Public Assessment Report

UKPAR

Gliclazide 40 mg tablets
Gliclazide 80 mg tablets

(gliclazide)

UK Licence Number: PL 42176/0005-06

Lucis Pharma Limited.
LAY SUMMARY

Gliclazide 40 mg tablets
Gliclazide 80 mg tablets

(gliclazide, tablets, 40 mg and 80 mg)

This is a summary of the Public Assessment Report (PAR) for Gliclazide 40 mg tablets (PL 42176/0005) and Gliclazide 80 mg tablets (PL 42176/0006). It explains how Gliclazide 40 mg and 80 mg tablets were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Gliclazide 40 mg and 80 mg tablets.

The products will be collectively referred to as Gliclazide tablets throughout the remainder of this public assessment report (PAR).

For practical information about using Gliclazide tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Gliclazide tablets and what are they used for?
Gliclazide 40 mg tablets are a ‘hybrid generic medicine’. This means that it is similar to a reference medicine containing the same active substance but is available at a lower strength (40 mg). The reference medicine for this product is Diamicron 80 mg Tablets (Servier Laboratories Ltd).

Gliclazide 80 mg tablets are a ‘generic medicine’. This means that Gliclazide 80 mg tablets are similar to a ‘reference medicine’ already authorised in the European Union (EU) called Diamicron 80 mg Tablets (Servier Laboratories Ltd).

Gliclazide tablets are used to keep blood sugar at the correct level in adults with non-insulin dependent diabetes when it is not controlled by diet, physical exercise and weight loss alone.

How do Gliclazide tablets work?
The active ingredient in this medicine is called gliclazide and is one of a group of medicines called sulfonylureas that are used to lower the blood sugar level.

How are Gliclazide tablets used?
The pharmaceutical form of this medicine is a tablet. The route of administration of this medicine is oral (by mouth).

The patient must always take this medicine exactly as their doctor has told them. The patient must check with their doctor or pharmacist if they are not sure.

Change in external factors (e.g. weight reduction, change in life style, stress) or improvements in the blood sugar control may require changed gliclazide doses.

This medicine should be taken with a glass of water before meals.

Doses:
The recommended dose is from 40 mg to 320 mg. This depends on the response to treatment. When the total daily dose exceeds 160 mg, it should be divided into two equal doses taken morning and evening.

If a combination therapy of Gliclazide tablets with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist or insulin is initiated, the
patient’s doctor will determine the proper dose of each medicine individually for them. If the patient
notices that their blood sugar levels are high although they are taking the medicine as prescribed, they
should contact their doctor or pharmacist.

Please read section 3 of the package leaflets for detailed information on dosing recommendations, the
route of administration, and the duration of treatment.

This medicine can only be obtained with a prescription.

**What benefits of Gliclazide tablets have been shown in studies?**
As Gliclazide tablets are generic/hybrid generic medicines of Diamicron 80 mg Tablets (Servier
Laboratories Ltd), studies have been limited to tests to determine that Gliclazide tablets are
bioequivalent/therapeutically equivalent to the reference medicine Diamicron 80 mg Tablets (Servier
Laboratories Ltd). Two medicines are bioequivalent when they produce the same levels of the active
substance in the body.

**What are the possible side effects of this medicine?**
Because Gliclazide tablets are either generic or hybrid generic medicines that are considered
bioequivalent/therapeutically equivalent to the reference medicine Diamicron 80 mg Tablets (Servier
Laboratories Ltd) the benefits and possible side effects are taken as being the same as the reference
medicines.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet
available on the MHRA website.

For the full list of restrictions, see the package leaflet.

**Why was Gliclazide tablets approved?**
It was concluded that, in accordance with EU requirements, Gliclazide tablets have been shown to have
comparable quality and to be bioequivalent/be comparable to Diamicron 80 mg Tablets (Servier
Laboratories Ltd). Therefore, the MHRA decided that, as for Diamicron 80 mg Tablets (Servier
Laboratories Ltd); the benefits are greater than the risks and recommended that Gliclazide tablets can be
approved for use.

