CANDIVOR

(Voriconazole for Injection 200 mg/vial)

1.5. PRODUCT INFORMATION

1.5.1 PRESCRIBING INFORMATION

(SUMMARY OF PRODUCTS CHARACTERISTICS)

1. Name of the medicinal product

INN Name: Voriconazole for Injection 200 mg/vial

Trade Name: CANDIVOR

Strength: 200 mg/vial

Pharmaceutical form: Injection

2. Qualitative and quantitative composition

Each vial contains Voriconazole Ph. Eur. 200 mg.

3. Pharmaceutical form

Dosage form: Injection

Description: A white to off –white lyophilized cake filled in 30 mL clear, Type I molded glass and sealed with grey bromobutyl lyophilisation rubber stopper and white colored flip off seal.

When constituted as directed the solution should be clear and colorless solution.

4. Clinical particulars

4.1 Therapeutic indications

Voriconazole is indicated for use in treatment of the following conditions:

- Treatment of invasive Aspergillosis
- Treatment of fluconazole-resistant serious invasive candida infection (including *C.krusei*)
- *Esophageal candidiasis*.
- Serious fungal infection caused by *Scedosporium spp.* (A sexual form of Pseudallescheria body) and *Fusarium spp.*, including Fusarium solani in patients intolerant of or refractory to other therapy.

Specimens for fungal culture and other relevant laboratory studies (including histopathology) should be obtained prior to therapy to isolate and identify causative organism(s), therapy may be instituted before the result of the cultures and other laboratory studies are known however once these result become available, an liable therapy should be adjusted accordingly

6. Over Dose

In clinical trails there were three cases of accidental overdose all occurred in pediatric patients who received up to five times recommended intravenous dose the voriconazole. A single adverse event of photophobia of 10 minutes duration was reported.

There is no known antidote to voriconazole.

voriconazole is hemodialysed with clearance of 121 mL/Kg the intravenous vehicle HPBCD is hemodialysed with clearance of 55mL/ min in an overdose hemodialysis and HPBCD form the body.

Injection: voriconazole for injection requires reconstitution of 10mg/mL and subsequent dilution to 5mg/mL or less prior to administration as an infusion at a maximum rate of mg/kg per hour over 1-2 hours.

Not for IV bolus injection

Electrolyte disturbance such as hypokalemia, hypomagnesemia and hypocalcemia should be corrected prior to initiation of voriconazole therapy.

Invasive aspergillus and serious fungal infections due to *Fusarium spp.*, and *Scedosporium apiospermum.*

Dose for adults: Therapy must be initiated with specified loading dose regimen of intravenous voriconazole or oral to achieve to plasma concentrations on Day 1 that are close to steady state. On the basis of high oral bioavailability switching between intravenous and oral administration is appropriate when clinically indicated.

	Intravenous	**Oral**	
		Patients 40kg and above	Patients less than 40kg
Loading dose (first 24hrs)	6mg/kg every 12hrs (for the first 24hrs)	400mg every 12hrs (for the first 24hrs)	200mg every 12hrs (for the first 24hrs)
Maintenance dose	4mg/kg twice daily	200mg every 12hrs	100mg every 12hrs

(after first 24hrs)			

Dose adjustments: If patient response is inadequate the oral maintained dose may be increased the oral maintenance dose may be increased from 200 mg every hour to 300 mg every 12 hours. For adult patients weighing less than 40Kg. The oral maintenance dose may be increased form 100mgevery 12 hours to 150 mg every 12 hours.

If patients are unable to tolerate treatment, reduce the intravenous maintenance dose to 2mg/kg every 12 hours and the oral maintenance dose by 50 mg steps to a minimum of 200mg every 12hours (or to 100mg every 12 hours for adult patients weighing less than 40kg).

Phenytoin may be co-administered with voriconazole it the intravenous maintenance dose of voriconazole increased 5 mg/ kg every 12 hours or the oral maintenance dose is increased from 200mg to 400rng every 12 hours (100mg to 200mg every in adults patients weighting less then 40 kg).

Duration therapy should be based on the seventy patients underlying disease recovery from immunosuppression, and clinical response.

