SUMMARY OF PRODUCT CHARACTERISITICS (SmPC)

(PRODUCT DATA SHEET)

1.0 Name of the medicinal product :

Brand name : ILET B1 & ILET B2.

Generic name : Glimepiride 1/2 mg and Metformin Hydrochloride 500 mg ER Tablets

Strength : 1+500 mg / 2+500 mg.

Dosage form : Bilayered uncoated tablets.

2.0 Qualitative & Quantitative composition :

Each bilayered uncoated tablets contains :

Metformin hydrochloride USP 500 mg

Glimepiride USP 1 / 2 mg

Excipients- refer section 6.1

3.0 Pharmaceutical form :

Glimepiride 1 mg and Metformin Hydrochloride 500 mg ER Tablets:

Caplet shaped, bi layered smooth surface, one layer with white colour and one layer with yellow colour uncoated tablets.

Glimepiride 2 mg and Metformin Hydrochloride 500 mg ER Tablets:

Caplet shaped, bi layered smooth surface, one layer with white colour and one layer with red colour uncoated tablets.

4. Clinical Application :

4.1 Therapeutic indications

For the management of patients with type 2 diabetes mellitus when diet, exercise and single agent (glimepiride or metformin alone) do not result in adequate glycemic control.

4.2 Posology and method of administration

In principle, the dosage of ILET B is governed by the desired blood glucose level. The dosage must be the lowest which is sufficient to achieve the desired metabolic control. During treatment with ILET B, glucose levels in blood and urine must be measured regularly. In addition it is recommended that regular determinations of the proportion of glycated hemoglobin be carried out.Mistakes e.g. forgetting to take a dose, must never be corrected by subsequently taking a larger dose.

Initial dose: One ILET B 1mg tablet should be administered as once daily with meals for those patients who are not already receiving glimepiride.

Maximum Dosing: For once daily administration maximum 2 tablets of ILET B can be given. For higher doses it may be necessary to divide the administration into 2 doses. Upto 4 tablets of ILET B 1mg or 2 mg can be given per day. Do not crush or chew the tablet. The whole tablet must be taken with water. As an improvement in control of diabetes is in place, associated with higher insulin sensitivity, glimepiride requirements may fall as treatment proceeds. To avoid hypoglycemia timely dose reduction or cessation of ILET B therapy must therefore be considered. Correction of dosage must also be considered whenever,

-The patient's weight changes

-The patient's lifestyle changes

-Other factors arise which cause an increased susceptibility to hypoglycemia or hyperglycemia.

Pediatrics -Safety and effectiveness of ILET B in pediatric patients has not been established.

Specific Patient Populations

ILET B is not recommended for use in pregnancy. The initial and maintenance dosing of ILET B should be conservative in patients with advanced age, due to the potential for decreased renal function in this population. There is limited information available on the use of glimepiride in renal insufficiency. Patients with impaired renal function may be more sensitive to the glucose lowering effect of ILET B. Any dosageadjustment should be based on a careful of renal function. Generally, elderly, debilitated, and malnourished patients should not be titrated to the maximum dose of ILET B.

4.3 Contraindications

ILET B must not be used:

In patients with known hypersensitivity to metformin, glimepiride, other sulfonylureas or sulfonamides

In patients with insulin-dependent (type 1) diabetes mellitus

In acute or chronic acidosis, including diabetic ketoacidosis with or without coma

In treatment of diabetic precoma or coma

In patients with serious renal dysfunction. (as suggested by serum creatinine “levels >1.5mgldL” (males),“levels>1.4mgldL” (femalesl or abnormal creatinine clearance), which may result from conditions such as cardiovascular collapse (shock), acute myocardial infarction and septicemia.

- In patients with serious hepatic dysfunction

-In pregnant women

-In breast feeding women

- In congestive heart failure requiring pharmacological treatment
- In paediatrics since the safety and effectiveness in paediatric patients have not been established ILET B should be temporarily discontinued in patients undergoing radiological studies involving intravascular administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function.

