For the use of a Registered Medical Practitioners only

1. Generic Name and Brand Name

Bilastine and Montelukast Oral Suspension

BILAZEST™ M Kids

2. Qualitative and Quantitative Composition

Each 5ml contains:

Bilastine I.P. 10 mg
Montelukast sodium I.P.
Eq. to Montelukast 4 mg
Excipients q.s
In flavoured syrupy base……q.s.
Colour: Ponceau 4R Supra

3. Dosage Form and Strength
Kindly refer to section 1 & 2

4. Clinical Particulars
4.1 Therapeutic Indication

For the treatment of Allergic rhinitis in children aged 6 to 11 yrs with body weight of at least 20 Kgs

4.2 Posology and Method of Administration

Posology:
5 ml of oral solution to be taken once daily for the relief of symptoms of allergic rhinitis based on individual dosage of Bilastine and Montelukast.
Bilastine:
Paediatric population
- Children 6 to 11 years of age with a body weight of at least 20 kg
  10 mg bilastine (5 ml of oral solution) once daily for the relief of symptoms of allergic rhino-conjunctivitis.
- Children under 6 years of age and under 20 kg. Bilastine Oral Solution should not be used in this age group.

Montelukast:
Montelukast 4-mg /5ml can be given once daily.

Duration of treatment:
For allergic rhino-conjunctivitis the treatment should be limited to the period of exposure to allergens.
Special populations
Bilastine:
Renal impairment

The safety and efficacy of bilastine in renally impaired children have not been established. Studies conducted in adults inspecial risk groups (renally impaired patients) indicate that it is not necessary to adjust the dose of bilastine in adults.

Hepatic impairment

The safety and efficacy of bilastine in hepatically impaired children have not been established. There is no clinical experience in both adult and paediatric patients with hepatic impairment. However, since bilastine is not metabolized and is eliminated as unchanged in urine and feces, hepatic impairment is not expected to increase systemic exposure above the safety margin in adult patients. Therefore, no dosage adjustment is required in adult patients with hepatic impairment.

Method of administration

Oral use

4.3 Contraindication

Hypersensitivity to the active substance or to any of the excipients. A very serious allergic reaction to this drug is rare.

4.4 Special Warnings and Precautions for Use

Bilastine

Paediatric population

Efficacy and safety of bilastine in children under 2 years of age have not been established, and there is little clinical experience in children aged 2 to 5 years, therefore bilastine should not be used in these age groups.

In patients with moderate or severe renal impairment co-administration of bilastine with P-glycoprotein inhibitors, such as e.g, ketoconazole, erythromycin, cyclosporine, ritonavir or diltiazem, may increase plasmatic levels of bilastine and therefore increase the risk of adverse effects of bilastine. Therefore, co-administration of bilastine and P-glycoprotein inhibitors should be avoided in patients with moderate or severe renal impairment.

Montelukast:

Eosinophilic Conditions: In rare cases, patients on therapy with Montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition, which is often treated with systemic corticosteroid therapy. These events usually, but not always, have been associated with the reduction of oral corticosteroid therapy.

4.5 Drug Interactions

Bilastine:

Interaction studies have only been performed in adults and are summarised below.

Interaction with food: Food significantly reduces the oral bioavailability of bilastine oral solution by 20%.

Interaction with grapefruit juice: concomitant intake of bilastine 20 mg and grapefruit juice decreased bilastine bioavailability by 30%. This effect may also apply to other fruit juices. The degree of

bioavailability decrease may vary between producers and fruits. The mechanism for this interaction is an inhibition of OATP1A2, an uptake transporter for which bilastine is a substrate. Medicinal products that are substrates or inhibitors of OATP1A2, such as ritonavir or rifampicin, may likewisehave the potential to decrease plasma concentrations of bilastine.

