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Asian Experiences in Treating School-Age Children with Bilastine 10 mg Orodispersible Tablets: Cases from Clinical Practice

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ABSTRACT

Allergic rhinitis (AR) and chronic urticaria (CU) are prevalent conditions in children worldwide, including in the Asia-Pacific (APAC) region. These conditions are associated with a substantial impact on health-related quality of life (HRQoL), affecting many aspects of children's daily functioning. Bilastine 10 mg orodispersible tablet (ODT) is a non-sedating second-generation H_1-antihistamine indicated in Asia for the symptomatic treatment of allergic rhinoconjunctivitis (seasonal and perennial) and urticaria in children aged 6–11 years with a body weight of ≥20 kg. Real-world evidence on the use of second-generation H_1-antihistamines, particularly bilastine 10 mg ODT, in paediatric populations in APAC remains limited. We present thirteen clinical-practice cases from experienced allergologists, dermatologists, ENT specialists, and paediatricians from APAC, discussed at the STAR NETWORK Expert Panel meeting. The cases illustrate the clinical use, efficacy, and safety of bilastine 10 mg ODT once daily in children aged 6–11 years with AR or CU, across a diverse range of clinical aetiologies and symptoms. Once-daily bilastine 10 mg ODT was found to be effective and well-tolerated in managing AR and CU in school-going children, improving symptom control compared with other antihistamines, without any sedative effects or other adverse events.

Keywords: *Asia-Pacific, Bilastine, Chronic Urticaria, Allergic Rhinitis, Orodispersible Tablet*

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Background

Both allergic rhinitis (AR) and chronic urticaria (CU) are prevalent in children, globally and in the Asia-Pacific (APAC) region (Caffarelli *et al*., 2020, Schuler Iv and Montejo, 2021). In different epidemiological studies across APAC, the prevalence of AR among children and adolescents was found to range from 9.8% in China to as high as 50% in Taiwan (Chong and Chew, 2018). Most individuals with AR develop symptoms before the age of 20 years, with nearly half of patients becoming symptomatic by the age of 6 years (Meltzer *et al*., 2009). CU is more prevalent in Asia (1.4%) than Europe (0.5%) and North America (0.1%) (Fricke *et al*., 2020). In Korea, a nationwide population-based study estimated the prevalence of CU to be 3,253.6 per 100,000 person-years for children aged <10 years (Lee *et al*., 2017). In some countries, CU primarily affects younger children (Saini *et al*., 2020, Gonçalo *et al*., 2021); in a Thai study of 142 children with CU aged 12 years or younger, 72.6% were below the age of 6 years (Tuchinda *et al*., 1986).

Both AR and CU are associated with a negative impact on health-related quality of life (HRQoL), affecting many aspects of daily life for children (Gonçalo *et al*., 2021, Bosnic-Anticevich *et al*., 2020). In particular, CU in adults has been shown to have a similar or greater impact on HRQoL than epilepsy, diabetes, moderate-to-severe psoriasis, atopic dermatitis, asthma, and severe coronary artery disease requiring bypass grafting (Gonçalo *et al*., 2021, Töndury *et al*., 2011). Both AR and CU can disrupt sleep due to nasal congestion, pruritus, and other symptoms, leading to daytime sleepiness and fatigue (Mir *et al*., 2012, Wasim *et al*., 2025). Sleep problems in children can impact body weight, memory, attention and performance, as well as behaviour (Liu *et al*., 2024). Consequently, AR and CU can also have a substantial impact on school performance through increased school absenteeism and distraction during class hours (Mir *et al*., 2012, Kim *et al*., 2022, Gonçalo *et al*., 2021). In a survey in APAC, nearly half (46%) of patients reported that AR interferes with their ability to perform well at school, leading to a productivity reduction of >20% during periods of peak symptom severity (Katelaris *et al*., 2011). Similarly, children with CU have a significantly lower school performance than those with other allergic diseases (p=0.029) (Ferrer, 2009). As demonstrated in an Australian study, treatment that leads to good symptom control, leads to considerable improvement in both sleep parameters and school performance (Bosnic-Anticevich *et al*., 2020).