4.4 Special warnings and precautions for use

Warnings

Periodic fasting blood glucose and glycosylated hemoglobin measurements must be performed to monitor therapeutic response to ILET B. Before initiation of ILET B, and at least annually thereafter, renaliuoction should be also assessed and verified as normal. In those in whom development of renal renal function is anticipated, renal function should be assessed more frequently and ILET B should be discontinued if evidence of renal impairment is present.

In exceptional stress situations (e.g. trauma, surgery,febrile infections), blood glucose regulation may deteriorate, and atemporary change to insulin may be necessary to maintain good metabolic control.

Persons allergic (to other sulfonamide derivatives may develop an allergic reaction to glimepiride as well.

If any previously well-controlled patient develops laboratory abnormalities or clinical illness (especially vague and poorly defined) while on ILET B therapy, prompt evaluation for ketoacidosis or lactIc acidosis must be carried out. If acidosis of either form occurs, ILET B must be immediately discontinued and appropriate corrective measures undertaken.

ILET B must also be temporarily withdrawn when radiologic (studies with contrast materials, or any surgical procedures are planned and done. Excessive alcohol intake, acute or chronic, is not recommended with ILET B. Those with inadequate vitamin B12 or calcium intake / absorption, may develop subclinical vitamin B12 levels whilst on metformin (in ILET B) therapy.

Precautions:

Impaired hepatic function: ILET B must be preferably avoided in those with any evidence of hepatic disease.

Monitoring of repal function: Metformin is known to be substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive ILET B. In patients with advanced age, ILET B should be carefully titrated to establish the minimum dose for adequate glycemic effect, because aging is associated with

reduced renal function. Before initiation of ILET B therapy and every 6 months while on ILET B therapy, renal function should be assessed and verified as being within normal range. In patients in whom development of renal dysfunction is anticipated, renal function should be assessed more frequently and ILET B discontinued if evidence of renal impairment is present.Concomitant medication(s) that may affect renal function or result in significant hemodynamic change or may interfere with dispositions of ILET B such as cationic drugs that are eliminated by renal tubular secretion should be used with caution.

Hypoxic states: 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 event occurs in patients on ILET B therapy, the drug should be promptly discontinued.

Surgical procedures: ILET B therapy should be temporarily suspended for any surgical procedure (except minor procedures not associaied with restricted intake of food and fluids). ILET B should be discontinued 2 days before surgical intervention and should not be restarted until the patient's oral intake has resumed and renal function has been evaluated as normal.

Alcohol intake: Alcohol is known to potentiate the effect of metformin on lactate metabolism. Patients, therefore, should be warned against excessive alcohol intake, acute or chronic,while receiving ILET B.

Vitamin B12 levels:Impairment of Vitamin B12 and folic acid absorption has been reported in some patients. Therefore, measurements of serum Vitamin B12 and folic acid are advisable everyone to two years in patients on long-term treatment with ILET B.

Hypoglycemia: In the initial weeks of treatment, the risk of hypoglycemia may be increased and necessitates careful monitoring. Hypoglycemia could also occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, or during concomitent use with other glucose lowering agents or ethanol. Elderty, debilitated or malnourished patients, and those with adrenal or Pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemia effects. Hypoglycemia may be difficult to recognize in the elderly, and in people who are taking beta-adrenergic blocking drugs. Hypoglycemia can almost always be promptly controlled by immediate intake of carbohydrates (glucose or sugar). It is known from other sulfonylureas that, despite initially successful countermeasures, hypoglycemia may recur. Patients must, therefore remain under close observation. Severe hypoglycemia further requires immediate treatment and follow up by a physician and in some circumstances in-patient hospital care.

Loss of control of blood glucose: When a patient stabilized on any diabetic regimen is exposed to stress such as fever, trauma, infection, or surgery, a temporary loss of glycemic control may occur.

At such times, it may be necessary to withhold ILET B and temporarily administer insulin. ILET B may be reinstituted after the acute episode is resolved. The effectiveness of oral antidiatietic drugs in lowering blood glucose to a targeted level decreases in many patients over a period of time. This phenomenon, which may be due to progression of the underlying disease or to diminished responsiveness to the drug, is known as secondary failure, to distinguish it from primary failure in which the drug is ineffective during initial therapy.