Interaction with ketoconazole or erythromycin: Concomitant intake of bilastine 20 mg o.d and ketoconazole 400 mg o.d or erythromycin 500 mg t.i.d. increased bilastine AUC 2-fold and Cmax 2-3 fold. These changes can be explained by interaction with intestinal efflux transporters, since bilastine is a substrate for P-gp and not metabolised (see section 5.2). These changes do not appear to affect the safety profile of bilastine and ketoconazole or erythromycin, respectively. Other medicinal products that are substrates or inhibitors of P-gp, such as cyclosporine, may likewise have the potential to increase plasma concentrations of bilastine. Interaction with diltiazem: Concomitant intake of bilastine 20 mg o.d. and diltiazem 60 mg o.d. increased Cmax of bilastine by 50%. This effect can be explained by interaction with intestinal efflux transporters (see section 5.2), and does not appear to affect the safety profile of bilastine.

Interaction with alcohol: The psychomotor performance after concomitant intake of alcohol and 20 mg o.d. bilastine was similar to that observed after intake of alcohol and placebo.

Interaction with lorazepam: Concomitant intake of bilastine 20 mg o.d. and lorazepam 3 mg o.d. for 8 days did not potentiate the depressant CNS effects of lorazepam.

Paediatric population

No interaction studies have been performed in children with bilastine oral solution. As there is no clinical experience regarding the interaction of bilastine with other medicinal products, food or fruit juices in children, the results obtained in adult interactions studies should be at present taken into consideration when prescribing bilastine to children. There are no clinical data in children to state whether changes to the AUC or Cmax due to interactions affect the safety profile of bilastine.

Montelukast:

Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic

treatment of asthma. In drug-interactions studies, the recommended clinical dose of montelukast did not have clinically important effects on the pharmacokinetics of the following medicinal products:

theophylline, prednisone, prednisolone, oral contraceptives (ethinyl estradiol/ norethindrone 35/1),

terfenadine, digoxin and warfarin.

The area under the plasma concentration curve (AUC) for montelukast was decreased approximately

40% in subjects with co-administration of phenobarbital. Since montelukast is metabolised by CYP

3A4, 2C8, and 2C9, caution should be exercised, particularly in children, when montelukast is co administered with inducers of CYP 3A4, 2C8, and 2C9, such as phenytoin, phenobarbital and rifampicin. In vitro studies have shown that montelukast is a potent inhibitor of CYP 2C8. However, data from a clinical drug-drug interaction study involving montelukast and rosiglitazone (a probe substrate representative of medicinal products primarily metabolized by CYP 2C8) demonstrated that montelukast does not inhibit CYP 2C8 in vivo. Therefore, montelukast is not anticipated to markedly

alter the metabolism of medicinal products metabolised by this enzyme (e.g., paclitaxel, rosiglitazone, and repaglinide.)

In vitro studies have shown that montelukast is a substrate of CYP 2C8, and to a less significant extent,of 2C9, and 3A4. In a clinical drug-drug interaction study involving montelukast and gemfibrozil (an inhibitor of both CYP 2C8 and 2C9) gemfibrozil increased the systemic exposure of montelukast by 4.4-fold. No routine dosage adjustment of montelukast is required upon co-administration with gemfibrozil or other potent inhibitors of CYP 2C8, but the physician should be aware of the potential for an increase in adverse reactions. Based on in vitro data, clinically important drug interactions with less potent inhibitors of CYP 2C8
(e.g., trimethoprim) are not anticipated. Co-administration of montelukast with itraconazole, a strong inhibitor of CYP 3A4, resulted in no significant increase in the systemic exposure of montelukast.

4.6 Use in Special Populations
Pregnancy and lactation:

Bilastine

Pregnancy

There are no or limited amount of data from the use of bilastine in pregnant women.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity, parturition or postnatal development. As a precautionary measure, it is preferable to avoid the use of Bilastine oral solution during pregnancy.

Breastfeeding
The excretion of bilastine in milk has not been studied in humans. Available pharmacokinetic data in animals have shown excretion of bilastine in milk. A decision on whether to continue/discontinue breast-feeding or to discontinue/abstain from Bilastine oral solution therapy must be made taking into account the benefit of breast-feeding for the child and the benefit of bilastine therapy for the mother.

