvenile onset diabetes
- Diabetes complicated by ketosis and acidosis
- Pregnancy
- Diabetes undergoing surgery, after severe trauma or during infections
- Patients known to have hypersensitivity to other sulphonylureas and related drugs
- Diabetes pre-coma and coma
- Severe renal or hepatic insufficiency

4.4 *Special warnings and precautions for use*

Care should be exercised in patients with hepatic impairment and a small starting dose should be used with careful patient monitoring.

All sulphonylurea drugs are capable of producing moderate or severe hypoglycaemia. As with other sulphonylureas, hypoglycaemia will occur if the patient's dietary intake is reduced or if they are receiving a larger dose of Gliclazide than required, particularly in the following conditions;

- In patients controlled by diet alone
- In cases of accidental overdose
- When calorie or glucose intake is deficient
- In patients with hepatic and/or renal impairment, however, in long-term clinical trials, patients with renal insufficiency have been treated satisfactorily, using gliclazide at reduced doses.

In order to reduce the risk of hypoglycaemia it is therefore recommended;

- To initiate treatment for non-insulin dependent diabetics by diet alone, if this is possible;
- To take into account the age of the patient: blood sugar levels not strictly controlled by diet alone might be acceptable in the elderly;
- To adjust the dose of Gliclazide according to the blood glucose response and to the 24 hour urinary glucose during the first days of treatment.

Dosage adjustments may be necessary;

- On the occurrence of mild symptoms of hypoglycaemia (sweating, pallor, hunger pangs, tachycardia, sensation of malaise). Such findings should be treated with oral glucose and adjustments made in drug dosage and/or meal patterns;
- On the occurrence of severe hypoglycaemic reactions (coma or neurological impairment, see overdose)
- Loss of control of blood glucose (hyperglycaemia). When a patient stabilised on any diabetic regimen is exposed to stress such as fever, trauma, infection or surgery, a loss of control may occur. At such times, it may be necessary to progressively increase the dosage of Gliclazide and if this is insufficient, to discontinue the treatment and to administer insulin.

4.5 *Interaction with other medicinal products and other forms of interaction*

Care should be taken when giving Gliclazide with drugs, which are known to alter the diabetic state or potentiate the drug's action. The hypoglycaemic effect of Gliclazide may be potentiated by phenylbutazone, salicylates, sulphonamides, coumarin derivatives, MAOIs, beta adrenergic blocking agents, tetracycline compounds, chloramphenicol, clofibrate, disopyramide, miconazole (oral forms) and cimetidine.

It may be diminished by corticosteroids, oral contraceptives, thiazide diuretics, phenothiazine derivatives, thyroid hormones and abuse of laxatives.

4.6 *Pregnancy and lactation*

Pregnancy: 'See Contra-indications'

Nursing mothers: It has not yet been established whether gliclazide is transferred to human milk. However, other sulphonylureas have been found in milk and there is no evidence to suggest that gliclazide differs from the group in this respect.

4.7 *Effects on ability to drive and use machines*

Patients should be informed that their concentration may be affected if their diabetes is not satisfactorily controlled, especially at the beginning of treatment (see other special warnings and precautions).

4.8 *Undesirable effects*

Hypoglycaemia (see special warnings and precautions).

Abnormalities of hepatic functions are not uncommon during gliclazide therapy. There are rare reports of hepatic failure, hepatitis and jaundice following treatment with gliclazide.

Mild gastro-intestinal disturbances including nausea, dyspepsia, diarrhoea and constipation have been reported, but this type of adverse reaction can be avoided, if Gliclazide is taken during the meal.

Skin reactions including rash, pruritis, erythema, bullous eruption, blood dyscrasia including anaemia, leucopenia, thrombocytopenia and granulocytopenia have been during treatment with gliclazide but are not known to be directly attributable to the drug.

4.9 *Overdose*

The symptoms to be expected with an overdose would be hypoglycaemia. The treatment is gastric lavage and correction of the hypoglycaemia by appropriate means with continued monitoring of the patient's blood sugar until the effect of the drug has ceased.

5 PHARMACOLOGICAL PROPERTIES

5.1 *Pharmacodynamic properties*

ATC Code: A10BB09

Gliclazide is a hypoglycaemic sulphonylurea differing from other related compounds by the addition of an azabicyclo octane ring. Oral sulphonylureas act by stimulating the release of insulin from beta cells, but they may also have long term extrapancreatic effects that reduce hepatic glucose production and increase the number of peripheral insulin receptors. Sulphonylureas are effective only in individuals with functional beta cells.