Laboratory tests: Response to all diabetic therapies should be monitored by periodic measurements of fasting blood glucose and glycosylated hemoglobin levels, with a goal of decreasing these levels toward the normal range. During initial dose titration, fasting blood glucose can be used to determine the therapeutic response. Therefore both glucose and glycosylated hemoglobin should be monitored. Measurements of glycosylated hemoglobin may be especially useful for evaluating long-term control. Initial and periodic monitoring of hematologic parameters (e.g, hemoglobin/ hematocrit and red blood cell indices) and renal function (serum creatinine) should be performed, at least on an annual basis.

Lactic acidosis: It is a rare but serious metabolic complication that can occur due to metformin accumulation during treatment with ILET B. When it occurs; it is fatal in approximately 50% of cases.In particular, treatment of the elderly should be accompanied by careful monitoring of renal function; ILET B treatment should not be initiated in patients >80 years age, unless measurement of creatinine clearance demonstrates that renal function is not reduced, as the patients are more susceptible to developing lactic acidosis. The risk of lactic acidosis increases with the degree of renal dysfunction and the patient's age. 'In addition, ILET B should be promptly withheld in the presence of any condition associated with hypoxemia,dehydration or sepsis. Lactic acidosis is a medical emergency that must be treated in the hospital setting. In a patient with 'lactic acidosis who is taking ILET B, the drug should be discontinued immediately and general supportive measures promptly instituted. Because metformin HCI is dialyzable (with clearance of upto 170 ml/min under good hemodynamic conditions),prompt hemodialysis is recommended to correct the acidosis and remove the accumulated metformin. Such management often results in prompt reversal of symptoms and recovery. If acidosis of any kind develops, ILET B should be discontinued immediately.

4.5 Interaction with other medicinal products and other forms of interaction

Glimepiride

Glimepiride is metlibolized by cytochrome P450 2C9 (CYP2C9).This should be taken into account when glimepiride is co-administered with inducers (e,g. Rifampicin) or inhibitors (e.g.fluconazole) of CYP2C9. Potentiation of the blood glucose lowering effect and, thus, in some instances

hypoglycemia may occur when one of the following drugs is taken,for example: insilin and other,oral antidiabetics: ACE inhibitors anabolic steroids and male sex hormones : chloramphenical : coumarindisopyramide, fenfluramine, fenyramidol, fibrates, fluoxetine, guanethidine, ifosfamide, MAO inhibitores, miconazole, fluconazole , para aminosalicylic acid, pentoxifyline (high dose parenteral phenylbutazone, probenecid;quinolones;oxyphenbutazone, salicylates,sulfinpyrazone,sulfonamide antibiotics, tetracyclines, tritoqualine, trofosfamide.Weaking of the blood-glucose-lowering effect and thus raised blood glucose levels may occur when one of the following drugs is taken for example acetazolamide, barbiturates. corticosteroids, diazoxide, diuretics,calcium channel blocking drugs,epinephrine,(adrenaline)and other sympathomimetic agents, glucagon, laxatives(after protracted use) nicotinic acid (in high doses) oestrogens and progestogens, phenothiazines, phenytoin,rifampicin,thyroid hormones.H2 receptors antagonist; beta-blockers, clonidine; and reserpine may lead to either potentiation or weakening of the blood-glucose- lowering effect.Under the influence of sympatholytic drugs such as beta – blockers,clonidine,guanethidine and reserpine,the signs of adrenergic counter-regulation to hupoglycemia may be reduced or absent.Both acute and chronic alcohol intake may potentiate or weaken the blood glucose; lowering action of glimepiride in,an unpredictable fashion. The effect of coumarin derivatives may be potentiated or weakened.

Metformin

Furosernide: It is reported in a metformin-furosemide drug interaction study in healthy subjects that pharmacokinetic parameters of both compounds were affected by co-administration. No information is available about the interaction of metformin and furosemide when co-administered chronically.