In addition to symptomatic management, that may include saline sprays or topical lotions, H_1-antihistamines are the most commonly prescribed medications for the treatment of AR and urticaria (Simons and Simons, 2011). For more severe cases, intranasal (for AR) and systemic corticosteroids can be added to antihistamine therapy to help manage exacerbations in the short term (Abdullah *et al*., 2022,

Kayiran and Akdeniz, 2019). Second-generation H_1-antihistamines are preferred in the management of allergic conditions in children due to their reduced sedative effects compared with first-generation antihistamines (Church and Church, 2011, Parisi *et al*., 2020). The sedative effects of first-generation drugs can compound the negative effects of AR or CU on children's school performance, which is not the case with second generation agents (Church *et al*., 2010). Taste and formulation are important factors in promoting medication adherence among children (Gardiner and Dvorkin, 2006). Paediatric oral dosage forms such as tablets, capsules, solutions, and suspensions can pose several challenges for children, including choking hazards and poor palatability, resulting in low adherence and non-compliance (Kean and Adeleke, 2023). Orodispersible tablet (ODT) formulations disintegrate rapidly in the buccal cavity without the need for water (Kean and Adeleke, 2023). In a study that evaluated dosage form preferences in children and young adults (aged 6–18 years), ODTs were the preferred oral dosage form (58%) (Alyami *et al*., 2017). By catering for children's preferences, being easy to use anywhere, without the need for water, and avoiding swallowing issues, ODTs have the potential to promote adherence and thus improve patient outcomes.

Bilastine is a non-sedating second-generation H_1-antihistamine, that has shown good efficacy against the symptoms of AR and CU, including improvements in quality of life, as well as a safety profile similar to that of placebo (Ridolo *et al*., 2015, Leceta *et al*., 2021). In regions of Asia where paediatric use is approved, bilastine 10 mg ODT is indicated for the symptomatic treatment of allergic rhinoconjunctivitis (seasonal and perennial) and urticaria in children aged 6–11 years with a body weight of ≥20 kg.

There is currently limited real-word evidence on the use of second-generation H_1-antihistamines in general and bilastine in particular in paediatric populations in APAC. Here we have collated case studies to illustrate the real-world clinical use, efficacy and safety of bilastine 10 mg ODT once daily in children (aged 6–11 years) with AR or CU. These cases represent experienced clinicians' perspectives on bilastine application in diverse Asian clinical settings, providing practical insights to complement existing clinical trial evidence.

Methods

The authors of this article are members of the STAR NETWORK Expert Panel, consisting of allergologists (n=5), dermatologists (n=1), ear, nose and throat (ENT) specialists (n=3), and paediatricians (n=2) from the Asia-Pacific region, all of whom routinely manage paediatric patients with AR and CU in clinical practice. The panellists have experience with the management of patients prescribed second-generation H_1-antihistamines, including bilastine.

This manuscript presents 13 paediatric case studies from the APAC region that were presented and discussed at the STAR NETWORK Expert Panel meeting, held on 27th June 2025 in Manila, Philippines. The panellists contributed real-world case studies, which were recorded in a predefined template. Inclusion criteria comprised paediatric (aged 6–11 years) case studies involving AR or CU, in which patients were treated with bilastine 10 mg ODT once daily, as per the approved indication. Parental/guardian consent was obtained by the experts for presenting the anonymised case studies. No identity disclosure was made in these cases. This manuscript was collaboratively developed and reviewed by all panellists.

Results

In the presented real-world case studies, paediatric patients were prescribed bilastine 10 mg ODT once daily for the symptom management of AR or CU, as per the label. Patients were aged between 6 and 11 years and 62% were male. Eight of the included patients were diagnosed with AR (Table 1) and five with CU (Table 2).