In man, apart from having a similar hypoglycaemic effect to the other sulphonylureas, gliclazide has been shown to reduce platelet adhesiveness and aggregation and increase fibrinolytic activity. These factors are thought to be implicated in the pathogenesis of long-term complications of diabetes mellitus.

5.2 *Pharmacokinetic properties*

The drug is well absorbed and its half-life in man is approximately 10 - 12 hours. Gliclazide is metabolised in the liver to inactive metabolites; less than 5% of the dose is excreted unchanged in the urine. Although there is a dose-dependent relationship between gliclazide and plasma concentrations, no clear correlation with hypoglycaemic activity exists.

5.3 *Preclinical safety data*

There is no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 *List of excipients*

Lactose monohydrate
Silicon dioxide
Pregelatinised maize starch
Talc
Magnesium stearate

6.2 *Incompatibilities*

None known.

6.3 *Shelf life*

36 months.

6.4 *Special precautions for storage*

Do not store above 25°C.

6.5 *Nature and contents of container*

The tablets are packaged into polyvinyl chloride (PVC)/aluminium foil blister packs. Boxes of 28 tablets or 60 tablets are available.

Boxes of 28 tablets contain 2 blister packs each of 14 tablets. Boxes of 60 tablets contain 6 blister packs each of 10 tablets or 3 blister packs each of 20 tablets or 4 blister packs each of 15 tablets.

6.6 *Special precautions for disposal*

No special instructions. Tablets to be taken as directed by a physician.

7 MARKETING AUTHORISATION HOLDER

Medreich Plc,
9 Royal Parade,
Kew Gardens,
Surrey,
TW9 3QD
United Kingdom

- 8** **MARKETING AUTHORISATION NUMBER(S)**
PL 21880/0070
- 9** **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
03/12/2010
- 10** **DATE OF REVISION OF THE TEXT**
03/12/2010

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gliclazide 80mg Tablets
(gliclazide)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Gliclazide Tablets are and what they are used for
2. Before you take Gliclazide Tablets
3. How to take Gliclazide Tablets
4. Possible side effects
5. How to store Gliclazide Tablets
6. Further information

1. WHAT GLICLAZIDE TABLETS ARE AND WHAT THEY ARE USED FOR

Gliclazide is a hypoglycaemic sulphonylurea used to treat diabetes mellitus in adults. Sulphonylureas act by stimulating the release of insulin from beta cells in the pancreas and so lower the amount of sugar in your blood.

2. BEFORE YOU TAKE GLICLAZIDE TABLETS

Do not take Gliclazide Tablets

- If you are allergic (hypersensitive) to sulphonylureas or related drugs or are allergic to any of the ingredients in the tablets (see Section 6 and end of Section 2).
- If you suffer from juvenile onset diabetes (diabetes which start in childhood)
- If you have severe liver or kidney problems
- If you are having an operation, or have a severe infection, or are suffering from extreme stress or trauma.
- If you have ketoacidosis (a complication of diabetes with ketones in the urine).
- If you are pregnant, thinking of becoming pregnant (see Section "Pregnancy and breastfeeding").
- If you suffer from an inherited metabolic disorder called porphyria.

Take special care with Gliclazide Tablets

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, you observe the dietary regimen, have physical exercise and, where necessary, reduce weight. During gliclazide treatment regular monitoring of your blood (and possibly urine) sugar level is required.

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 gliclazide,
- 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.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, e.g. glucose tablets, sugar cubes, sweet juice, sweetened tea.

You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes).

Remember that artificial sweeteners are not effective. Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Symptom 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 (those acting on the central nervous system and beta blockers).

Symptoms of high blood sugar (Hyperglycaemia) may occur when Gliclazide 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 occurred you must contact your doctor or pharmacist.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, as they may interact with your tablet.

The blood sugar lowering effect of Gliclazide may be strengthened 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 (e.g. sulphonamides, chloramphenicol)
- medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril, or enalapril),
- medicines to treat fungal infections (miconazole),
- medicines to treat ulcers in the stomach or duodenum (cimetidine)
- medicines to treat depression (monoamine oxidase inhibitors),
- painkiller or antirheumatics (phenylbutazone, ibuprofen),
- medicine for high blood fat levels (Clofibrate)
- medicine for treating irregular heart beats (Disopyramide)
- blood thinning medicines such as warfarin

The blood sugar lowering effect of Gliclazide may be weakened 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),
- Oral contraceptives
- Thiazide diuretics (bendrofluazide),
- Thyroid hormone medicine to treat underactive thyroid.
- Laxative, if used excessively.