Esophageal candidiasis: The recommended dosing regimen is an Oral dose of 200mg every 12 hours for patient's who weights 40 kg or more. Adult patients who weight less than 40kg should receive an oral dose of 100mg every 12 hours. Patients should be treated for a minimum of 14 days and for at least 7 days following resolution of symptoms.

Elderly: No dose adjustment is necessary for elderly for patients.

Children: Safely and effectiveness is pediatric patients below the age of 2 years has not been established therefore voriconazole is not recommended for children less than 2 years of age. Limited data are currently available to determine the posology. However, the following regimen has been used in pediatric studies.

Children aged 2 to <12 years:

	Intravenous	**Oral**
Loading dose regimen (First 24 hours)	6mg/Kg every 12 hours (for the first 24 hours)	6mg/Kg every 12 hours (for the first 24hours)
Maintenance dose (after first 24 hours)	4m/kg twice daily	4m/kg twice daily

If a child is able to swallow tables the dose should be administered to the nearest mg/kg dose possible using whole 50mg tables.

The pharmacokinetics and tolerability of higher doses have not been characterized in pediatric populations.

Adolescents 12to 16 years age: should be given the same dose as adults.

Hepatic impairment: No dose adjustment is necessary in patients with acute hepatic injury manifested by elevated liver function tests (ALAT, ASAT) but continued monitoring of liver function tests for further elevations is recommended.

It is recommended that the slandered loading dose regimens used but that the maintenance dose be halved in patients with mild to moderate hepatic cirrhosis (Child-Pugh class A and B).

voriconazole has not been studied in patients with severe hepatic cirrhosis (Child-Pugh class C) or in patients with chronic hepatitis B or chronic hepatitis C disease. voriconazole has been associated with elevations in liver function tests and clinical signs of liver damage, such as jaundice, and should only be used in patients with severe hepatic insufficiency if the benefit outweighs the potential risk. Patients with hepatic insufficiency must be carefully monitored for drug toxicity.

Renal Impairment: The pharmacokinetics of orally administered voriconazole are not significantly affected by renal insufficiency. Therefore, no adjustment is necessary for oral dosing in patients with mild to severe renal impairment.

In patients with moderate or severe renal insufficiency (creatinine clearance <50 mL/min). Accumulation of the intravenous vehicle, HPBCD occurs. Oral voriconazole should be administered to these patients, unless an assessment of the benefit/risk to the patient justifies the use of intravenous voriconazole. Serum creatinine levels should be closely monitored in these patients and if increases occur, consideration should be given to changing to oral voriconazole therapy.

voriconazole is hemodialyzed with clearance of 121 mL/min. The intravenous vehicle, HPBCD is hemodialyzed with clearance of 55 mL/min A 4 hour hemodialysis session does not remove a sufficient amount of voriconazole to warrant dose adjustment.

Intravenous administration

Reconstitution: The powder is reconstituted with 19 mL of Water for Injection to obtain an extractable volume of 20 mL of clear concentrate containing 10 mg/mL of voriconazole. It is recommended that a standard 20 mL (none automated) syringe be used to ensure that the exact amount (19.0 mL) of water for injection is dispensed, Discard the vial if a vacuum does not pull the diluent into the vial. Shake the vial until all the powder is dissolved.

Dilution: voriconazole must be infused over 1-2 hours, at a concentration of 5 mg/mL or less. Therefore, the required volume of the 10 mg/mL voriconazole concentrate should be further diluted as follows:

1) Calculate the volume of 10mg/mL voriconazole concentrate required based on the patient's weight (as per the table given below.)

2) In order to allow the required volume of voriconazole to be added, withdraw and discard at least an equal volume of diluent from the infusion bag or bottle to be used. The volume of diluent remaining in the bag or bottle should be such that when the 10 mg/mL voriconazole concentrate is added the final concentration is not less then 0.5 mg/mL or greater than 5 mg/mL.

3) Using a suitable size syringe and aseptic technique, withdraw the required volume of voriconazole concentrate from the appropriate number of vials and add to the infusion bag or bottle. Discard partially used vials.

The final voriconazole solution must be infused over 1-2 hours at a maximum rate of 3 mg/kg per hour.

