ORBIZIDE M FORTE®
GLICLAZIDE & METFORMIN HYDROCHLORIDE TABLETS

Orbizide M Forte® is a combination of Gliclazide, an oral hypoglycemic agent belonging to the sulfonylurea group which act mainly by increasing insulin secretion and Metformin, a biguanide that acts mainly by decreasing insulin resistance.

COMPOSITION

Each Orbizide M Forte® Tablet contains:
Gliclazide BP 80mg
Metformin HCL BP 500mg
Also contains Maize Starch, Microcrystalline Cellulose, Povidone K-30, Magnesium Stearate, Croscarmellose Sodium, Colloidal Anhydrous Silica as excipients.

INDICATIONS

Orbizide-M Forte® is indicated for the treatment of type-2 diabetes mellitus in association with dietary measures and with physical exercise, when these measures alone are not sufficient to normalize the blood glucose levels.

DOSAGE & ADMINISTRATION

The initial dose of Orbizide M Forte® is one tablet daily, after breakfast. In case the desired response is not obtained, the dose may be increased to 1 tablet twice daily. The maximum dose of Orbizide M Forte® is 6 tablets per day in divided doses.

CONTRAINDICATIONS

Orbizide M Forte® is contraindicated in the following situations:

- **Type-1 diabetes mellitus**
- **Hypersensitivity to sulfonylureas and Metformin**
- **Renal disease or renal dysfunction e.g. as suggested by serum creatinine levels ≥1.5 mg/dL in males or ≥ 1.4 mg/dL in females or abnormal creatinine clearance which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia.**
- **Severe hepatic failure**
- **Congestive heart failure requiring pharmacologic treatment**
- **Pregnancy and lactation**
- **Patients with ketoacidosis**
- **Patients undergoing surgery, after severe trauma or during severe infections**
- **Orbizide M Forte® should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function.**

WARNINGS & PRECAUTIONS

As Orbizide M Forte® contains Gliclazide, it can cause episodes of hypoglycemia. Hypoglycemia may present with sweating, intense hunger, trembling, pallor, visual disturbances, feeling of malaise and abnormal behaviour. If untreated it can lead to drowsiness, convulsions or coma. Hypoglycemic coma can be fatal. Hence all patients given Orbizide M Forte® must be taught to recognise the symptoms of hypoglycemia and if it occurs, be told to take either sugar or sugar containing food immediately and inform the doctor. Hypoglycemia can occur because of irregular meal times, missed meals, changes in diet, prolonged or stenous exercise, by intake of alcohol or other hypoglycemic drugs. The patient should be told to avoid these situations which are likely to cause hypoglycemia. The patient should be warned about the dangers of hypoglycemia while driving or operating machinery. Patients who develop frequent episodes of hypoglycemia should not drive or operate machinery.

Lactic acidosis is a rare, but serious, metabolic complication that can occur due to Metformin accumulation during treatment with Orbizide M Forte®; when it occurs, it is fatal in approximately 50% of cases. Lactic acidosis is characterized by elevated blood lactate levels (>5 mmol/L), decreased blood pH, electrolyte disturbances with an increased anion gap, and an increased lactate/pyruvate ratio. The reported incidence of lactic acidosis in patients receiving Metformin is very low (approximately 0.03 cases/1000 patients years). Reported cases have occurred primarily in diabetic patients with significant renal insufficiency, including both intrinsic renal disease and renal hypoperfusion, often in the setting of multiple concomitant medical/surgical problems and multiple concomitant medications. Patients with congestive heart failure requiring pharmacologic management, in particular those with unstable or acute congestive heart failure who are at risk of hypoperfusion and hypoxemia are at increased risk of lactic acidosis. The risk of lactic acidosis increases with the degree of renal dysfunction and the patients age. The risk of lactic acidosis may, therefore, be significantly decreased by regular monitoring of renal function in patients taking Orbizide M Forte®. Because impaired hepatic function may significantly limit the ability to clear lactate, Orbizide M Forte® should generally be avoided in patients with clinical or laboratory evidence of hepatic disease. Patients should be cautioned against excessive alcohol intake, either acute or chronic, when taking Orbizide M Forte®, since alcohol potentiates the effects of Metformin on lactate metabolism. In addition, Orbizide M Forte® should be temporarily discontinued prior to any intramuscular radiocontrast study and for any surgical procedure. Cardiovascular collapse (shock) from whatever cause, acute congestive heart failure, acute myocardial infarction and other conditions characterized by hypoxemia have been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur in patients on Orbizide M Forte® therapy, the drug should be