The primary reason for switching to bilastine 10 mg ODT once daily was an insufficient clinical response to their previous treatment (generally a second-generation antihistamine, in some cases with supportive nasal decongestants or saline sprays, or topical treatments) in seven cases, five AR cases (Case 1, 2, 4, 5, and 8) (Table 1) and two CU cases (Case 10 and 11) (Table 2). In Case 1 (AR), the patient suffered from continued nasal obstruction, which caused daytime somnolence, as well as rhinorrhoea, despite being treated with cetirizine syrup. Four weeks after initiating bilastine 10 mg ODT once daily, the patient reported no sleep disturbances, minimal rhinorrhoea, and no daytime somnolence during school hours or while doing homework. The paediatric patient in Case 2 (AR) was treated with desloratadine, but faced frequent epistaxis, which caused disruption of school attendance. Switching to bilastine 10 mg ODT once daily reduced symptoms so as to be no longer bothersome, allowing the patient to remain focused and active in school. Another child (Case 4, AR) experienced worsening conjunctivitis, despite treatment with desloratadine, which resulted in him not attending school. After initiation of bilastine 10 mg ODT once daily, their symptoms gradually decreased, from a VAS score of 9/10 to 0–1/10 after three months. In Case 5 (AR), the paediatric patient suffered from chronic nasal obstruction, snoring, and poor weight gain while under treatment with cetirizine syrup. Two months after switching to bilastine 10 mg ODT once daily, there was no observable nasal obstruction, and the patient slept quietly. Similarly, despite cetirizine treatment, nasal congestion, rhinorrhoea, and snoring, affecting both sleep and daily activities, continued for Case 8 (AR). Bilastine 10 mg ODT once daily led to marked relief from bothersome symptoms, improved sleep quality and daytime performance, and allowed dose reduction of supporting medications (intranasal steroids). While cetirizine provided some relief of intensely itching lesions for Case 10 (CU), there was no

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complete clearance, which was also not achieved after switch to desloratadine with supporting treatments (calamine lotion and topical corticosteroids). A switch to bilastine 10 mg ODT once daily was therefore initiated. After two months, the patient reported only minimal hives remaining, and considerable improvements in sleep and itch, with symptoms not being bothersome anymore, allowing full participation in school. The hives and itchy lesions of Case 11 (CU) initially resolved with chlorpheniramine (a first-generation antihistamine) but returned after treatment was stopped. The patient was started on bilastine 10 mg ODT once daily, which resulted in sustained improvements at three months.

Cases 12 and 13 (CU) reported both partial response and daytime sleepiness while on cetirizine. In Case 12, two weeks after changing treatments to bilastine 10 mg ODT once daily, the sedative symptoms had completely resolved, allowing the patient to return to a normal school routine. CU symptom resolution was achieved after six weeks. Similarly, in Case 13, the patient achieved CU symptom improvement within two months of initiating bilastine 10 mg ODT once daily, with no reported side effects.

Case 3 (AR) experienced mild drowsiness on levocetirizine and cetirizine that negatively impacted their school performance. Bilastine 10 mg ODT once daily was therefore initiated and demonstrated improved symptom control.

In Case 6 (overweight patient with AR and adenotonsillar hypertrophy), cetirizine was avoided due to its known association with increased appetite and potential weight gain (Ratliff *et al*., 2010). Instead, treatment was initiated with bilastine 10 mg ODT once daily, an intranasal corticosteroid, and montelukast. After 6 weeks, the patient's snoring had markedly decreased, sleep apnoea symptoms had resolved, and a 5% reduction in body weight was achieved.

In Case 7 (AR), the patient had previously struggled with treatment adherence due to the bitter taste of the desloratadine formulation they had been prescribed. Before initiating bilastine 10 mg ODT once daily, the taste was tested in the clinic, and the patient confirmed that they liked it. Since then, adherence to bilastine 10 mg ODT once daily treatment was consistent, and the patient has shown considerable symptom improvement.

The favourable safety profile and absence of immunosuppressive effects of bilastine 10 mg ODT once daily were considered in the treatment choice in Case 1. In Case 6 (AR) and Case 9 (CU), bilastine 10 mg ODT once daily was prescribed as first-line treatment and provided rapid symptom relief, as well as a notable absence of sedation or cognitive side effects.