Required volumes of 10 mg/mL voriconazole concentrate:

	Volume for voriconazole concentrate (10 mg/mL) required for:		
Body weight	**(number of vials)**	**(number of vials)**	**(number of vials)**
(kg)	**3mg/kg dose**	**4mg/kg dose**	**6mg/kg dose**
30	9.0mL (1)	12mL (1)	18mL (1)
35	10.5mL (1)	14mL (1)	21mL (2)
40	12.0mL (1)	16mL (1)	24mL (2)
45	13.5mL (1)	18mL (1)	27mL (2)
50	15.0mL (1)	20mL (1)	30mL (2)
55	16.0mL (1)	22mL (2)	33mL (2)
60	18.0mL (1)	24mL (2)	36mL (2)
65	19.5mL (1)	26mL (2)	39mL (2)
70	21.0mL (2)	28mL (2)	42mL (3)
75	22.5mL (2)	30mL (2)	45mL (3)
80	24.0mL (2)	32mL (2)	48mL (3)
85	25.5mL (2)	34mL (2)	51mL (3)

90	27.0mL (2)	36mL (2)	54mL (3)
95	28.5mL (2)	38mL (2)	57mL(3)
100	30mL (2)	40mL (2)	60mL (3)

voriconazole for injection is a single dose unpreserved sterile lyophile. Therefore, from a microbiological point of view, once reconstituted, the product should be used immediately. If not used immediately in use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2° to 8° C (36° to 46° F) this medicinal product is for single use only and any unused solution should be discarded. Only clear solutions without particles should be used.

The reconstituted solution can be diluted with 9mg/mL (0.9%) Sodium Chloride; Lactated Ringers USP; 5% Dextrose and Lactated Ringers USP; 5% Dextrose and 0.45% Sodium Chloride; 5% Dextrose; 5% Dextrose and 20 mEq Potassium Chloride USP; 0.45% Sodium Chloride; 5% Dextrose or 0.9% Sodium Chloride.

The compatibility of voriconazole with diluents other than those described above is unknown.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Incompatibilities voriconazole injection must not be infused into the same line or cannula concomitantly with other drug infusions including parenteral nutrition, e.g. Aminofusin 10% Plus. Aminofusin 10% Plus is physically incompatible with an increase in sub visible particulate matter after 24 hours storage at 4° C.

Infusion of blood products must not occur simultaneously with voriconazole injection.

Infusion of total parenteral nutrition can occur simultaneously with voriconazole injection.

voriconazole injection must not be diluted with 4.2% Sodium Bicarbonate Infusion. The mildly alkaline nature of this diluent caused slight degradation of voriconazole after 24 hours storage at room temperature. Although refrigerated storage is recommended following

reconstitution, use of this diluent is not recommended as a precautionary measure. Compatibility with other concentration is unknown.

4.3 Contraindications

voriconazole is contraindicated in patients with known hypersensitivity to voriconazole E or to any of the excipients.

Co-administration of CY3A4 substrates, terfenadine, astemizole cisapride, pimozide or quinidine since increased plasma concentration of these drugs can lead to QTc prolongation and rare occurrences of torsades de points.

Coadministration of voriconazole with sirolimus is contraindicated because voriconazole significantly increases plasma concentrations sirolimus.

Co-administration of voriconazole with rifampin, carbamazepine and long acting barbiturates (e.g. phenobarbital mephobarbital) is contraindicated since these drugs are likely to decrease Plasma voriconazole concentrations significantly.

Co-administration of voriconazole with ritonavir (400 mg twice daily) is contraindicated because ritonavir significantly decreases plasma voriconazole . Co-administration of voriconazole with rifabutin is contraindicated since voriconazole significantly increases rifabutin plasma concentration and nlabulin also significantly decreases voriconazole plasma concentrations.

Co-administration of voriconazole with ergot alkaloids (ergotamine and dihydroergotamine) is contraindicated because voriconazole may increase the plasma concentration of ergot alkaloids which may lead to ergotism.

8. Interactions of medicines

voriconazole is metabolised by the human cytochrome P450 enzymes CYP2C19, CYP2C9 and CYP3A4 Inhibitors or inducers of these three enzymes may increase or decrease voriconazole systemic exposure (plasma concentrations) respectively.

Co-administration of voriconazole with ergot alkaloids (ergotamine and dihydroergotamine) is contraindicated because voriconazole may increase the plasma concentration of ergot alkaloids, which may lead to ergotism.