Nifedipine:Nifedipine appears to enhance the absorption of metformin. Metformin had minimal effects on nifedipine.

Cationic drugs: Cationic drugs (e.g. amiloride, digoxin, morphine, procainamide quinidine,ranitidine, triamterene trimethoprim, and vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems,Therefore,careful patient monitoring and dose adjustment of metformin or the interfering drug is recommended in patients who are taking cationic medications that are excreted via renal tubular secretion.

Other: Other drugs tend to produce hyperglycemia and may lead to a loss of blood sugar control. These include thiazide and other diuretics,corticosteroids, Phenothiazines,thyroid products, estrogens,estrogen plus progestogen, oral,contraceptives,phenytoin, nicotinic acid, sympathomimetics,calcium channelblocking drugs,and isoniazid. When such drugs are

administered to patients receiving metformin, the patient should be closely observed to maintain adequate glycemic control. When such drugs are withdrawn from a patient receiving metformin, the patient should be observed closely for hypoglycemia.

In Healthy volunteers, the pharmacokinetics of propranolol and ibuprofen were not affected by metformin when co-administered in single-dose interaction studies. Metformin is negligibly bound to plasma proteins and is, therefore, less likely to interact with highly protein bound drugs such as salicylates, sulfonamides, chloramphenicol and probenecid, as compared to sulfonylureas, which are extensively bound to serum proteins.

4.6 Pregnancy and lactation

Pregnancy

ILET B must not be taken during pregnancy. The patient must change over to insulin during pregnancy. Patients planning a pregnancy must inform their physician. It is recommended that such patients change over to insulin.

Lactation

To prevent possible ingestion with breast milk, ILET B must not be taken by breast-feeding women. If necessary the patient must change over to insulin or must stop breast-feeding.

4.7 Effects on ability to drive and use machines

Alertness and reactions may be impaired by hypo-glycemic episodes; especially when beginning or after altering treatment or when ILET B is not taken regularly. This may for example,affect the ability to drive or operate machinery.

4.8 Undesirable effects

Glimepiride

Hypoglycemia As a result of the blood glucose lowering action of ILET B, hypoglycemia may occur. Possible symptoms of hypoglycemia include headacne, ravenous hunger, nausea, vomiting, lassitude, sleepiness, disordered sleep, restlessness, aggressiveness, impaired concentration, impaired alertness and reactions, depression, confusion, speech disorders, aphasia, visual disorders, tremor; pareses, sensory disturbances, dizziness, helplessness, loss of self-control, delirium, cerebral convulsions, somnolence and loss of consciousness upto and including coma, shallow respiration and, bradycardia. ln addition, signs of adrenergic counter-regulation may be present such as sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris and cardiac arrhythmias. The clinical picture of a severe hypoglycemic attack may resemble that of a stroke. The symptoms nearly always subside when hypoglycemia is corrected.

Eyes

Especially at the start of treatment, there may be temporary visual impairment due to the change in blood glucose levels. The cause is a temporary alteration in the turgidity and hence the refractive index of the lens, this being dependent on blood glucose level.

Digestive tract : Occasionally, gastrointestinal symptoms such as nausea, vomiting; sensations of pressure or fullness in the epigastrium, abdominal pain and diarrhea may occur. In rare cases there may also be elevation of liver. enzyme levels. Sulfonylureas, including glimepiride may also -in isolated instances -cause impairment of liver function (e.g. with cholestasis and jaundice) as well as and hepatitis which may also lead to liver failure.

Blood: Changes in the blood picture may occur: Rarely, thrombopenia and in isolated cases, leucopenia, hemolytic anemia, erythrocytopenia, granulocytopenia, agranulocytosis,or pancytopenia may develop.

Other adverse effects: Occasionally allergic or pseudo allergic reactions may occur e.g.in the form of itching urticaria or rashes. Such mild reactions may develop into serious reactions with dyspnoea and a fall in blood pressure, some times progressing to shock. In the event of urticaria a physician must therefore be notified immediately. In isolated cases, a decrease in serum sodium concentration and allergic vasculitis or hypersensitivity of the skin to light may occur.