The most important safety concern raised by patients' caregivers was drowsiness, affecting the child's performance at school and participation in activities (Cases 3, 12, and 13). Inconvenience and potential long-term effects of cetirizine syrup were considered by parents in Case 8, contributing to the choice of bilastine 10 mg ODT once daily. Safety concerns were also raised by carers about supportive treatments, some of which could be discontinued or their dose reduced, upon initiation of bilastine (Case 3). Loteprednol could be discontinued in Case 4.

Table 1: Cases of AR treated with bilastine 10 mg ODT OD.

Presentation	Previous treatment and diagnosis	Treatment decision	Clinical outcome
Case 1: 8-year-old girl complained of watery rhinorrhoea, itchiness of the eyes and nasal congestion for the previous 2 years			
An 8-year-old female patient developed watery rhinorrhoea, itchiness of the eyes and nasal congestion since she was given a pet dog two years ago.	• The patient was previously prescribed cetirizine syrup and saline nasal wash for 4 weeks. • After the initial treatment period, her parents noticed loud snoring and the patient consistently complained of nasal obstruction upon waking up. • A further consultation with a paediatric pulmonologist ruled out asthma but advised to perform a sleep study for the loud snoring. • Cetirizine-phenylephrine fixed dose syrup, montelukast chewable, and nasal wash were prescribed for 2 months.	• Bilastine 10 mg ODT OD was chosen as bothersome symptoms of nasal obstruction causing daytime somnolence and continuous rhinorrhoea were not addressed with previous medications. • Additionally, the parents requested a medication that is not only efficacious but also has a tolerable safety profile with no immunosuppressive effects.	• After 4 weeks of treatment with bilastine 10 mg ODT OD, nasal obstruction persisted, although the patient reported no sleep disturbances. • The patient experienced minimal rhinorrhoea and itchiness and reported that they liked the taste of bilastine. • The patient reported no difficulties at school or while completing homework.
Case 2: Recurrent epistaxis in a 10-year-old boy with persistent AR			
A 10-year-old male patient presented with epistaxis triggered by sneezing episodes, resulting in lost classroom hours.	• The patient's paediatrician had previously prescribed phenylpropanolamine tablets, desloratadine 5 mg, and hypertonic nasal saline for a week. • Blood tests (CBC, PT, and PTT) were requested, and an ENT consultation was advised if the symptoms persisted. • Two days prior to the ENT consultation, the patient had active epistaxis after bouts of sneezing and nose picking due to itchiness.	• The treatment objective was complete resolution of epistaxis to avoid disruption to the patient's school attendance. • Bilastine 10 mg ODT OD was initiated for 3 weeks, alongside oxymetazoline nasal spray as needed. • The patient was advised not to blow or pick his nose.	• After 3 weeks of treatment with bilastine 10 mg ODT OD, the patient had no episodes of epistaxis, despite intermittent sneezing bouts. • The patient has remained focused in school and actively participated in sports activities. • The mother reported that the sneezing, nasal blockage, and pruritus on both the nose and eyes were no longer bothersome. • The ENT examination revealed normal nasal mucosa. • Bilastine 10 mg ODT OD was continued for a further 8 weeks.

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Case 3: 8-year-old boy complaining of non-productive cough and rhinorrhoea for 3 years			

An 8-year-old male patient complained of non-productive cough and rhinorrhoea for the previous 3 years.	• Two years prior to consultation, the patient experienced daily morning episodes of rhinorrhoea and sneezing, accompanied by a non-productive cough, with no other associated symptoms.
	  ○ Cetirizine 10 mg OD provided temporary relief.
	• One year prior to consultation non-productive cough and rhinorrhoea without systemic manifestations persisted.
	• Fluticasone furoate 27.5 mcg 1 spray in each nostril BID, montelukast + levocetirizine 5 mg/5 mg OD, azelastine + fluticasone 137 mcg/50 mcg BID, and sodium chloride nasal spray BID provided no substantial improvement in symptoms after two weeks of treatment.
	  ○ The patient experienced intolerance to azelastine and fluticasone propionate throughout the course of treatment.
		• Due to the patient's intolerance to azelastine and fluticasone propionate, bilastine 10 mg ODT OD was selected as the preferred treatment alongside nasal douche.
		• The patient reported that previous use of levocetirizine and cetirizine caused mild drowsiness, which affected the patient's school performance.
			• The patient experienced improved control of nasal symptoms, which was facilitated by the ease of taking bilastine immediately upon waking up.
			• Specific immunotherapy was also initiated as an add-on therapy to provide a personalised approach to managing his AR.