Taking Gliclazide Tablets with food and drink

Gliclazide Tablets can be taken with breakfast and non-alcoholic drinks.

Drinking alcohol is not recommended as it can alter the control of your diabetes in an unpredictable manner.

Pregnancy and breast-feeding

Do not take Gliclazide tablets if you are pregnant, thinking of becoming pregnant or breast-feeding. Tell your doctor if you are taking Gliclazide tablets and are breastfeeding or planning to breast-feed your baby.

Effects on the ability to drive and use machines

Low blood sugar may occur at the beginning of the treatment while your doctor is trying to find the dose that best suits you. If you experience the symptoms of low blood sugar (hypoglycaemia) – sweating, trembling, weakness, double vision, palpitations, confusion, you should not drive or operate machinery.

When your blood sugar is stabilized you may drive or operate machinery.

Important information about some of the ingredients of Gliclazide Tablets

Lactose: - if you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE GLICLAZIDE TABLETS

Always take Gliclazide Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Gliclazide Tablets should be taken orally with food, either with breakfast or the first main meal of the day.

The usual dosage is as follows:

Adults and Elderly: The usual starting dose is 40 to 80mg (½ or 1 tablet) daily, adjusted according to your response, up to a maximum of 320mg (four tablets) daily. Up to 160mg (two tablets) can be taken at one time.

Your starting dose will be reduced if you are elderly or have liver or kidney problems.

Children: Gliclazide is not recommended for use in children.

You should continue to take these tablets for as long as your doctor tells you to.

Do not stop taking the tablets or alter the dosage without consulting your doctor.

If you take more Gliclazide Tablets than you should

If you or someone else accidentally takes too many Gliclazide Tablets seek immediate medical help by contacting your doctor or nearest hospital casualty department. Take the carton and any remaining tablets you have with you.

If you forget to take Gliclazide Tablets

If you forget to take a dose, do not worry, just wait until it is time for your next dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Gliclazide Tablets

You should take your medicine for as long as your doctor tells you to. Do not stop taking this medicine without consulting your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Gliclazide Tablets can cause side effects, although not everybody gets them.

You may suffer an allergic reaction, symptoms of which include rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue. If this happens to you, **stop taking** the tablets immediately and seek medical help.

The following have also been reported:

Common side effects (affecting between 1 in 10 and 1 in 100 patients):

- changes in taste sensation
- changes in appetite (increased or decreased)
- constipation
- diarrhea
- dizziness
- frequent urination
- gas in stomach
- heartburn

- increased amounts of urine
- nausea, vomiting
- stomach pain or discomfort

Uncommon side effects (affecting between 1 in 100 and 1 in 1000 patients):

- difficulty focussing eyes
- itching and/or rash
- peeling of skin
- reddening of skin

Rare side effects (affecting between 1 in 1000 and 1 in 10000 people)

- inflammation of the liver
- yellowing of eyes or skin
- shortness of breath
- leucopenia (abnormally low white blood cell count)
- sore throat
- unusual bleeding or bruising
- unusual tiredness

Very Rare side effects (affecting 1 in 10,000 people)

- increased sensitivity to skin to the sun

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE GLICLAZIDE TABLETS

Keep out of the reach and sight of children

Do not use your medicine after the expiry date stated on the label.

The expiry date refers to the last day of that month.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Gliclazide tablets contain

The active substance is gliclazide.

Each tablet contains 80mg of gliclazide.

The other ingredients are: lactose monohydrate, silicon dioxide, pregelatinised maize starch, talc and magnesium stearate.

What Gliclazide Tablets look like and the contents of the pack

Gliclazide tablets 80mg are white, round tablets scored on one side with G80 on the other side.

The registered pack sizes are 28 and 60 tablets.

The Manufacturer is:

Milpharm Limited,
Ares Block, Odyssey Business Park,
West End Road, Ruislip,
HA4 6QD, UK

The MA Holder is:

Medreich Plc, 9 Royal Parade, Kew Gardens, Surrey, TW9 3QD, UK*

This leaflet was last approved in September 2010

MA Holder:
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Surrey TW9 3QD, England.

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LABELLING