Metformin: ILET B incorporates controlled release metformin and hence the incidence of gastrointestinal intolerance due to metfofmin is much less as compared to plain metformin. Most commonly reported adverse events include diarrhea, nausea and vomiting. Additionally the following adverse reactions have been more commonly reported in >1.0% - < 5% of patients: Abdominal pain, constipation, distension of abdomen, dyspepsia/heartburn, flatulence, dizziness, headache, upper respiratory infection, taste disturbances.

4.9 Overdose

Metformin Hydrochloride

Hypoglycaemia has not been seen with metformin doses of up to 85g, although lactic acidosis has occured in such circumstances. High overdose or concomitant risks of metformin 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.

Glimepiride

Symptoms

After ingestion of an overdose hypoglycaemia may occur, lasting from 12 to 75 hours, and may recur after an intial recovery. Symptoms may not be present for up to 24 hours after ingestion. In general observation in hosptial is recommended. Nausea, vomitting and epigastric pain may occur. The hypoglycaemia may in general be accompained by neurological symptoms like restlessness, tremor, visual disturbances, coordination problems, sleepiness, coma and convulsions.

Management

Treatment primarily consists of preventing absorption by inducing vomiting and then drinking water or lemonade with activated charcoal (adsorbent) and sodium sulphate (laxative).If large quantities have been ingested,gastric lavage is indicated, followed by activated charcoal and sodium sulphate. In case of (severe) overdose hospitalisation in an intensive care department is indicated. Start the administration of glucose as soon as possible,if necessary by a bolus intravenous injection of 50 ml of a 50% solution, followed by an infusion of a 10% solution with strict monitoring of blood glucose. Further treatment should be symptomatic. In particular when treating hypoglycaemia due to accidental intake of Amaryl in infants and young children, the dose of glucose given must be carefully controlled to avoid the possibility of producing dangerous hyerglycaemia. Blood glucose should be closely monitored.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group with ATC Code:

Glimepiride:

A Alimentary track and metabolism

A10 Drugs used in Diabetes

A10B Blood glucose lowering drugs, excel insulins

A10BB Sulfonamides, urea derivatives

A10BB12 Glimepiride

Metformin :

A Alimentary track and metabolism

A10 Drugs uses in Diabetes

A10B Blood glucose lowering drugs, excel insulins

A10BA Biguanides

A10BA02 Metformin

Sulfonylureas and biguanides act complementary to each other. Both compounds have an additiveantihyperglycaemic effect without increasing the adverse effects of either pharmacological class.Glimepiride acts via stimulating beta cells of pancreas to release insulin and also increases peripheralsensitivity of insulin. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

5.2 Pharmacokinetic properties

GlimepirideThe bioavailability of glimepiride after oral administration is complete. Food intake has no relevant influence on absorption, only absorption rate is slightly diminished. Maximum serum concentrations (C) are reached approx. 2.5 maxhours after oral intake (mean 0.3 µg/ml during multiple dosing of 4 mg daily) and there is a linear relationship between dose and both C and AUC (area under the time/concentration curve). maxGlimepiride has a very low distribution volume (approx. 8.8 litres) which is roughly equal to the albumin distribution space, high protein binding (>99%), and a low clearance (approx. 48 ml/min). In animals, glimepiride is excreted in milk. Glimepiride is transferred to the placenta. Passage of the blood brain barrier is low.

Mean dominant serum half-life, which is of relevance for the serum concentrations under multiple-dose conditions, is about 5 to 8 hours.

After high doses, slightly longer half-lives were noted.After a single dose of radiolabelled glimepiride, 58% of the radioactivity was recovered in the urine, and 35% in the faeces. No unchanged substance was detected in the urine. Two metabolites most probably resulting from hepatic metabolism (major enzyme is CYP2C9) - were identified both in urine and faeces: the hydroxy derivative and the carboxy derivative. After oral administration of glimepiride, the terminal half-lives of these metabolites were 3 to 6 and 5 to 6 hours respectively.

