SUMMARY OFPRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Afrab Metformin Tablet

2 QUALITATIVEAND QUANTITATIVECOMPOSITION

Each tablet contains 500mg of Metformin Hydrochloride

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Tablet
A white round tablet with AFRAB inscription on one side and a line on the other side.

4 CLINICALPARTICULARS

4.1 Therapeutic indications

Afrab Metformin tablet is indicated in the treatment of non-insulin-dependent diabetes mellitus.

4.2 Posology and method of administration

It is important that Metformin Hcl Tablets be taken in divided doses with meals. Initially, one 850 mg tablet twice a day or one 500 mg tablet three times a day, with or after food. Good diabetic control may be achieved within a few days, but it is not usual for the full effect to be delayed for up to two weeks. If control is incomplete a cautious increase in dosage to a maximum of 3 g daily is justified. Once control has been obtained it may be possible to reduce the dosage of Metformin Hcl Tablets. Children: Metformin Hcl Tablets is not recommended for use. Elderly: Metformin Hcl Tablets is indicated in the elderly, but not when renal function is impaired. Combination therapy - see “Special Precautions” Gastro-intestinal adverse effects with anorexia, nausea and vomiting. Metallic taste. Lactic acidosis has been associated with Metformin Hcl but, has occurred to a greater extent in patients with contraindications to therapy. In patients with a metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonaemia) lactic acidosis should be suspected and Metformin Hcl Tablets therapy stopped. Lactic acidosis is a medical emergency which must be treated in hospital. Metformin Hcl is excreted by the kidney and regular monitoring of renal function is advised in all diabetics. Metformin Hcl therapy should be stopped 2-3 days before surgery and clinical investigations such as intravenous urography and intravenous angiography and reinstated only after control of renal function has been regained. The use of Metformin Hcl is not advised in conditions which may cause dehydration or in patients suffering from serious infections, trauma or on low calorie

intake. Patients receiving continuous Metformin Hcl therapy should have an annual estimation of Vitamin B12 levels because of reports of decreased Vitamin B12 absorption. During concomitant therapy with a sulphonylurea, blood glucose should be monitored because combined therapy may cause hypoglycaemia. Stabilisation of diabetic patients with Metformin Hcl and insulin should be carried out in hospital because of the possibility of hypoglycaemia until the correct ratio of the two drugs has been obtained. Reduced renal clearance of Metformin Hcl has been reported during cimetidine therapy, so a dose reduction should be considered. An interaction between Metformin Hcl and anticoagulants is a possibility and dosage of the latter may need adjustment. Contra-indications should be carefully observed.

4.3 Contra-indications

Sensitivity to Metformin hydrochloride. Diabetic coma and ketoacidosis, impairment of renal function, chronic liver disease, cardiac failure and recent myocardial infarction. History of, or states associated with, lactic acidosis such as shock or pulmonary insufficiency, alcoholism (acute or chronic), and conditions associated with hypoxemia. Pancreatitis. The use of Metformin Hcl Tablets during pregnancy is not advised. There is no information available concerning the safety of Metformin Hcl Tablets during lactation.

4.4 Special warnings and precautions for use

Sensitivity to metformin hydrochloride. Diabetic coma and ketoacidosis, impairment of renal function, chronic liver disease, cardiac failure and recent myocardial infarction. History of, or states associated with, lactic acidosis such as shock or pulmonary insufficiency, alcoholism (acute or chronic), and conditions associated with hypoxemia. Pancreatitis. The use of Metformin Hcl Tablets during pregnancy is not advised. There is no information available concerning the safety of Metformin Hcl Tablets during lactation.

4.5 Interaction with other medicinal products and other forms of interaction

Sensitivity to Metformin hydrochloride. Diabetic coma and ketoacidosis, impairment of renal function, chronic liver disease, cardiac failure and recent myocardial infarction. History of, or states associated with, lactic acidosis such as shock or pulmonary insufficiency, alcoholism (acute or chronic), and conditions associated with hypoxemia. Pancreatitis.

4.6 Pregnancy and lactation

The use of Metformin Hcl Tablets during pregnancy is not advised. There is no information available concerning the safety of Metformin Hcl Tablets during lactation.

4.7 Effects on ability to drive and use machines

Not available

4.8 Undesirable effects

Gastro-intestinal adverse effects with anorexia, nausea and vomiting. Metallic taste. Lactic acidosis has been associated with Metformin Hcl but, has occurred to a greater extent in patients with contraindications to therapy. In patients with a metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonaemia) lactic acidosis should be suspected and Metformin Hcl Tablets therapy stopped. Lactic acidosis is a medical emergency which must be treated in hospital. Metformin Hcl is excreted by the kidney and regular monitoring of renal function is advised in all diabetics. Metformin Hcl therapy should be stopped 2-3 days before surgery and clinical investigations such as intravenous urography and intravenous angiography and reinstated only after control of renal function has been regained. The use of Metformin Hcl is not advised in conditions which may cause dehydration or in patients suffering from serious infections, trauma or on low calorie intake. Patients receiving continuous Metformin Hcl therapy should have an annual estimation of Vitamin B12 levels because of reports of decreased Vitamin B12 absorption. During concomitant therapy with a sulphonylurea, blood glucose should be monitored because combined therapy may cause hypoglycaemia. Stabilisation of diabetic patients with Metformin Hcl and insulin should be carried out in hospital because of the possibility of hypoglycaemia until the correct ratio of the two drugs has been obtained. Reduced renal clearance of Metformin Hcl has been reported during cimetidine therapy, so a dose reduction should be considered. An interaction between Metformin Hcl and anticoagulants is a possibility and dosage of the latter may need adjustment. Contra-indications should be carefully observed.

4.9 Overdose

Hypoglycaemia can occur when Metformin Hcl is given concomitantly with a sulphonylurea, insulin or alcohol. In excessive dosage, and particularly if there is a possibility of accumulation, lactic acidosis may develop. Intense symptomatic and supportive therapy is recommended which should be particularly directed at correcting fluid loss and metabolic disturbance.

5 PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamic Properties

Insulin is an important hormone that regulates blood glucose levels. Type II diabetes is characterized by a decrease in sensitivity to insulin, resulting in eventual elevations in blood glucose when the pancreas can no longer compensate. In patients diagnosed with type 2 diabetes, insulin no longer exerts adequate effects on tissues and cells (called insulin resistance) and insulin deficiency may also be present.

Metformin reduces liver (hepatic) production of glucose, decreases the intestinal absorption of glucose, and enhances insulin sensitivity by increasing both peripheral glucose uptake and utilization. In contrast with drugs of the sulfonylurea class, which lead to hyperinsulinemia, the secretion of insulin is unchanged with Metformin use.

5.2 Pharmacokinetic Properties

Metformin Hcl is a biguanide oral anti-hyperglycaemic agent. Its mode of action is thought to be multifactorial and includes delayed uptake of glucose from the gastrointestinal tract, increased peripheral glucose utilisation mediated by increased insulin sensitivity, and inhibition of increased hepatic and renal gluconeogenesis. No hypoglycaemia occurs when Metformin Hcl is used alone but can occur when given concomitantly with a sulphonylurea, insulin or alcohol.

5.3 Preclinical safety data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Avicel (Microcrystalline cellulose), Corn starch, Aerosil, Magnesium stearate, Povidon PVP-30, Pregel starch, Sodium starch glycollate and Talcum powder.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3years.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

PVC/ PVDC with Aluminium blisters contains 10 x 10 Tablets packed in a printed cardboard case with a folded package insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Afrab Chem Limited

22 Abimbola Street,Isolo Ind.Estate,Isolo-Lagos