Case 4: 6-year-old boy presenting with nasal itching, sneezing, nasal congestion, and red eyes			
• A 6-year-old male patient presented with nasal itching, sneezing, nasal congestion, and red eyes almost every day for nearly a year. • Global VAS for ocular and nasal symptoms was 9 out of 10.	• The patient was previously diagnosed with allergic conjunctivitis and treated with, olopatadine 0.2%, loteprednol 0.5% BID, levofloxacin hydrate 0.5% BID, and desloratadine 5 mg OD. • Symptoms were initially well-managed. However, increased frequency of redness and itching prevented a reduction in the loteprednol dose. • Consequently, the patient struggled to concentrate on his studies and stopped attending school. • After a skin prick test, the patient was diagnosed with severe, persistent, allergic rhinoconjunctivitis, sensitised to house dust mite.	• Due to insufficient clinical response, treatment was switched from desloratadine to bilastine 10 mg ODT OD. • The loteprednol dose was gradually reduced until discontinuation. • Olopatadine 0.2% was prescribed to be used as needed for treating itchy eyes. • An intranasal corticosteroid (fluticasone propionate [1 puff/nostril OD]) and sublingual immunotherapy for house dust mites was also prescribed.	• Following 2 weeks of treatment with bilastine 10 mg ODT OD, the patient's global VAS score decreased from 9 to 5 out of 10. • After a further two weeks of bilastine 10 mg ODT OD, the score further improved to 2 out of 10. • At the 3-month follow-up, the global VAS score was 0–1 out of 10, indicating considerable improvement.
Case 5: 6-year-old boy presented with chronic nasal obstruction			
• A 6-year-old male patient presented with chronic nasal obstruction and complained of snoring, mouth breathing, and poor weight gain.	The patient was previously diagnosed with AR and treated with cetirizine syrup for 1 year.	Due to insufficient clinical response of the previous treatment, the patient was prescribed bilastine 10 mg ODT OD before bedtime and 1 puff of intranasal corticosteroid for 2 months.	• At follow up, no nasal obstruction was observed, and the patient had gained 1 kg. • The parents reported that the patient no longer snored, slept quietly, and breathed through his nose.