promptly discontinued. Lactic acidosis is a medical emergency that must be treated in a hospital setting. In a patient with lactic acidosis who is taking Orbizide M Forte®, the drug should be discontinued immediately and general supportive measures promptly instituted. Because hydrochloride is dialyzable, prompt hemodialysis is recommended to correct the acidosis and remove the accumulated Metformin. Such management often results in prompt reversal of symptoms and recovery.

DRUG INTERACTIONS

An increased hypoglycemic effect can occur on co-administration of Orbizide M Forte®, with the following drugs: Salicylates, Sulfonamides, Alcohol, Betablockers, Azole antifungals like Fluconazole, Ketoconazole and Miconazole, ACE inhibitors, Tricyclic anti-depressants, Chloramphenicol, Tetracyclines, Thyroid hormones, Cimetidine, Ranitidine, Clofibrate, Allopurinol and oral anti coagulants. Care should be taken when Gliclazide is administered with these drugs.
Alcohol may also increase the risk of lactic acidosis. Care should be taken if Orbizide M Forte® is given concomitantly with drugs that may impair renal function.
A diminished hypoglycemic effect, possibly requiring an increase in Orbizide M Forte® dose may occur with drugs like Danazol, Chlorpromazine, Glucocorticoids, Oral Contraceptives, Rifamycins, Thiazide diuretics and Epinephrine.

USE IN SPECIAL POPULATION

Pregnancy: Orbizide M Forte® is contraindicated in pregnancy.
Nursing Mothers: Orbizide M Forte® is contraindicated in a mother who is breast feeding her baby.
Pediatric Use: As most patients in paediatric segment with diabetes mellitus have type-1 diabetes, Orbizide M Forte® is not indicated in such patients.
Geriatric Use: As elderly individuals are prone to some degree of renal failure, Orbizide M Forte® shoud be used with caution.
Use in Hepatic & Renal Impairment: Orbizide M Forte® should be used with caution in patients with mild to moderate hepatic or/and should be avoided in patients with severe hepatic. Orbizide M Forte® should be avoided in patients with renal impairment.

ADVERSE REACTIONS

The following adverse reactions may occur with Orbizide M Forte® :
Hypoglycemia, gastrointestinal disturbances like nausea, vomiting, anorexia, diarrhoea and a metallic taste, dermatological side effects like skin rashes, pruritus and photosensitivity have been reported. Rarely hypersensitivity reactions like raised liver enzymes and cholestatic jaundice, leukopenia, thrombocytopenia, aplastic anaemia, erythema multiforme or exfoliative dermatitis may occur.
Lactic acidosis is a very rare but potentially fatal side effect of Orbizide M Forte® which usually occurs when the contraindications to the use of Metformin are not adhered to.

STORAGE INSTRUCTIONS

Store in a cool, dry place. Protect from light.

PACKING

Orbizide M Forte® tablet is packed in packs of 30 by PHARMADEX SAL, Kahaleh, Lebanon under licence from:

Orbucell Pharma

4380 Levesque Ouest
Laval QC H7W 5M8
Canada

THIS IS A MEDICAMENT	إن هذا الدواء
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. - The doctor and the pharmacist are the experts in medicines, their benefits and risks. - Do not by yourself interrupt the period of treatment prescribed. - Do not repeat the same prescription without consulting your doctor. - Keep all medicaments out of reach of children.	مستحضر يؤثر على صحتك واستهلاكه خلافا" للتعليمات يعرضك للخطر. اتبع بدقة وصفة الطبيب وطريقة الاستعمال المنصوص عليها وتعليمات الصيدلي الذي صرفها لك. - الطبيب والصيدلي هما الخبيران في الدواء وفي نفعه وضرره. - لا تقطع مدة العلاج المحددة لك من تلقاء نفسك. - لا تكرر صرف الدواء بدون استشارة الطبيب. - لا تترك الادوية في متناول الاطفال.