**What measures are being taken to ensure the safe and effective use of Gliclazide tablets?**
A risk management plan (RMP) has been developed to ensure that Gliclazide tablets are used as safely
as possible. Based on this plan, safety information has been included in the Summary of Product
Characteristics and the package leaflet for Gliclazide tablets including the appropriate precautions to be
followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by
patients/healthcare professionals will be monitored/reviewed continuously.

**Other information about Gliclazide tablets**
The MHRA agreed to grant marketing Authorisations for Gliclazide tablets on 16 March 2017.

The full PAR for this medicine follows this summary.

For more information about treatment with this medicine, read the package leaflet, or contact your
doctor or pharmacist.

This summary was last updated in April 2017.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>I</th>
<th>Introduction</th>
<th>Page 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>II</td>
<td>Quality aspects</td>
<td>Page 6</td>
</tr>
<tr>
<td>III</td>
<td>Non-clinical aspects</td>
<td>Page 7</td>
</tr>
<tr>
<td>IV</td>
<td>Clinical aspects</td>
<td>Page 7</td>
</tr>
<tr>
<td>V</td>
<td>User consultation</td>
<td>Page 10</td>
</tr>
<tr>
<td>VI</td>
<td>Overall conclusion, benefit/risk assessment and recommendation</td>
<td>Page 10</td>
</tr>
<tr>
<td></td>
<td>Table of content of the PAR update</td>
<td>Page 14</td>
</tr>
</tbody>
</table>
I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Lucis Pharma Limited, marketing authorisations for the medicinal product Gliclazide tablets (PL 42176/0005-06). The product is a prescription-only medicine (POM) indicated for non-insulin dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose.

The application for Gliclazide 40 mg tablets (PL 42176/0005) was submitted under Article 10(3) of Directive 2001/83/EC, as amended, as a hybrid application. The application for Gliclazide 80 mg tablets (PL 42176/0006) was submitted under Article 10(1) of Directive 2001/83/EC, as amended, as a generic application.

The reference product for Gliclazide 40 mg and 80 mg tablets (PL 42176/0005-06) is Diamicron 80 mg Tablets which was first authorised to Servier Laboratories Ltd, UK (PL 00093/0024) on 21 December 1979.

Gliclazide reduces blood glucose levels by stimulating insulin secretion from the β-cells of the islets of Langerhans. Increase in postprandial insulin and C-peptide secretion persists after two years of treatment.

In addition to these metabolic properties, gliclazide has haemovascular properties.

One bioequivalence study was submitted to support these applications comparing the applicant’s test product Gliclazide 80 mg tablets (Lucis Pharma Limited, UK) with the reference product Diamicron 80 mg Tablets (Servier Laboratories Ltd) under fasting conditions. The applicant has stated that the bioequivalence study was conducted in accordance with Good Clinical practice (GCP) guidelines.

With the exception of the bioequivalence study, no new non-clinical or clinical data were submitted, which is acceptable given that these applications were based on being generic/hybrid medicinal products of originator products that have been in clinical use for over 10 years.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place at all sites responsible for the manufacture, assembly and batch release of these products.

No new or unexpected safety concerns arose during the review of information provided by the Marketing Authorisation Holder and it was, therefore, judged that the benefits of taking Gliclazide tablets outweigh the risks and Marketing Authorisations were granted.
II QUALITY ASPECTS

II.1 Introduction
Each tablet contains 40 mg or 80 mg gliclazide.

Other ingredients consist of the pharmaceutical excipients lactose monohydrate, maize starch, pregelatinised maize Starch, talc and magnesium stearate. Both strengths of the finished product are packed into polyvinyl chloride (PVC)/polyvinylidene chloride (PVdC)/aluminium blisters and are available in pack sizes of 20, 28, 56, 60, 84 and 100 tablets. Not all pack sizes may be marketed. Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2 Drug Substance
INN: Gliclazide
Chemical name: 1-(Hexahydrocyclopenta[c]pyrrol-2(1H)-yl)-3-[(4-methylphenyl)sulfonyl]urea.