Montelukast

Use during pregnancy
Animal studies do not indicate harmful effects with respect to effects on pregnancy or embryonal/foetal development.
Limited data from available pregnancy databases do not suggest a causal relationship between Montelukast and malformations (i.e. limb defects) that have been rarely reported in worldwide post marketing experience.
Montelukast may be used during pregnancy only if it is considered to be clearly essential.
Use during breastfeeding
It is unknown whether montelukast is excreted in human milk. Studies in rats have shown that montelukast is excreted in milk.
Montelukast may be used in breast-feeding only if it is considered to be clearly essential

4.7 Effects on Ability to Drive And Use Machines

Bilastine

A study performed in adults to assess the effects of bilastine on the ability to drive demonstrated that treatment with 20 mg did not affect the driving performance. However, as the individual response to the medicinal product may vary, patients should be advised not to drive or use machines until they have established their own response to bilastine.

Montelukast

Montelukast has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable Effects

Bilastine

Summary of safety profile in paediatric population
The percentage of children (2-11 years) which reported adverse events (AEs) after treatment with Bilastine 10 mg for allergic rhinoconjunctivitis or chronic idiopathic urticarial in a 12 week controlled clinical trial was comparable with the percentage in the group receiving placebo (68.5 % versus 67.5 %).
The related AEs most commonly reported by 291 children (2-11 years) receiving Bilastine 10 mg during clinical trials (#260 children exposed in the clinical safety study, 31 children exposed in the pharmacokinetic study) were headache, allergic, conjunctivitis, rhinitis and abdominal pain. These related adverse events occurred with a comparable frequency in 249 patients receiving placebo.

Tabulated summary of adverse reactions in paedriatic population
AEs at least possibly related to bilastine and reported in more than 0.1% of children (2-11 years) receiving bilastine during the clinical development are tabulated below.
Frequencies are assigned as follows:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Not known (cannot be estimated from the available data)
Rare, very rare and reactions with unknown frequency have not been included in the table.

System Organ Class
Frequency Adverse reaction
Bilastine 10 mg
(n=291) #
Placebo
(n=249)

System Organ Class	**Adverse reaction**	**Bilastine 10 mg (n=291)#**	**Placebo (n=249)**
Frequency			
Infections and Infestations			

Common	**Rhinitis**	**6 (2.1 %)**	**3 (1.2 %)**
Nervous System Disorders.			
Common	**Allergic Conjuctivitis**	**4 (1.4 %)**	**5 (2.0 %)**
Uncommon	**Eye irritation**	**1 (0.3 %)**	**0 (0.0 %)**
Gastrointestinal disorders			
Common	**Abdominal pain/Upper abdominal pain**	**3 (1.0 %)**	**3 (1.2 %)**
Uncommon	**Diarrhea**	**2 (0.7 %)**	**0 (0.0 %)**
	Nausea	**1 (0.3 %)**	**0 (0.0 %)**
	Lip swelling	**1 (0.3 %)**	**0 (0.0 %)**
Skin and subcutaneous tissue disorders			
Uncommon	**Eczema**	**1 (0.3 %)**	**0 (0.0 %)**
	Urticaria	**2 (0.7 %)**	**2 (0.8 %)**
General disorders and administration site conditions			
Uncommon	**Fatigue**	**2 (0.7 %)**	**0 (0.0 %)**

#260 children exposed in the clinical safety study, 31 children exposed in the pharmacokinetic study

4.9 Overdose

There are no data for overdose in children.
Information regarding acute overdose of bilastine is retrieved from the experience of clinical trials conducted during the development in adults and the post-marketing surveillance. In clinical trials, after administration of bilastine at doses 10 to 11times the therapeutic dose (220 mg as single dose or 200 mg/day for 7 days) to 26 adult healthy volunteers, frequency of treatment emergent adverse events was two times higher than with placebo. The adverse reactions most frequently reported were dizziness, headache and nausea. No serious adverse events and no significant prolongation in the QTc interval were reported. The information collected in the post-marketing surveillance is consistent with that reported in clinical trials.
Critical evaluation of bilastine's multiple dose (100 mg x4 days) effect on ventricular repolarization by a "thorough QT/QTccross-over study" involving 30 healthy adult volunteers did not show significant QTc prolongation.
In the event of overdose symptomatic and supportive treatment is recommended.
Montelukast:

At this time, there is no experience of overdose to permit definition of the consequence is found. Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness, followed by drowsiness in children.

