For the use of a Registered Medical Practitioner only

1. Generic Name & Brand Name

Bilastine Oral Solution

Bilazest™ Kids

2. Qualitative and Quantitative Composition

Each ml contains:
Bilastine….2.5mg
Flavoured base….. q.s.
Colour: Quinoline Yellow WS

3. Dosage Form and Strength

Refer section 1 & 2

4. Clinical Particulars

4.1 Therapeutic Indication

Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Bilastine is indicated in children aged 6 to 11 years with a body weight of at least 20 kg.

4.2 Posology and Method of Administration

Posology

Children 6 to 11 years of age with a body weight of at least 20 kg: 10 mg bilastine (4ml of oral solution) once daily for the relief of symptoms of allergic rhino-conjunctivitis (seasonal allergic rhinitis and perennial allergic rhinitis) and urticaria or as directed by the Physician.

Duration of treatment: For allergic rhino-conjunctivitis the treatment should be limited to the period of exposure to allergens. For seasonal allergic rhinitis treatment could be discontinued after the symptoms have resolved and reinitiated upon their reappearance. In perennial allergic rhinitis continued treatment may be proposed to the patients during the allergen exposure periods. For urticaria the duration of treatment depends on the type, duration and course of the complaints.

The safety and efficacy of bilastine in renally and hepatically impaired children have not been established.

Method of administration: For oral use only.

The oral solution should be taken on hour before and two hour after intake of food or juice.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special Warnings and Precautions for Use

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.

4.5 Drugs Interactions

Interaction studies have only been performed in adults and are summarized below:

Interaction with food: Food significantly reduces the oral bioavailability of bilastine 20 mg tablets by 30% and that of bilastine 2.5mg/ml 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 likewise have 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. 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 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.

4.6 Use in Special Populations

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 tablet during pregnancy.

Breast-feeding

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 discontinue/abstain from Bilastine 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.

Fertility

There are no or limited amount of clinical data. A study in rats did not indicate any negative effect on fertility.

Paediatric Patients

Children under 6 years of Age and under 20 kg: The safety and efficacy of bilastine in children under 6 years of age and under 20 kg have not yet been established.

Renal Impairment

The safety and efficacy of bilastine in renally impaired children have not been established. Studies conducted in adults in special risk group (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 dose adjustment is required in adult patients with hepatic impairment.

4.7 Effects on Ability to Drive and Use Medicines

A study performed in adults to assess the effects of bilastine on the ability to drive demonstrated that treatment with 20 mg bilastine did not affect 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.

4.8 Undesirable Effects

Summary of safety profile in Paediatric population

During the clinical development the frequency, type and severity of adverse reactions in adolescents (12 years to 17 years) were the same as observed in adults. The information collected in this population (adolescents) during post-marketing surveillance has confirmed clinical trial findings.

The percentage of children (2-11 years) which reported adverse events (AEs) after treatment with bilastine 10 mg for allergic rhinoconjunctivitis or chronic idiopathic urticaria in a 12-week controlled clinical trial was comparable with patients receiving placebo (68.5% versus 67.5%). The related AEs most commonly reported by 291 children (2-11 years) receiving bilastine (oral solution formulation) 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

ADRs at least possibly related to bilastine and reported in more than 0.1% of the patients receiving 20 mg bilastine during the clinical development (N = 1697) 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), Rare (≥1/10,000 to <1/1,000), Very rare (<1/10,000), and 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		**Bilastine 10 mg (N=291)#**	**Placebo N=249**
Frequency	**Adverse reaction**		

Infections and infestations			
Uncommon	Rhinitis	3(1.0%)	3 (1.2%)
Nervous system disorders			
Common	Headache	6(2.1%)	3 (1.2%)
Uncommon	Dizziness	1(0.3%)	0(0.0%)
Eye disorder			
Common	Allergic conjunctivitis	4(1.4%)	5(2.0%)
Uncommon	Eye irritation	1(0.3%)	0(0.0%)
Gastrointestinal Disorders			
Common	Abdomen pain/upper abdominal pain	3(1.0%)	3(1.2%)
Uncommon	Nausea	1(0.3%)	0(0.0%)
	Diarrhoea	2(0.7%)	0(0.0%)
	Lip swelling	1(0.3%)	0(0.0%)
Skin and subcutaneous tissue disorders			
Uncommon	Eczerma	1 (0.3 %)	0(0.0%)
	Urticaria	2 (0.7 %)	2 (0.8 %)
General disorders and administration site condition			
Uncommon	Fatigue	2(0.7%)	0(0.0%)

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

Description of selected adverse reactions in paediatric population

Headache, abdominal pain, allergic conjunctivitis and rhinitis were observed either in children treated with bilastine 10 mg or with placebo. The frequency reported was 2.1% vs. 1.2% for headache; 1.0% vs. 1.2% for abdominal pain; 1.4% vs. 2.0% for allergic conjunctivitis, and1.0% vs. 1.2% for rhinitis.