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• Rhino hygrometry revealed absent left nasal airflow and a nasal exam showed mild swelling of both inferior turbinates, with slight mucoid nasal discharge. • No tonsillar enlargement was observed.			• Rhino hygrometry revealed symmetrical nasal airflow. • No upper respiratory tract infection was observed. • The parents and patients indicated that they would prefer to stop intranasal corticosteroid and continue bilastine 10 mg OD for 2 months.
Case 6: 6-year-old boy presented with AR with adenotonsillar hypertrophy			
• A 6-year-old male patient with obesity presented with AR with adenotonsillar hypertrophy. • Symptoms included chronic nasal obstruction, regular snoring, and mouth breathing during the night.	The patient had not received any previous treatment.	• The patient was prescribed a weight loss plan including diet, exercise, and behavioural therapy (specifically restricting junk foods). • Cetirizine was avoided due to its known association with increased appetite and potential weight gain (Ratliff *et al*., 2010). • Instead, bilastine 10 mg ODT OD, intranasal corticosteroid OD, and montelukast OD were prescribed.	• After 6 weeks of treatment with bilastine 10 mg ODT OD, the patient's snoring had considerably decreased, and there were no symptoms of sleep apnoea. • The patient had also achieved a 5% reduction in body weight.
Case 7: 10-year-old boy complained of early morning sneezing and rhinorrhoea			
• A 10-year-old male patient with 6-year history of chronic atopic dermatitis complained of early morning sneezing and rhinorrhoea for the past year, triggered by dust. • There was a strong family history of atopies. • Sneezing was triggered when exposed to dust. • The patient tended to breathe through his mouth, due to narrowed nasal passages, as well as skin xerosis and ill-defined, excoriated eczematous plaques at folded areas.	• The patient had previously visited an ENT specialist and was diagnosed with AR. • Intranasal corticosteroids and oral antihistamines (desloratadine) were prescribed. • The patient did not adhere to the recommended treatment regimen. • A skin prick test conducted by the ENT specialist confirmed an allergy to house dust mite.	• The patient had previously avoided the prescribed antihistamine, desloratadine, due to its bitter taste. • After discussions with both the patient and his parents, bilastine 10 mg ODT OD was proposed. • Bilastine was tested in the clinic, and the patient confirmed that he liked the taste. • Consequently, bilastine 10 mg ODT OD were prescribed, alongside intranasal corticosteroids and a normal nasal saline spray. • The patient was counselled on the importance of treatment adherence for effective symptom control.	• At the next clinic review, both the patient and his parents expressed satisfaction with bilastine 10 mg ODT OD. • The patient had been consistently adhering to the regimen, and his symptoms had shown considerable improvement.
Case 8: 7-year-old boy complaining of nasal congestion, rhinorrhoea, and snoring			
• A 7-year-old male patient presented with considerable and progressively	• The patient and their parents expressed frustration with the insufficient clinical response of	• After 3 months of treatment with intranasal mometasone spray and cetirizine, the parents reported ongoing	• After 3 months of treatment with bilastine 10 mg ODT OD, the parents reported

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worsening nasal congestion, rhinorrhoea, and snoring, with symptom onset around the age of 3 years. • The condition severely impacted the patient's sleep, resulting in persistent fatigue and daytime sleepiness. • No other comorbid allergic conditions were reported. • Notably, there was maternal history of AR.	OTC medicines including chlorpheniramine and cetirizine. • The patient had been previously prescribed pseudoephedrine and a topical decongestant; however, this resulted in unacceptable side effects, such as hyperactivity and agitation. • A skin prick test was positive for house dust mite allergen. An X-ray revealed adenoid gland enlargement (70%). • The patient was diagnosed with AR accompanied with adenotonsillar enlargement. • Treatment was initiated with oral cetirizine syrup 5 mg OD and intranasal mometasone spray OD.	symptoms affecting sleep quality and daytime activity. • Parents expressed reluctance towards adenotonsillectomy. • Concerns were raised regarding the inconvenience and potential long-term effects of antihistamine syrup use. • Therefore, treatment was switched to: o Bilastine 10 mg ODT OD o Intranasal mometasone spray (1 puff BID) o Montelukast 5 mg OD	considerable improvement in the child's symptoms, particularly in sleep quality and daytime performance. • The patient reduced the intranasal steroid dose to OD, and continued bilastine 10 mg ODT OD.

Abbreviations: AR, allergic rhinitis; BID, twice daily; CBC, complete blood count; ENT, ear nose and throat; IgE. Immunoglobulin E; OD, once daily; ODT, orodispersible tablet; OTC, over-the-counter; PT, prothrombin time; PTT, partial thromboplastin time; VAS, visual analogue scale.

Table 2: Cases of CU treated with bilastine 10 mg ODT OD.