Structural formula:

![Structural formula of gliclazide]

Molecular formula: C₁₅H₂₁N₃O₃S
Molecular mass: 323.4
Appearance: A white or almost white powder.
Solubility: Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in acetone, slightly soluble in ethanol (96 per cent).

Gliclazide is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, gliclazide, are covered by the European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3 Medicinal Product

Pharmaceutical Development
The objective of the development programme was to formulate safe, efficacious, stable tablets containing 40 mg or 80 mg gliclazide per tablet that are generic/hybrid generic versions of the reference product Diamicron 80 mg Tablets (Servier Laboratories Ltd). A satisfactory account of the pharmaceutical development has been provided.

Comparable in-vitro dissolution and impurity profiles have been provided for the test and reference product.

All excipients comply with their respective European Pharmacopoeia monographs. Satisfactory Certificates of Analysis have been provided for all excipients. Suitable batch analysis data have been provided for each excipient.

None of the excipients contain materials of animal or human origin.

No genetically modified organisms (GMO) have been used in the preparation of this product.
**Manufacture of the product**
Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. The manufacturing process has been validated at the commercial-scale batch size and shown satisfactory results. The process validation protocol to be followed for the full scale production batch size has been submitted and is satisfactory.

**Finished Product Specification**
The finished product specifications proposed are acceptable. Test methods have been described that have been adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for all working standards used.

**Stability of the Product**
Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. The data from these studies support a shelf-life of 30 months with the storage condition ‘Store in the original package.’

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

**II.4 Discussion on chemical, pharmaceutical and biological aspects**
There are no objections to the approval of these applications from a pharmaceutical viewpoint.

**III NON-CLINICAL ASPECTS**

**III.1 Introduction**
As the pharmacodynamic, pharmacokinetic and toxicological properties of gliclazide are well-known, no new non-clinical studies are required and none have been provided. An overview based on the literature review is, thus, appropriate.

The MAH’s non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

**III.2 Pharmacology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.3 Pharmacokinetics**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.4 Toxicology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.5 Ecotoxicity/environmental risk assessment (ERA)**
Since Gliclazide tablets are intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

**III.6 Discussion on the non-clinical aspects**
There are no objections to the approval of these applications from a non-clinical viewpoint.

**IV CLINICAL ASPECTS**

**IV.1 Introduction**
The clinical pharmacology of gliclazide is well-known. With the exception of data from the bioequivalence study detailed below, no new pharmacodynamics or pharmacokinetic data are provided or are required for this application.
No new efficacy or safety studies have been performed and none are required for this type of application. A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of gliclazide.

Based on the data provided, Gliclazide 80 mg tablets (Lucis Pharma Limited) can be considered bioequivalent to Diamicron 80 mg Tablets (Servier Laboratories Ltd).

IV.2 Pharmacokinetics

In support of this application, the applicant submitted the following bioequivalence study:

STUDY

An open label, randomised, two-period, two-treatment, two-sequence, single dose, crossover study to compare the pharmacokinetics of the applicant’s test product Gliclazide 80 mg tablets (Lucis Pharma Limited) versus the reference product, Diamicron 80 mg Tablets (Servier Laboratories Ltd), in healthy adult subjects under fasting conditions.

After an overnight fast of at least 8 hours the subjects were administered a single dose (1 x 80 mg tablet) of either the test or the reference product with 240 mL of 20% glucose solution in water to prevent hypoglycaemia. Subjects were administered 60 mL of 20% glucose solution approximately every hour up to four hours post dose in each period. Blood samples were collected for plasma levels before dosing and up to and including 72 hours after each administration. The washout period between the treatment phases was 9 days. The pharmacokinetic results are presented below:

Summary statistics for the pharmacokinetic parameters for gliclazide are shown below:

<table>
<thead>
<tr>
<th>Pharmacokinetic parameter</th>
<th>Arithmetic Means (± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test product</td>
</tr>
<tr>
<td>AUC₀⁻₇₂</td>
<td>73.403 (±31.628)</td>
</tr>
<tr>
<td>AUC₀⁻∞</td>
<td>83.492 (±50.605)</td>
</tr>
<tr>
<td>Cₘₐₓ</td>
<td>4.347 (±1.232)</td>
</tr>
<tr>
<td>Tₘₐₓ</td>
<td>4.667 (2.500, 7.000)</td>
</tr>
</tbody>
</table>