Summary of safety profile in adults and adolescent patients

The incidence of adverse events in adult and adolescent patients suffering from allergic rhinoconjunctivitis or chronic idiopathic urticaria treated with 20 mg bilastine in clinical trials was comparable with the incidence in patients receiving placebo (12.7% versus 12.8%).

The phase II and III clinical trials performed during the clinical development included 2525 adult and adolescent patients treated with different doses of bilastine, of which 1697 received bilastine 20 mg. In these trials 1362 patients received placebo. The ADRs most commonly reported by patients receiving 20 mg bilastine for the indication of allergic rhinoconjunctivitis or chronic idiopathic urticaria were headache, somnolence, dizziness, and fatigue. These adverse events occurred with a comparable frequency in patients receiving placebo.

Tabulated summary of adverse reactions in adult and adolescent patients

ADRs at least possibly related to bilastine and reported in more than 0.1% of the patients receiving 20 mg bilastine during the clinical development (N = 1697) 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), Rare (≥1/10,000 to <1/1,000), Very rare (<1/10,000), and 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		**Bilastine 20 mg N=1697**	**All Bilastine Doses N=2525**
Frequency	**Adverse reaction**		
Infections and infestations			
Uncommon	Oral herpes	2 (0.12%)	2 (0.08%)
Metabolism and nutrition disorders			
Uncommon	Increased appetite	10 (0.59%)	11 (0.44%)
Psychiatric disorders			
Uncommon	Anxiety	6 (0.35%)	8 (0.32%)
	Insomnia	2 (0.12%)	4 (0.16%)
Nervous system disorders			
Common	Somnolence	52 (3.06%)	82 (3.25%)
	Headache	68 (4.01%)	90 (3.56%)
Uncommon	Dizziness	14 (0.83%)	23 (0.91%)
Ear and labyrinth disorders			
Uncommon	Tinnitus	2 (0.12%)	2 (0.08%)
	Vertigo	3 (0.18%)	3 (0.12%)

Cardiac disorders			
Uncommon	Right bundle branch block	4 (0.24%)	5 (0.20%)
	Sinus arrhythmia	5 (0.30%)	5 (0.20%)
	Electrocardiogram QT prolonged	9 (0.53%)	10 (0.40%)
	Other ECG abnormalities	7 (0.41%)	11 (0.44%)
Respiratory, thoracic and mediastinal disorders			
Uncommon	Dyspnoea	2 (0.12%)	2 (0.08%)
	Nasal discomfort	2 (0.12%)	2 (0.08%)
	Nasal dryness	3 (0.18%)	6 (0.24%)
Gastrointestinal disorders			
Uncommon	Upper abdominal pain	11 (0.65%)	14 (0.55%)
	Abdominal pain	5 (0.30%)	5 (0.20%)
	Nausea	7 (0.41%)	10 (0.40%)
	Stomach discomfort	3 (0.18%)	4 (0.16%)
	Diarrhoea	4 (0.24%)	6 (0.24%)
	Dry mouth	2 (0.12%)	6 (0.24%)
	Dyspepsia	2 (0.12%)	4 (0.16%)
	Gastritis	4 (0.24%)	4 (0.16%)
Skin and subcutaneous tissue disorders			
Uncommon	Pruritus	2 (0.12%)	4 (0.16%)
General disorders and administration site conditions			
Uncommon	Fatigue	14 (0.83%)	19 (0.75%)
	Thirst	3 (0.18%)	4 (0.16%)
	Improved pre-existing condition	2 (0.12%)	2 (0.08%)

	Pyrexia	2 (0.12%)	3 (0.12%)
	Asthenia	3 (0.18%)	4 (0.16%)
Investigations			
Uncommon	Increased gamma-glutamyltransferase	7 (0.41%)	8 (0.32%)
	Alanine aminotransferase increased	5 (0.30%)	5 (0.20%)
	Aspartate aminotransferase increased	3 (0.18%)	3 (0.12%)
	Blood creatinine increased	2 (0.12%)	2 (0.08%)
	Blood triglicerides increased	2 (0.12%)	2 (0.08%)
	Increased weight	8 (0.47%)	12 (0.48%)

Frequency not known (cannot be estimated from the available data): Palpitations, tachycardia, hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, rash, localised oedema/local swelling, and erythema), and vomiting have been observed during the post-marketing period.