Comparison of single and multiple once-daily dosing revealed no significant differences in pharmacokinetics, and the intraindividual variability was very low. There was no relevant accumulation. Pharmacokinetics were similar in males and females, as well as in young and elderly (above 65 years) patients. In patients with low creatinine clearance, there was a tendency for glimepiride clearance to increase and for average serum concentrations to decrease, most probably resulting from a more rapid elimination because of lower protein binding. Renal elimination of the two metabolites was impaired. Overall no additional risk of accumulation is to be assumed in such patients. Pharmacokinetics in five non-diabetic patients after bile duct surgery were similar to those in healthypersons.

A fed study investigating the pharmacokinetics, safety, and tolerability of a 1 mg single dose of glimepiride in 30 paediatric patients (4 children aged 10-12 years and 26 children aged 12-17 years) with type 2 diabetes showed mean AUC0-∞ , Cmax and t1/2 similar to that previously observed in adults.

Metformin

After an oral dose of metformin hydrochloride tablet, maximum plasma concentration (C_{max}) is reached maxinapproximately 2.5 hours (t_{max}). Absolute bioavailability of a 500 mg or 850 mg metforminmaxhydrochloride 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 dosing schedules, steady state plasma concentrations are reached within 24 to 48 hours and are generally less than 1 microgram/ml. In controlled clinical trials, maximum metformin plasma levels (C_{max}) did not exceed 5 microgram/ml, even at maximum doses. maxFood decreases the extent and slightly delays the absorption of metformin. Following oral administrationof a 850 mg tablet, a 40% lower plasma peak concentration, a 25% decrease in AUC (area under thecurve) and a 35 minute prolongation of the time to peak plasma concentration were observed. The clinicalrelevance of these findings is unknown. Plasma protein binding is negligible. Metformin partitions into erythrocytes. The blood peak is lower than the plasma peak and appears at approximately the same time. The red blood cells most likely represent a secondary compartment of distribution. The mean volume of distribution (Vd) ranged between 63-276 l. Metformin is excreted unchanged in the urine. No metabolites have been identified in humans. Renal clearance of metformin is> 400 ml/min, indicating that metformin is eliminated by glomerular filtration and tubular secretion. Following an oral dose, the apparent terminal elimination half-life is approximately 6.5 hours. When renal function is impaired, renal clearance is decreased in proportion to that of creatinine and thus the elimination half-life is prolonged, leading to increased levels of metformin in plasma.

Single dose study: After single doses of metformin hydrochloride 500 mg paediatric patients have shown similar pharmacokinetic profile to that observed in healthy adults. Multiple dose study: Data are restricted to one study. After repeated doses of 500 mg twice daily for 7 days in paediatric patients the peak plasma concentration (Cmax) and systemic exposure (AUC0-t) were reduced by maxapproximately 33% and 40%, respect.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Metformin hydrochloride layer: Hydroxy propyl methyl cellulose, Sodium-CMC, Povidone K-30, Colloidal silicon dioxide, Magnesium stearate.

Glimepiride layer: Lactose monohydrate, Sodium starch glycolate, Colloidal silicon dioxide, Povidone K-30, Polysorbate 80, Microcrystalline cellulose PH 102, Magnesium stearate. Iron oxide Yellow (For ILET B1) and Iron oxide Red (For ILET B2) and Purified Water.

6.2 Incompatibilities: Not Applicable.

6.3 Shelf life : 2 years

6.4 Special precautions for storage

Do not store above 30°C, Protect from light and moisture. Keep out of reach of children

6.5 Nature and contents of container

10 tablets of ILET B1 & ILET B2 (Glimepiride 1/2 mg and Metformin Hydrochloride 500 mg ER Tablets) are sealed with PVC aluminium foil on one side and printed Aluminium foil on the other side in the form of a PVC-Alu Blister pack and such 3 PVC/PVdC-Alu Blister packs are further packed in a printed carton along with instruction for use.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder:

MSN Laboratories Private Limited,

MSN House, Plot No. : C-24, Industrial Estate,

Sanath Nagar, Hyderabad – 500 018, India.