* median (min, max)

<table>
<thead>
<tr>
<th>Pharmacokinetic parameter</th>
<th>Geometric Mean Ratio Test/Ref</th>
<th>Confidence Intervals</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC₀⁻₇₂</td>
<td>100.67</td>
<td>(97.68 % - 103.76 %)</td>
<td>7.007</td>
</tr>
<tr>
<td>Cₘₐₓ</td>
<td>109.56</td>
<td>(104.86 % - 114.47 %)</td>
<td>10.178</td>
</tr>
</tbody>
</table>

AUC₀⁻₇₂ area under the plasma concentration-time curve from zero to 72 hours
Cₘₐₓ maximum plasma concentration

Conclusion

The 90% confidence intervals of the test/reference ratio for AUC, and Cₘₐₓ values for gliclazide lie within the acceptable limits of 80.00% to 125.00%, in line with the ‘Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1/Corr**). Thus, the data support the claim that the applicant’s test product Gliclazide 80 mg tablets (Lucis Pharma Limited), is bioequivalent to the reference product Diamicron 80 mg Tablets (Servier Laboratories Ltd).

As the 40 mg and 80 mg strength test products meet the biowaiver criteria specified in the current bioequivalence guidance, the results and conclusions of the bioequivalence study with the 80 mg strength can be extrapolated to the 40 mg strength tablets.

IV.3 Pharmacodynamics

No new pharmacodynamic data were submitted and none were required for an application of this type.
IV.4 Clinical efficacy
No new efficacy data were submitted and none were required for an application of this type.

IV.5 Clinical safety
No new safety data were submitted and none were required for these applications.

IV.6 Risk Management Plan (RMP)
The marketing authorisation holder (MAH) has submitted a risk management plan (RMP), in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to gliclazide.

A summary of safety concerns and planned risk minimisation activities, as approved in the RMP, are listed below:

<table>
<thead>
<tr>
<th>Important identified risks</th>
<th>Hypersensitivity to gliclazide or to any of the excipients, other sulfonylureas or sulphonamides</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hypoglycaemia</td>
</tr>
<tr>
<td></td>
<td>Hypoglycaemia in patients with hepatic insufficiency</td>
</tr>
<tr>
<td></td>
<td>Hypoglycaemia in patients with renal insufficiency</td>
</tr>
<tr>
<td></td>
<td>Secondary failure</td>
</tr>
<tr>
<td></td>
<td>Haemolytic anaemia in patients with G6PD deficiency</td>
</tr>
<tr>
<td></td>
<td>Pre-coma, coma and diabetic ketoacidosis</td>
</tr>
<tr>
<td></td>
<td>Overdose of gliclazide tablets</td>
</tr>
<tr>
<td></td>
<td>Hypoglycaemia in elderly patients</td>
</tr>
<tr>
<td></td>
<td>Use during pregnancy and lactation</td>
</tr>
<tr>
<td></td>
<td>Drug interactions:</td>
</tr>
<tr>
<td></td>
<td>Increased risk of hypoglycaemia caused by interaction with:</td>
</tr>
<tr>
<td></td>
<td>• Miconazole, fluconazole</td>
</tr>
<tr>
<td></td>
<td>• Phenylbutazone and other NSAIDs</td>
</tr>
<tr>
<td></td>
<td>• Alcohol</td>
</tr>
<tr>
<td></td>
<td>• Antidiabetic agents (insulins, acarbose, metformin, thiazolidinediones, peptidyl peptidase-4 inhibitors, GLP-1 receptor agonists)</td>
</tr>
<tr>
<td></td>
<td>• Beta blockers</td>
</tr>
<tr>
<td></td>
<td>• ACE inhibitors, H2-receptor antagonists, MAOIs, sulphonamides and NSAIDs, danazol, chlorpromazine, glucocorticoids, ritodrine, salbutamol, terbutaline, anticoagulant therapy (warfarin)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Important potential risks</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing information</td>
<td>Use in the paediatric population</td>
</tr>
</tbody>
</table>

Routine pharmacovigilance and routine risk minimisation are proposed for all safety concerns.
IV.7 Discussion on the clinical aspects
There are no objections to the approval of these applications from a clinical viewpoint.