Presentation	Previous treatment and diagnosis	Treatment decision	Clinical outcome
Case 9: 7-year-old boy complaining of pruritus wheals			
• A 7-year-old male patient presented with a 10-week history of pruritus wheals on his trunk, limbs, and face, without residual pigmentation. • There was no family history of atopy.	• The patient was diagnosed with CU. • Upon examination, all physical and laboratory parameters were within normal limits. • Stool analysis revealed no evidence of parasites. • Skin examination demonstrated non blanching erythematous plaques with serpiginous borders without angioedema or dermographism.	Bilastine 10 mg ODT OD was chosen as the treatment option.	• Within 1 week of bilastine 10 mg ODT OD initiation, 90% symptom reduction was observed. • No sedation or cognitive side effects were reported. • Bilastine was continued and after 2 weeks of treatment, the rash completely resolved. • Overall, the patient responded well to bilastine 10 mg ODT OD with rapid resolution of rashes and no reported drowsiness or cognitive side effects.
Case 10: 11-year-old girl complaining of recurrent hives for 3 months			
• An 11-year female patient presented with recurrent hives, with symptoms persisting for approximately 3 months after the first encounter. • Lesions occurred daily, considerably affecting the patient's quality of life due to intense itching and sleep disturbances. • The patient was sent home from school several times per month due to the rash.	• A GP previously prescribed oral cetirizine 5 mg BID for 1 month. • The patient had a partial response to treatment; some lesions had resolved without any discoloration. o However, there was no complete clearance of lesions. • After a consultation with another GP, antihistamine treatment was switched to desloratadine 5 mg OD as well	Due to the insufficient clinical response of the previous treatments, treatment with bilastine 10 mg ODT OD was initiated.	• After 2 weeks of treatment with bilastine 10 mg ODT OD, symptoms had improved; however, there was no complete clearance. • It was agreed to continue bilastine 10 mg ODT OD for a further 4 weeks. o Symptoms improved with <5 lesions at Week 8. • After 2 months of treatment with bilastine 10 mg, the patient had minimal hives

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• There was no family history of similar conditions.
• The patient experienced angioedema without anaphylaxis twice, both requiring emergency care.
  ○ No identifiable trigger was identified.
  ○ Both the patient and mother expressed considerable frustration.
  ○ The UAS on examination was 3, indicating severe pruritus.
	as topical calamine lotion and topical corticosteroid.
	• Despite these interventions, the patient did not experience remission.
			and reported considerable improvements in sleep and itch severity, with a UAS score of 1 (<20 wheals).
			  ○ The patient's symptoms were no longer bothersome and were able to fully participate in their school routine.

Case 11: 9-year-old girl presenting with scattered hives with no identifiable trigger			
• A 9-year-old female patient presented with scattered hives on the hands, feet, and trunk for the past 5 months, with no identifiable triggering factors. • Lesions appeared and disappeared within 24 hours and were very itchy. • No angioedema was present and there was no history of hives or atopic disease.	• In August 2023, the patient was diagnosed with CU and treated with chlorpheniramine 4 mg OD for 2–3 weeks. • Symptoms were fully resolved but returned after discontinuing medication. • In December 2023, a provocation test was negative, and the patient was diagnosed with chronic spontaneous urticaria. • The UAS7 score was 28 (HSS7: 14, ISS7: 14).	Due to the relapse in symptom control following discontinuation of chlorpheniramine, treatment was initiated with bilastine 10 mg ODT OD for 2 weeks.	• By January 2024, the UAS7 score had decreased to 4 (HSS7: 2, ISS7: 2), and the UCT score was 14. The patient continued treatment with bilastine 10 mg ODT OD for one month. • In February 2024, both UAS7 and UCT scores showed further improvement, with UAS7 at 0 and UCT at 16. The patient remained on bilastine 10 mg ODT OD for another month. • In March 2024, the UAS7 remained at 0 and UCT at 16, and treatment with bilastine 10 mg ODT OD continued for a further month.
Case 12: 8-year-old girl presenting with recurrent CU and AR			
• An 8-year-old female patient presented with a 4-month history of severe, generalised urticaria and facial angioedema. • The patient showed an excellent response to oral hydroxyzine and a three-day course of oral prednisolone, but the urticaria consistently recurred upon discontinuation of the medication. • She also had a history of recurrent watery rhinorrhoea and sneezing, which had started at six years of age. • A diagnosis of AR with CU was made.	• The patient was initially prescribed oral cetirizine 10 mg OD by her paediatrician. • This treatment yielded a partial response; while her respiratory symptoms resolved and the severity of her skin lesions and pruritus considerably improved, she continued to experience daily urticaria. • Furthermore, she complained of daytime sleepiness, despite taking the cetirizine dose in the evening, which her parents were concerned was affecting her school performance.	• Given the sedative side effects and partial control of urticaria, treatment was switched to bilastine 10 mg ODT OD.	• Within 2 weeks of initiating bilastine 10 mg ODT OD, a 68% reduction in the UAS7 score was observed (from 25 to 8). • Concurrently, the bothersome sedative symptoms completely resolved, allowing her to fully participate in her school routine. • After 6 weeks of continued bilastine ODT OD treatment, her UAS7 score reached 0. • The patient continued on bilastine 10 mg ODT OD, which was well tolerated, as the urticaria recurred upon attempts to discontinue the medication.