Description of selected adverse reactions in adult and adolescent patients

Somnolence, headache, dizziness and fatigue were observed either in patients treated with bilastine 20 mg or with placebo. The frequency reported was 3.06 % vs. 2.86% for somnolence; 4.01% vs. 3.38% for headache; 0.83% vs. 0.59% for dizziness, and 0.83% vs. 1.32% for fatigue. The information collected during the post-marketing surveillance has confirmed the safety profile observed during the clinical development.

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 11 times 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 multiple dose (100 mg x4 days) effect on ventricular repolarization by a "thorough QT/QTc cross-over study" involving 30 healthy adult volunteers did not show significant QTc prolongation.

In the event of overdose symptomatic and supportive treatment is recommended.

There is no known specific antidote to bilastine.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antihistamines for systemic use; other antihistamines for systemic use.

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.

Clinical efficacy and safety

In clinical trials performed in adult and adolescent patients with allergic rhinoconjunctivitis (seasonal and perennial), bilastine 20 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 was 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 coadministered 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. Elderly patients (≥ 65 years) included in phase II and III studies showed no difference in efficacy or safety with respect to younger patients. A post-authorization study in 146 elderly patients showed no differences in the safety profile with respect to the adult population.

Paediatric population

Adolescents (12 years to 17 years) were included in the clinical development. 128 adolescents received bilastine during the clinical studies (81 in double blind studies in allergic rhino-conjunctivitis). A further 116 adolescent subjects were randomised to active comparators or placebo. No differences in efficacy and safety between adults and adolescents were seen.

According to guidelines, the proved efficacy in adults and adolescents 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 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, 95 at 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 bilastine 10 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 rhinoconjunctivitis or chronic urticaria 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 rhinoconjunctivitis and 30 subjects diagnosed of chronic urticaria. 260 children received bilastine, 252 (96.9%) for allergic rhinoconjunctivitis and 8 (3.1%) for

chronic urticaria. In analogy, 249 children received placebo, 227 (91.2%) for allergic rhinoconjunctivitis and 22 (8.8%) for chronic urticaria.

5.2 Pharmacokinetics Properties

Absorption

Bilastine is rapidly absorbed after oral administration with a time to maximum plasma concentration of around 1.3 hours. No accumulation was observed. The mean value of bilastine oral bioavailability is 61%.

Distribution

In vitro and in vivo studies have shown that bilastine is a substrate of P-gp (see section "Drug Interaction" with ketoconazole, erythromycin and diltiazem) and OATP (see section "Drug Interaction" with grapefruit juice). Bilastine does not appear to be a substrate of the transporter BCRP or renal transporters OCT2, OAT1 and OAT3. Based on in vitro studies, bilastine is not expected to inhibit the following transporters in the systemic circulation: P-gp, MRP2, BCRP, BSEP, OATP1B1, OATP1B3, OATP2B1, OAT1, OAT3, OCT1, OCT2, and NTCP, since only mild inhibition was detected for P-gp, OATP2B1 and OCT1, with an estimated IC50 $\geq$ 300 µM, much higher than the calculated clinical plasma Cmax and therefore these interactions will not be clinically relevant. However, based on these results inhibition by bilastine of transporters present in the intestinal mucosa, e.g., P-gp, cannot be excluded.

At therapeutic doses bilastine is 84-90% bound to plasma proteins.

Biotransformation

Bilastine did not induce or inhibit activity of CYP450 isoenzymes in in vitro studies.

Elimination

In a mass balance study performed in healthy adult volunteers, after administration of a single dose of 20 mg ^{14}C-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 was 14.5 h.

Linearity

Bilastine presents linear pharmacokinetics in the dose range studied (5 to 220 mg), with a low inter individual variability.

Renal impairment

The effects of bilastine in patients with renal impairment have been studied in adults.

In a study in subjects with renal impairment the mean (SD) $AUC_{0-\infty}$ increased from 737.4 (±260.8) ng x hr/ml in subjects without impairment (GFR: >80 ml/min/1.73 m^2) to: 967.4 (±140.2) ng x hr/ml in subjects with mild impairment (GFR: 50-80 ml/min/1.73m^2), 1384.2 (±263.23) ng x hr/ml in subjects with moderate impairment (GFR: 30 - <50 ml/min/1.73m^2), and 1708.5 (±699.0) ng x hr/ml in subjects with severe impairment (GFR: <30 ml/min/1.73m^2). Mean (SD) half-life of bilastine was 9.3 h (±2.8) in subjects without impairment, 15.1 h (±7.7) in subjects with mild impairment, 10.5 h (±2.3) in subjects with moderate impairment and 18.4 h (±11.4) in subjects with severe impairment. Urinary excretion of bilastine was essentially complete after 48-72 h in all subjects. These pharmacokinetic changes are not expected to have a clinically relevant influence on the safety of bilastine, since bilastine plasma levels in patients with renal impairment are still within the safety range of bilastine.