5. Pharmacological Properties

5.1 Mechanism of Action

Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H1 receptor antagonist affinity and no affinity for muscarinic receptors.
Bilastine inhibited histamine-induced wheal and flare skin reactions for 24 hours following single doses.

Montelukast:

The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are potent inflammatory eicosanoids released from various cells including mast cells and eosinophils. These important pro-asthmatic mediators bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 (CysLT1) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis.
In allergic rhinitis, CysLTs are released from the nasal mucosa after allergen exposure during both early- and late-phase reactions and are associated with symptoms of allergic rhinitis. Intranasal challenge with CysLTs has been shown to increase nasal airway resistance and symptoms of nasal obstruction.

5.2 Pharmacodynamic Properties

Clinical efficacy

The efficacy of bilastine has been studied in adults and adolescents. According to guidelines, the proved efficacy in adults andadolescents can be extrapolated to children, having demonstrated that the systemic exposure with 10 mg bilastine in children from 6 to 11 years with a body weight of at least 20 kg is equivalent to the exposure in adults with 20 mg bilastine. The extrapolation from adult and adolescent data is deemed appropriate for this product as the pathophysiology of allergic rhino conjunctivitis and urticaria is the same for all age groups.
In clinical trials performed in adult and adolescent patients with allergic rhino conjunctivitis (seasonal and perennial), bilastine20 mg, administered once daily for 14-28 days, was effective in relieving symptoms such as sneezing, nasal discharge, nasal itching, nasal congestion, ocular itching, tearing and ocular redness. Bilastine effectively controlled symptoms for 24 hours.
In two clinical trials performed in patients with chronic idiopathic urticaria, bilastine 20 mg, administered once daily for 28 days were effective in relieving the itching intensity and the number and size of wheals, as well as the patients discomfort due to urticaria. Patients improved their sleep conditions and their quality of life.
No clinically relevant prolongation of QTc interval or any other cardiovascular effect has been observed in the clinical trials performed with bilastine, even at doses of 200 mg daily (10 times the clinical dose) for 7 days in 9 subjects, or even when co-administered with P-gp inhibitors, such as ketoconazole (24 subjects) and erythromycin (24 subjects). Additionally, a thorough QT study including 30 volunteers has been performed.
In controlled clinical trials at the recommended dose of 20 mg once daily, the CNS safety profile of bilastine was similar to placebo and the incidence of somnolence was not statistically different from

placebo. Bilastine at doses of up to 40 mg q.d. did not affect psychomotor performance in clinical trials and did not affect driving performance in a standard driving test.
Older patients (≥ 65 years) included in phase II and III studies showed no difference in efficacy or safety with respect to younger patients.

Clinical safety
In a 12-week controlled clinical trial with children aged 2-11 years (total 509 children, 260 treated with bilastine 10 mg: 58 at age 2 to <6 years, 105 at age 6 to <9 years and 97 at 9 to <12 years and 249 treated with placebo: 58 at age 2 to <6 years, 95at age 6 to <9 years and 96 at 9 to <12 years), at the recommended paediatric dose of 10 mg once daily, the safety profile of bilastine (n=260) was similar to placebo (n=249), with adverse drug reactions seen in 5.8% and 8.0% of patients taking bilastine10 mg and placebo, respectively. Both bilastine 10 mg and placebo showed a slight decrease in somnolence and sedation scores on the Paediatric Sleep Questionnaire during this study, with no statistically significant differences between treatment groups. In these children aged 2 to 11 years, no significant differences in QTc were observed following 10 mg bilastine daily compared with placebo. Quality of Life questionnaires specific for children with allergic rhino conjunctivitis or chronic urticarial showed a general increase in scores over 12 weeks with no statistically significant difference between the bilastine and placebo arms. The total population of 509 children encompassed: 479 subjects with allergic rhino conjunctivitis and 30 subjects diagnosed of chronic urticaria. 260 children received bilastine, 252 (96.9%) for allergic rhino conjunctivitis and 8 (3.1%) for chronic urticaria. In analogy, 249 children received placebo, 227 (91.2%) for allergic rhino conjunctivitis and 22 (8.8%) for chronic urticaria.