Co-administration of voriconazole at 400mg twice daily with rifabutin 300mg twice daily increased the C_{max} and AUC of rifabutin by an average of 3 times and 4 times respectively compared to when rifabutin is given alone. Co-administration of voriconazole and rifabutin is contraindicated.

Cimetidine (400mg twice daily) increased voriconazole steady C_{max} and AUC by an average of 18% and 23% respectively following oral doses of 200mg voriconazole No dosage adjustment of voriconazole concentrations significantly.

Repeat dose administration of oral voriconazole increased the C_{max} and AUC of sirolimus and average of 7 fold and 11 fold respectively, in healthy subjects co-administration of voriconazole and sirolimus is this contraindicated.

Concomitant administration of voriconazole with terfenadine, astemizole, cisapride, pimozide or quinidine may result in inhibition of metabolism of these drugs. Increased plasma concentrations of these drugs can lead to QTc prolongation and are occurences of torsade de points co-administration of VORICONAZOLE with these drugs is thus contraindicated.

In stable renal transplant recipients receiving chronic cyclosporine therapy voriconazole increased cyclosporine C_{max} and AUC by atleast 1.1 and 1.7 times respectively , when initiating therapy with voriconazole in patients already receiving cyclosporine it is recommended that the cyclosporine dose be reduced to one half of the original dose and followed with frequent monitoring of cyclosporine blood levels. Increased cyclopedia levels have been associated with nephrotoxicity when voriconazole is discontinued, cyclosporine levels should be frequently monitored and the dose is increased as necessary.

Repeat oral dose administration of voriconazole (400mg every 12 hours on day 1 and 200mg every 12 hours for 6 days) increased tacrolimus (0.1mg/kg single dose) C_{max} and AUC by an average of 2 fold and 3 fold respectively when initiating therapy with voriconazole in patients already receiving tacrolimus it is recommended that the tacrolimus dose be reduced to one third of the original dose

and followed with frequent monitoring of the tacrolimus blood levels increased tacrolimus level have been associated with nephrotoxicity. When a discounted tacrolimus level is should be carefully monitored and the dose increased as necessary.

Co-administration voriconazole (300mg twice daily) with warfarin (300mg single dose) significantly increased maximum prothrombin time by approximately 2 times that of placebo close monitoring of prothrombin time or other suitable anticoagulation test is recommended if warfarin and VORICONAZOLE are co-administered and the warfarin dose adjusted accordingly.

Although not studied *invitro- invivo*, voriconazole may increase the plasma concentrations of coumarin anticoagulants (e.g., phenprocoumon, acenocoumarol) and there fore may cause an increasing in prothrombin time if patients receiving coumarin preparations are treated simultaneously with voriconazole the prothrombin time or other suitable anticoagulation tests should be mentioned at close intervals and the dosage of anticoagulants adjusted accordingly.

Although not studied clinically voriconazole has been shown to inhibit lovastatin metabolism in vitro (human liver microsomes) therefore voriconazole likely to increase the plasma concentrations of stains that are metabolized by CYP3A4 it is recommended that dose adjustment of the statin be considered during co-administration increased stain concentration in plasma have been associated with rhabdomyolysis.

Although not studied clinically voriconazole have been shown to inhibit midazolam metabolism *invitro* therefore voriconazole is likely to increase the plasma concentrations of benzodiazepines that are metabolite by CYP3A4 (e.g. midazolam, triazolam and alprazolam) therefore voriconazole may increase the plasma concentrations of calcium channel blockers that are metabolized by CYP3A4 frequent monitoring for adverse events and toxicity related to calcium channel blockers is recommended during co-administrations dose adjustment of the calcium channel blocker may be needed.

Although not studied voriconazole may increase plasma concentration, if sulphonylureas (e.g tolbutamide, glipizide and glyburide) and therefore cause hypoglycemia frequent monitoring of blood glucose and appropriate adjustments (i.e reduction of the sulphonylurease is recommended during co-administration.

Although not studied voriconazole may increase the plasma concentrations of the Vinca alkaloids (e.g. vincristine and vinblastine) and lead to neurotoxicity therefore it is recommended that dose adjustment of the vinca alkaloid be considered C_{max} and AUC of prednisolone (60mg single dose) by an average of 11% and 34% respectively. No dosage adjustment is recommended.