The grant of marketing authorisations is recommended for these applications.

V User consultation

**Gliclazide 40 mg tablets (PL 42176/0005):**

The package leaflet has been evaluated via a user consultation study, in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.

The results show that the package leaflet meets the criteria for readability, as set out in the *Guideline on the readability of the label and package leaflet of medicinal products for human use.*

**Gliclazide 80 mg tablets (PL 42176/0006):**

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to Gliclazide 40 mg tablets (PL 42176/0005; Lucis Pharma Limited). The bridging report submitted by the applicant is acceptable.

VI Overall conclusion, benefit/risk assessment and recommendation

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. 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.
Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The approved labelling for Gliclazide 40 mg tablets is presented below:
PAR Gliclazide 40 mg and 80 mg tablets

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton – Blister strips

1. NAME OF THE MEDICINAL PRODUCT

Gliclazide 40 mg tablets
Gliclazide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 40 mg gliclazide.

3. LIST OF EXCIPIENTS

Contains lactose. See the leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Tablets.

20 tablets
28 tablets
56 tablets
60 tablets
84 tablets
100 tablets

(blisters in carton box)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Not applicable.

8. EXPIRY DATE

EXP (MM/YYYY)

9. SPECIAL STORAGE CONDITIONS

Store in the original package.
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Not applicable.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Lucis Pharma Limited,
Aston Chase,
14 Aston Magna,
Moreton-in-Marsh, GL56 9QQ
UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 42176/0005

13. BATCH NUMBER-, DONATION AND PRODUCT CODES-

BN:

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Not applicable.

16. INFORMATION IN BRAILLE

Gliclazide 40 mg tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters

1. NAME OF THE MEDICINAL PRODUCT

Gliclazide 40 mg tablets
Gliclazide

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Lucis Pharma Limited

3. EXPIRY DATE

EXP (MM/YYYY)

4. BATCH NUMBER

BN

5. OTHER

Not applicable.
The following text is the approved label text for Gliclazide 80 mg tablets, no label mock-ups have been provided. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock-ups has been obtained:

<table>
<thead>
<tr>
<th>PARTICULARS TO APPEAR ON THE OUTER PACKAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carton – Blisters</td>
</tr>
</tbody>
</table>

1. **NAME OF THE MEDICINAL PRODUCT**

Gliclazide 80 mg tablets

Gliclazide

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

Each tablet contains 80 mg gliclazide.

3. **LIST OF EXCIPIENTS**

Contains lactose. See the leaflet for further information.

4. **PHARMACEUTICAL FORM AND CONTENTS**

Tablets.

- 20 tablets
- 28 tablets
- 56 tablets
- 60 tablets
- 84 tablets
- 100 tablets

(Blisters in carton box)

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use.

Read the package leaflet before use.

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

Not applicable.

8. **EXPIRY DATE**

EXP (MM/YYYY)

9. **SPECIAL STORAGE CONDITIONS**

Store in the original package.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**
Not applicable.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Lucis Pharma Limited,
Aston Chase,
14 Aston Magna,
Moreton-in-Marsh, GL56 9QQ
UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 42176/0006

13. BATCH NUMBER(< DONATION AND PRODUCT CODES>)

BN:

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Not applicable.

16. INFORMATION IN BRAILLE

Gliclazide 80 mg tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE MEDICINAL PRODUCT

Gliclazide 80 mg tablets
Gliclazide

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Lucis Pharma Limited

3. EXPIRY DATE

EXP (MM/YYYY)

4. BATCH NUMBER

BN

5. OTHER

Not applicable.
Annex 1

Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

<table>
<thead>
<tr>
<th>Scope</th>
<th>Procedure number</th>
<th>Product information affected</th>
<th>Date of start of the procedure</th>
<th>Date of end of procedure</th>
<th>Approval/ non approval</th>
<th>Assessment report attached Y/N (version)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>