Paediatric population
The European Medicines Agency has waived the obligation to submit the results of studies with bilastine in all subsets of the paediatric population below 2 years of age.
Montelukast is an orally active compound that binds with high affinity and selectivity to the CysLT1 receptor. Montelukast inhibits physiologic actions of LTD4 at the CysLT1 receptor without any agonist activity. In patients with seasonal allergic rhinitis aged 15 years and older who received montelukast, a mean increase of 0.2% in peripheral blood eosinophil counts was noted, compared with a mean increase of 12.5% in placebo-treated patients, over the double-blind treatment periods; this reflects a mean difference of 12.3% in favor of montelukast. The relationship between these observations and the clinical benefits of montelukast noted in the clinical trials is not known.
Montelukast:

Pharmacotherapeutic group: Montelukast sodium is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinly leukotriene (CysLT 1).

5.3 Pharmacokinetic Properties
Absorption
Bilastine
Bilastine is rapidly absorbed after oral administration with a time to maximum plasma concentration of around 1.3 hours. Noaccumulation was observed. The mean value of bilastine oral bioavailability is 61%.
Montelukast
Montelukast is rapidly absorbed following oral administration. The mean peak plasma concentration (Cmax) is achieved 3 hours (Tmax) after administration in adults in the fasted state.

The mean oral bioavailability is 64%. The oral bioavailability and Cmax are not influenced by a standard meal. Safety and efficacy were demonstrated in clinical trials where montelukast was administered without regard to the timing of food ingestion.

Distribution
Bilastine
In vitro and *in vivo* studies have shown that bilastine is a substrate of Pgp and OATP.
At therapeutic doses bilastine is 84-90% bound to plasma proteins.
Montelukast
Montelukast is more than 99% bound to plasma proteins. The steady-state volume of distribution of montelukast averages 8-11 litres. Studies in rats with radiolabelled montelukast indicate minimal distribution across the blood-brain barrier. In addition, concentrations of radiolabelled material at 24 hours post-dose were minimal in all other tissues.

Elimination
Bilastine
In a mass balance study performed in healthy adult volunteers, after administration of a single dose of 20 mg 14C-bilastine, almost 95% of the administered dose was recovered in urine (28.3%) and faeces (66.5%) as unchanged bilastine, confirming that bilastine is not significantly metabolized in humans. The mean elimination half-life calculated in healthy volunteers was14.5 h.
Montelukast
The plasma clearance of montelukast averages 45 ml/min in healthy adults. Following an oral dose of radiolabelled montelukast, 86% of the radioactivity was recovered in 5-day faecal collections and <0.2% was recovered in urine. Coupled with estimates of montelukast oral bioavailability, this indicates that montelukast and its metabolites are excreted almost exclusively via the bile
Paediatric population
Pharmacokinetic data in children were obtained in a Phase II pharmacokinetic study including 31 children aged 4 to 11 years with allergic rhinoconjunctivitis or chronic urticaria, administered once daily with bilastine 10 mg orodispersible tablet. This formulation has been shown to be bioequivalent to bilastine 2.5 mg/ml oral solution. Pharmacokinetic analysis of plasmaconcentration data showed that the pediatric dose of bilastine 10 mg once daily results in systemic exposure equivalent to that seen after a 20 mg dose in adults and adolescents, being the mean AUC value 1014 ng*hr/ml for children 6 to 11 years. These results were largely below the safety threshold based on data from 80 mg once daily dose in adults in accordance to the drugsafety profile. These results confirmed the choice of bilastine 10 mg p.o. once daily as the appropriate therapeutic dose for the pediatric population in the age range 6 to 11 years with a body weight of at least 20 kg.