Repeat dose administration of phenytoin (300 mg once daily) decreased the steady state C_{max} and AUC of administered voriconazole (200 mg every 12 hour for 14 days) by an average of 50% and 70% respectively. Repeat dose administration of voriconazole (400 mg twice daily) increased the steady C_{max} and AUC of phenytoin C_{max} and AUC estimates when phenytoin is given without voriconazole. Therefore frequent monitoring of plasma phenytoin concentrations and phenytoin related adverse effects is recommended when phenytoin is co-administered with VORICONAZOLE.

Co-administered of omeprazole (40 mg once daily) with oral voriconazole (400 mg every 12 hours for day 1 then 200 mg every 12 hours for 9 days) increased the state C_{max} and AUC of voriconazole by an average of 15% and voriconazole with omeprazole (40 mg once daily) significantly increased the steady state C_{max} and AUC of omeprazole an average of 2 times and 4 times respectively. When initiating voriconazole in patients already receiving omeprazole dose of 40 mg or greater it is recommended that the omeprazole dose de reduced by one-half. The metabolism of other proton pump inhibitors that are CYP2C19 substrates may also be inhibited by voriconazole and may result in increased plasma concentration of these drugs.

Co-administration of voriconazole with ritonavir (400 mg twice daily) is contraindicated because ritonavir significantly decreases plasma voriconazole C_{max} and AUC following repeat dose administration of voriconazole (200 mg every 12 hour for 17 days) in healthy subjects. repeat dose administration of voriconazole (200 mg twice daily for 7 days) did not have a significant effect on steady state C_{max} and AUC of indinavir following repeat dose administration (200 mg twice daily for 7 days) did not have a significant effect on steady state C_{max} and AUC of indinavir following repeat dose administration (800 mg TID or 7 days) in healthy subjects.

In-vitro studies (human liver microsomes) suggest that voriconazole may inhibit the metabolism of HIV protease inhibitors (e.g. saquinavir, amprenavir and nelfinavir).

In-vitro studies (human liver microsomes) also show that the metabolism of voriconazole may be inhibited by HIV Protease inhibitors. Patients should be frequently monitored for drug toxicity during the co-administration of voriconazole and HIV protease inhibitors.

In-vitro studies (human liver microsomes) show that the metabolism of voriconazole may be inhibited by non-nucleoside reverse transcriptase inhibitors (NNRTI) (e.g. delavirdine and efavirenz). voriconazole may also inhibit the metabolism of an NNRTI.

voriconazole had no significant effect on steady state C_{max} and AUC of digoxin (0.25 mg once daily for 10 days). voriconazole had no significant effect on the C_{max} and AUC of mycophenolic acid and its major metabolite, mycophenolic acid glucuronide after administration of a 1g single oral dose of Mycophenolate mofetil. Ranitidine had no significant effect on voriconazole C_{max} and AUC following oral dose 200mg twice daily. Co-administration of erythromycin (CYP 34A inhibltor; 19 every 12h for 7 days) or azithromycin (500 mg four times a day for 3 days) with voriconazole 200 mg twice daily for 14 days had no significant effect on voriconazole steady state C_{max} and AUC in healthy subjects.

9. Use during pregnancy & Precautions

voriconazole can cause foetal harm when administered to pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the foetus. voriconazole must not be used during pregnancy unless the benefits to the mother clearly out weight the potential risk to the foetus. Women of child bearing potential should be effective contraception during treatment.

The excretion of voriconazole in breast milk has not been investigated. Breast feeding must be stopped on initiation of treatment voriconazole.

10. Effects regarding abilities of driving or using machinery

11. Side effects

The most commonly reported adverse effects with voriconazole were visual disturbances (including altered/ enhanced visual percentage, blurred vision, blurred color vision change photophobia chromatopsia) eye hemorrhage, chills, fever, headache, abdominal pain, chest pain, sepsis, hypertension, vasodilation, nausea, vomiting, elevated diarrhea, cholestic jaundice, dry mouth, jaundice chills, gastroenteritis, thrombocytopenia anemia (including macrocytic microcytic normocytic megaloblastic aplastic) leukemia, pancytopenia purpura, increased alkaines phoophates, increased hepatic enzymes, increased SGOT, increased SGPT, hypokalemia, peripheral edema, hypomagnesemia, bilurubinemia, increased creatinine, hypoglycemia, respiratory disorder, anxiety, tremor, agiation, paresthesia, rash, purtius, maculopapular rash, photo sensitivity, skin reaction, alopecia exfoliative dermatitis, abnormal kidney function, acute kidney failure, hematuria, thrombocytosis, phlebitis, injection site reactor inflammation and fur syndrome.