Hepatic impairment

There are no pharmacokinetic data in subjects with hepatic impairment. Bilastine is not metabolized in human. Since the results of the renal impairment study indicate renal elimination to be a major contributor in the elimination, biliary excretion is expected to be only marginally involved in the elimination of bilastine. Changes in liver function are not expected to have a clinically relevant influence on bilastine pharmacokinetics.

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 oral solution 2.5mg.

Pharmacokinetic analysis of plasma concentration 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 drug safety profile. These results confirmed the choice of bilastine 10 mg p.o. once daily as the appropriate therapeutic dose for the paediatric population in the age range 6 to 11 years with a body weight of at least 20 kg.

6. Nonclinical Properties

6.1 Animal Toxicology or Pharmacology

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.

7. Description

Bilazest Kids is supplied for oral administration, as an oral solution of Bilastine. Each ml of Bilazest kids contains Bilastine 2.5 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 Instruction

Refer pack

9. Patient Counselling Information

Bilastine oral solution 2.5mg/ml is used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked-up nose and red and watery eyes) and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes (hives or urticaria)

Bilastine oral solution is indicated in children aged 6 to 11 years with a body weight of at least 20 kg.

Do not use if your child is allergic.

Talk your doctor or pharmacist before using Bilastine oral solution if your child has moderate or severe renal or hepatic impairment or if your child is taking other medicines.

Do not give this medicine to children under 6 years of age with a body weight below 20kg since no sufficient data are available.

Tell your doctor or pharmacist if your child is taking, has recently taking or might take any other medicines, including medicines obtained without a prescription. Some medicine should not be taken together and others may need their doses to be altered when taken together.

Always inform your doctor or pharmacist if you child is using or receiving any of following medicines in addition to Bilastine: Ketoconazole, Erythromycin, Diltiazem, Cyclosporine(to reduce the activity of your immune system, thus avoiding transplant rejection or reducing disease activity in autoimmune and allergic disorders, such as psorosis, atopic dermatitis or rheumatoid arthritis, Ritonavir, and Rifampicin.

Bilastine oral solution should **not be taken with food or with grapefruit juice or other fruit juice**, as this will decrease the effects of bilastine. To avoid this, you can:

- give your child the oral solution and wait for one hour before your child takes food or fruit juice or
- If your child has taken food of fruit in adults (bilastine), does not increase the drowsiness produced by alcohol.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose in children 6 to 11 years of age with a body weight of at least 20kg is 10mg bilastine once daily for the relief of symptoms of allergic rhino-conjunctivitis and urticaria.do not give this medicine to children under 6 years of age with a body weight below 20kg since no sufficient data are available.

For adults, including elderly and adolescents aged 12 years and over, the recommended dose is 20mg bilastine once daily. For this patient population a more suitable dosage form- tablet is available, ask your doctor or pharmacist.

The bilastine oral solution 2.5mg/ml is for oral use only.

Please place the oral solution in the mouth of your child. It will disperse rapidly in saliva and can they be easily swallowed.

Alternatively, you may disperse the oral solution in a tea-spoon of water before giving it to your child.

You should use exclusively water for dispersion, do not use grapefruit juice or any other fruit juices.

You should give the oral solution to your child one hour before or two hour after your child has taken any food or fruit juice.

If your child or anyone else, use too much of this medicine, tell your doctor immediately or go to the emergency department of your nearest hospital. Please remember to take this medicine pack or this leaflet with you.

If you forget to give your child the daily dose on time, give it on the same days as soon as you remember, then give the next dose on the next day at the usual time as prescribed by the doctor. In any case, do not give a double dose to make up for a forgotten one.

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

10. Manufactured By

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

2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302, India.

TM-Trademark of Abbott Healthcare Pvt. Ltd.

11. Details of Permission or Licence Number

Refer pack for Permission/License details.

12. Date of Revision

Version 2.0, dated 13/05/2024

For Product Complaints/Adverse events or Queries please write to **webmasterindia@abbott.com**

Version 2.0, dated 13th May 2024
Replaces Version 1.0, dated 29th May 2022