6. Non- Clinical Properties

6.1 Animal Toxicology or Pharmacology

Bilastine

Non-clinical data with bilastine reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

In reproduction toxicity studies effects of bilastine on the foetus (pre-and post-implantation loss in rats and incomplete ossification of cranial bones, sternebrae and limbs in rabbits) were only observed at

maternal toxic doses. The exposure levels at the NOAELs are sufficiently in excess (> 30 fold) to the human exposure at the recommended therapeutic dose.

In a lactation study, bilastine was identified in the milk of nursing rats administered a single oral dose (20 mg/kg). Concentrations of bilastine in milk were about half of those in maternal plasma. The relevance of those results for humans is unknown.

In a fertility study in rats, bilastine administered orally up to 1000 mg/kg/day did not induce any effect on female and male reproductive organs. Mating, fertility and pregnancy indices were not affected.

As seen in a distribution study in rats with determination of drug concentrations by autoradiography, bilastine does not accumulate in the CNS.

Montelukast

In animal toxicity studies, minor serum biochemical alterations in ALT, glucose, phosphorus and triglycerides were observed which were transient in nature. The signs of toxicity in animals were increased excretion of saliva, gastrointestinal symptoms, loose stools and ion imbalance. These occurred at dosages which provided >17-fold the systemic exposure seen at the clinical dosage. In monkeys, the adverse effects appeared at doses from 150 mg/kg/day (>232-fold the systemic exposure seen at the clinical dose). In animal studies, montelukast did not affect fertility or reproductive performance at systemic exposure exceeding the clinical systemic exposure by greater than 24-fold. A slight decrease in pup body weight was noted in the female fertility study in rats at 200 mg/kg/day (>69-fold the clinical systemic exposure). In studies in rabbits, a higher incidence of incomplete ossification, compared with concurrent control animals, was seen at systemic exposure >24-fold the clinical systemic exposure seen at the clinical dose. No abnormalities were seen in rats. Montelukast has been shown to cross the placental barrier and is excreted in breast milk of animals.

No deaths occurred following a single oral administration of montelukast sodium at doses up to 5,000 mg/kg in mice and rats (15,000 mg/m2 and 30,000 mg/m2 in mice and rats, respectively), the maximum dose tested. This dose is equivalent to 25,000 times the recommended daily adult human dose (based on an adult patient weight of 50 kg).

Montelukast was determined not to be phototoxic in mice for UVA, UVB or visible light spectra at doses up to 500 mg/kg/day (approximately >200-fold based on systemic exposure).

Montelukast was neither mutagenic in in vitro and in vivo tests nor tumorigenic in rodent species.

Data on animal study is not available.

7. Description

Bilazest M Kids is supplied for oral administration, as a suspension of Bilastine and Montelukast. Each 5ml suspension contains Bilastine 10 mg & Montelukast sodium equivalent to Montelukast 4 mg.

8. Pharmaceutical Particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf Life

Refer pack

8.3 Packaging Information

Refer pack

8.4 Storage and Handling Instructions

Refer pack

9. Patient Counselling Information

Talk to your doctor before using this medicine.

Children

Do not give this medicine to children under 6 years of age an weight less than 20kgs

Do not exceed the recommended dose. If symptoms persist, consult your doctor.

Other medicines and bilastine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, please discuss with your doctor if you are taking any of the following medicines:

- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Cyclosporine (to reduce the activity of your immune system, thus avoiding transplant rejection or reducing disease activity in autoimmune and allergic disorders, such as psoriasis, atopic dermatitis or rheumatoid arthritis)
- Ritonavir (to treat AIDS)
- Rifampicin (an antibiotic)

Bilastine with food, drink Bilastine + Montelukast suspension should not be taken with food or with grapefruit juice or other fruit juices, as this will decrease the effect of bilastine. To avoid this, you can:

- take the suspension and wait for one hour before taking food or fruit juice or
- if you have taken food or fruit juice, wait for two hours before taking the suspension.

10. Details of Manufacturer

Refer pack for manufacturer details.

Marketed By:

Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 6 &
11 to 16 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216

Version 3.0, dated 12th July 2024
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12. Date of Revision

Version 3.0, dated 12/07/24

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