12. Warnings and Precautions

Caution should be used when prescribing voriconazole to patients with hypersensitivity to other azoles.

Some azoles including voriconazole have been associated with prolongation of QTc interval. There have been rare cases of torsades de pointers in patients taking voriconazole these reports involved seriously ill patients with multiple confounding risk factors such as history of cardiotoxic chemotherapy; cardiomyopathy, hypokalaemia and concomitant medication that may have been contributory. voriconazole should be administered with caution to patients with these potentially proarrhythmic conditions such as congenital or acquired or QTc prolongation, cardiomyopathy in particular when heart failure is present, sinus bradycardia, existing symptomatic arrthymias and concomitant medication that is known to prolong QTc interval.

If treatment continues beyond 28 days, visual function including visual acuity, visual field and color perception should mentioned voriconazole may cause vision changes, therefore patients on this drug should be advised to avoid potentially hazardous tasks, such as driving or operating machinery, if they perceive any change in vision.

There have been uncommon cases of serious hepatic reactions during treatment with voriconazole (including clinical hepatitis, cholestasis failure, including fatalities) liver function test should be evaluated at the start of and during the course of voriconazole therapy. Patients who develop abnormal liver function test during voriconazole therapy should be monitored for the development of more severe hepatic injury. Patient management should include laboratory evaluation of hepatic function (particularly liver function tests and bilirubin). Discontinuation of voriconazole must be considered clinical signs and symptoms consistent with liver disease develop that may be attributable to voriconazole.

voriconazole labels contain lactose and should not be given to patients with rare hereditary problems of galactose in clearances. Lapplactose deficience/ or glucose galactose malabsorption.

Electrolytes distrubances such as hypokalemia, hypomagnesemia and hypocalcemia should be monitored and corrected if necessary, prior to initiation and during voriconazole therapy.

Anaphylactic type reactions including flushing, fever, sweating, tachycardia, chest tightness, dyspnoea, faintness, nausea, pruritus and rash have been observed during administration of intravenous infusion of voriconazole in healthy subject's symptoms appeared immediate upon initiating the infusion. Depending on the diversity of symptoms consideration should be given to stopping the treatment.

Acute renal failure has been observed in severely if patients undergoing treatment with voriconazole patients being treated with are likely to be treated concomitantly with nephrotoxic medications and have concurrent conditions that may result in decreased renal function. This should include laboratory evaluations, particularly serum k creatinine.

Patients have rarely developed serious cutaneous reactions. Such as Stevens – Johnson syndrome toxic epidermal necrolysis and erythema multiforme doing treatment with voriconazole. If patients develop a rash they should be monitored closely and consideration given to discontinuation of voriconazole, voriconazole has been infrequently associated with photosensitivity skin reaction. Especially during long term therapy it is recommended that patients avoid strong direct sunlight during voriconazole therapy.

6. Pharmaceutical particulars

6.1 List of excipients

Voriconazole , Hydroxypropyl beta-cyclodextrin, Hydrochloric acid , Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months (2 years)

6.4 Special precautions for storage

Store below 30°C,protect from light

6.5 Nature and contents of container

1 x 30 ml single vial

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder

7.1 Name and Address of Manufacturer

Name: **Aspiro Pharma Limited**

Business Address: Survey No. 321, Biotech Park, Phase III,, Karkapatla village, Markook Mandal, Siddipet (Dist) – 502281, Telangana. India

Country: INDIA

Phone: +91 9959644022, 9959644077

7.2 Name and Address of Principal

Name : **Aspiro Pharma Limited**

Business Address : H.No.8-3-166/7/1, 3rd floor, Erragadda, Hyderabad – 500018, Telangana.

Country : INDIA

Telephone : 91-40-23704923/24/25

8. REGISTRATION NUMBER

Not applicable

9. DATE OF PUBLICATION OF THIS PACKAGE INSERT

Not applicable