SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glyconon

Tolbutamide Tablets 500mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolbutamide BP 500.00 mg

3 PHARMACEUTICAL FORM

Tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an oral hypoglycaemic agent in the treatment of diabetes mellitus of the maturity-onset type, where control cannot be achieved by diet alone. Glyconon is especially suitable for elderly patients.

The hypoglycaemic effect of Tolbutamide only occurs when the beta cells of the islet tissue in the pancreas are intact and retain some functional capacity. Glyconon has no place in the treatment of the severe diabetic but finds its chief use in the treatment of maturity-onset diabetes, responding inadequately to dietary treatment alone. In some of these patients it can replace low doses of insulin or reduce the requirement for high doses.

4.2 Posology and method of administration

Adults:
Glyconon should be given with or just before meals for optimum control of blood sugar.

1st day:	6 tablets
2nd day:	3 tablets
3rd day:	2-4 tablets

Maintenance: 2-3 tablets daily taken either as a single dose or divided into 2 or 3 doses. The correct dose is that which is sufficient to correct glycosuria and hyperglycaemia without producing hypoglycaemia. The full effect of therapy may take up to a week to develop. Patients who do not respond to 4 tablets daily will generally not respond to higher doses. Where a patient is already taking insulin, the change to Tolbutamide may be effected immediately where the dose of insulin is 20 units or less per day. Where insulin is being given in greater amounts, the number of units should be decreased over several days and glycosuria should be monitored.

Elderly:
Glyconon is particularly suitable for elderly patients. However, since this patient group may be more liable to sulphonylurea- induced hypoglycaemia, treatment should be initiated at a lower dose.

Children:
As non-insulin dependent diabetes is not usually a disease of childhood, Glyconon is not recommended for use in children.

Route of Administration: Oral.

4.3 Contraindications

Diabetes complicated by fever, trauma or gangrene and diabetic ketoacidosis.
Impaired renal, hepatic or thyroid function.

4.4 Special warnings and precautions for use

The possibility of thrombocytopenia and blood dyscrasias should be borne in mind and a platelet count performed if indicated.
Cases which initially respond to Tolbutamide may relapse and this should be considered as a possibility should glycosuria or hyperglycaemia appear during treatment.
If fever or sore throat occurs, a white cell count should be performed and should be repeated after five days as blood abnormalities may develop slowly.

4.5 Interaction with other medicinal products and other forms of interaction

Hypoglcaemia has occurred with the concomitant administration of alcohol, azapropazone, beta-adrenergic blocking agents, cimetidine, chloramphenicol, coumarins, fluconazole, miconazole, monoamine oxidase inhibitors, phenylbutazone, phenytoin, sulfinpyrazone and sulphonamides. A diminishing effect occurs with corticosteroids, loop and thiazide diuretics, oral contraceptives and rifamycins.

4.6 Pregnancy and lactation

Use in Pregnancy: Do not use during pregnancy, particularly during the first and last trimester unless clinically imperative. Safety in pregnancy has not been proven.

Nursing mothers: Tolbutamide has been detected in small quantities in breast milk.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Gastric irritation may occur and be reduced by dividing the doses. Skin sensitisation, weakness, paraesthesias, tinnitus, headache, intolerance to alcohol and jaundice have been reported. Reversible blood dyscrasias have also been observed. A small proportion of patients have difficulty in metabolising Tolbutamide and as a result develop hypoglycaemia even with low doses.

4.9 Overdose

Hypoglycaemia may be treated with oral dextrose or lump sugar (3-4 lumps) and repeated if necessary. In the comatose patient glucose may be given by sub-cutaneous or intra- muscular injection of 1 mg to produce consciousness.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tolbutamide is a sulphonylurea and an orally active hypoglycaemic agent which reduces blood-sugar concentration.
It is thought to act by stimulating insulin secretion and is only effective in the presence of functioning islet tissue.
After a single dose the maximum effect on blood-sugar concentration occurs in about 5 hours and lasts for 8-10 hours.

5.2 Pharmacokinetic properties

Tolbutamide is readily absorbed from the gastro-intestinal tract and is extensively bound to plasma proteins.
Tolbutamide is metabolised in the liver and the metabolites are excreted in the urine, with up to 75% of a dose being recovered in 24 hours.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize Starch
Methylcellulose
Purified water
Pregelatinised Starch
Sodium Starch Glycollate
Magnesium Stearate
Stearic Acid

6.2 Incompatibilities

There are no major incompatibilities.

6.3 Shelf life

36 months all pack sizes

6.4 Special precautions for storage

Protect from light.

6.5 Nature and contents of container

Polypropylene or high density polystyrene with polythene closures and polyurethane wads or polythene inserts.

Pack sizes: 100, 500

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
11 Boumpoulinas Street,
3rd floor, 1060 Nicosia
Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0114

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/07/1987 / 28/10/2002

10 DATE OF REVISION OF THE TEXT

26/02/2009