GLYFORMIN TABLETS

Metformin Hydrochloride B.P 500mg

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Document type: Summary of Product Characteristics

Document status: Final

Release date: 17th August 2020

Number of pages: 7 pages

1. NAME OF THE MEDICINAL PRODUCT

METFORMIN HYDROCHLORIDE B.P. 500mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains Metformin Hydrochloride 500mg.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

White coloured, circular scored tablet with break line on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Metformin is indicated in the treatment of Diet-failed, maturity or Non-Insulin Dependent Diabetes Mellitus, especially if overweight, along as initial therapy or combination therapy with sulphonylurea. Also in adjuvant therapy in Insulin Dependent Diabetes Mellitus especially if overweight.

4.2 Posology and method of administration.

Posology

Adults:

Adults with normal renal function, monotherapy and combination with other oral antidiabetic agents are

• Usual starting is dose of 500mg 2 or 3 times daily given during or after meals. After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability.

The maximum recommended dose of metformin hydrochloride is 3g daily, taken as 3 divided doses.

• If transfer from another oral antidiabetic agent is intended, discontinue the other agent and initiate metformin at the dose indicated above.

Combination with insulin

Metformin and insulin may be used in combination therapy to achieve better blood glucose control. Metformin hydrochloride is given at the usual starting dose of 500mg 2 or 3 times daily, while insulin dosage is adjusted on the basis of blood glucose measurements.

Elderly

Due to potential for decreased renal function in elderly subjects, the metformin dosage should be adjusted based on renal function.

Paediatric population:

Monotherapy and combination with insulin

• Metformin tablets can be used in children from 10 years of age and adolescents.

• The usual starting dose is one tablet of 500mg metformin hydrochloride once daily, given during or after meals.

After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability. The maximum recommended dose of metformin hydrochloride is 2g daily, taken as 2 or 3 divided doses.

4.3 Contraindications

Metformin is contraindicated in the following conditions, diabetic coma and ketoacidosis, impaired renal or hepatic functions, heart failure, alcoholism or other conditions likely to predispose to lactic acidosis.

4.4 Special warnings and precaution for use.

Lactic acidosis, a very rare but serious metabolic complication, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis.

In case of dehydration (severe diarrhoea or vomiting, fever or reduced fluid intake), metformin should be temporarily discontinued and contacting a healthcare professional is recommended.

Patients with heart failure are more at risk of hypoxia and renal insufficiency. In patients with stable chronic heart failure, metformin may be used with a regular monitoring of cardiac and renal function.

All patients should continue their diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet

4.5 Interaction with other medicinal product and other forms of interaction.

Concomitant use not recommended; Alcohol intoxication is associated with an increased risk of lactic acidosis, particularly in case of fasting, malnutrition or hepatic impairment.

Some medicinal products can adversely affect renal function which may increase the risk of lactic acidosis, e.g. NSAIDs, including selective cyclooxygenase (COX) II inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics, especially loop diuretics. When starting or using such products in combination with metformin, close monitoring of renal function is necessary.

Caution is therefore advised, especially in patients with renal impairment, when these drugs are co-administered with metformin, as metformin plasma concentration may increase. If needed, dose adjustment of metformin may be considered as OCT inhibitors/inducers may alter the efficacy of metformin.

4.6 Pregnancy and Lactation.

Pregnancy

Uncontrolled diabetes during pregnancy (gestational or permanent) is associated with increased risk of congenital abnormalities and perinatal mortality.

A limited amount of data from the use of metformin in pregnant women does not indicate an increased risk of congenital abnormalities.

When the patient plans to become pregnant and during pregnancy, it is recommended that diabetes is not treated with metformin but insulin be used to maintain blood glucose levels as close to normal as possible, to reduce the risk of foetal malformations of the foetus.

Lactation

Metformin is excreted into human breast milk. No adverse effects were observed in breastfed newborns/infants. However, as only limited data are available, breast-feeding is not recommended during metformin treatment. A decision on whether to discontinue breast-feeding should be made, taking into account the benefit of breast-feeding and the potential risk to adverse effects on the child.

4.7 Effect on the ability to drive and use machine.

Metformin monotherapy does not cause hypoglycaemia and therefore has no effect on the ability to drive or to use machines.

However, patients should be alerted to the risk of hypoglycaemia when metformin is used in combination with other antidiabetic agents.

4.8 Undesirable effect.

During treatment initiation, the most common adverse reactions are nausea, vomiting, diarrhoea, abdominal pain and loss of appetite which resolve spontaneously in most cases. To prevent them, it is recommended to take metformin in 2 or 3 daily doses and to increase slowly the doses.

4.9 Overdose.

Hypoglycaemia has not been seen with metformin hydrochloride doses of up to 85 g, although lactic acidosis has occurred in such circumstances. High overdose of metformin or concomitant risks may lead to lactic acidosis. Lactic acidosis is a medical emergency and must be treated in hospital. The most effective method to remove lactate and metformin is haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

Metformin is a biguanide with antihyperglycaemic effects, lowering both basal and post-prandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycaemia.

The use of metformin was associated with either a stable body weight or modest weight loss.

In humans, independently of its action on glycaemia, metformin has favourable effects on lipid metabolism. This has been shown at therapeutic doses in controlled, medium-term or long-term clinical studies: Metformin reduces total cholesterol, cholesterol and triglyceride levels

5.2 Pharmacokinetic properties.

Absorption

After an oral dose of metformin hydrochloride tablet, maximum plasma concentration is reached in 2.5 hours. Absolute bioavailability of a 500mg metformin hydrochloride tablet is approximately 50-60% in healthy subjects. After an oral dose, the non-absorbed fraction recovered in faeces was 20-30%.

After oral administration, metformin absorption is saturable and incomplete. It is assumed that the pharmacokinetics of metformin absorption is non-linear. At the recommended metformin doses and the dosing schedules, steady state plasma concentrations are reached within 24 to 48 hours and are generally less than 1μg/ml. In controlled clinical trials, maximum metformin plasma levels did not exceed 5μg/ml, even at maximum doses.

Metabolism

Metformin is excreted unchanged in the urine. No metabolites have been identified in humans

5.3 Preclinical safety data.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch

Purified Talcum

Magnesium Stearate

Aerosil

Gelatine

Methyl Paraben

Propyl Paraben

6.2 Incompatibilities

Unknown

6.3 Shelf-life

24 Months

6.4 Special precautions for storage

Protect from light and store in a cool dry place below 30^0C

Dosage: as prescribed by the Physician

6.5 Nature and composition of immediate packaging

Blister with Transparent PVC/Aluminium foil. Packs of 10 x 10 tablets in a carton

7. MARKETING AUTHORISATION HOLDER

SAM PHARMACEUTICALS LIMITED.
2, WESTERN RESERVOIR ROAD,
ILORIN,
KWARA STATE, NIGERIA.
08057075266
sampharmaceuticalltd@gmail.com

8. MARKETING AUTHORISATION NUMBER(S)

04 - 7968.

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 27th April 2021

10. DATE OF REVISION OF THE TEXT

17th August 2025