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Case 13: 7-year-old girl presenting with scattered hives with no identifiable trigger			
• A 7-year-old female patient presented with scattered hives on the hands, feet, and trunk for the past 12 months, with no identifiable triggers. • Lesions appeared and disappeared within 24 hours and were very itchy. • No angioedema was present and there was no history of hives or atopic disease.	• In August 2023, the patient was diagnosed with CU. The patient was treated with desloratadine 2.5 mg OD and her symptoms were well controlled for the first two months following treatment initiation. • Symptoms gradually worsened and the dose of desloratadine was increased to 10 mg OD; symptoms remained inadequately controlled. • Desloratadine was replaced by cetirizine 10mg OD, resulting in partial symptom relief. Despite this, the patient experienced daytime somnolence and reported difficulty concentrating on her studies.	Due to the sedative side effects of cetirizine, treatment was initiated with bilastine 10 mg ODT OD for 2 weeks.	• Following 2 weeks of treatment with bilastine 10 mg ODT OD, UAS7 scores decreased from 10 (HSS7: 6, ISS7: 4) to 7 (HSS7: 4, ISS7: 3). • After a further 4 weeks of treatment with bilastine 10 mg ODT OD, the UAS7 score further decreased to 4 (HSS: 4, ISS7: 0), indicating effective control of urticaria. • Although the patient was not entirely symptom-free, both she and her parents expressed satisfaction with the level of symptom control achieved, particularly in the absence of any side effects.

Abbreviations: AR, allergic rhinitis; BID, twice daily; CU, chronic urticaria; GP, general practitioner; HSS7, Hives Severity Score over 7 days; ISS7, Itch Severity Score over 7 days; OD, once daily; ODT, orodispersible tablet; UAS, Urticaria Activity Score; UAS7, Urticaria Activity Score over 7 days; UCT, Urticaria Control Test.

Discussion

The presented collection of real-world case studies demonstrates that treatment with bilastine 10 mg ODT in Asia, administered once daily as per the label in children aged 6–11 years, for the symptomatic treatment of AR and CU, was effective and well tolerated. The main reason for selecting bilastine in these diverse case studies was insufficient clinical response to other, mostly second generation, antihistamines. In all these cases, a switch to bilastine 10 mg ODT once daily resulted in marked improvement or resolution of symptoms. Other reasons for switching to or using bilastine included concerns about sedative effects of other antihistamines (including other second-generation antihistamines), which were effectively avoided through the use of bilastine 10 mg ODT once daily. The pleasant taste of the bilastine 10 mg ODT once daily formulation, as well as its ease of use, were a key deciding factor in one case. In all cases, both patients and carers expressed their satisfaction with bilastine 10 mg ODT once daily, based on symptom improvement, resolution of side effects of other medications, reduction of the need for concomitant medications, as well as taste and convenience. Parents/carers in this case series expressed their safety concerns about medications for children, particularly regarding immunosuppressive and sedating effects. Based on results from multiple research groups, bilastine is categorised as a 'non-sedating antihistamine' and classified as a 'non-brain penetrating antihistamine', which is in line with our findings. Across the 13 case studies presented here, there were no reports of sedation associated with bilastine. Patients were able to maintain or return to their regular daily activities,

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including attending school. The safety observations we made here are also in keeping with the results of a large Phase 3 randomised clinical trial involving children aged 2–11 years with allergic rhinoconjunctivitis or CU, in which the primary hypothesis, that there was non-inferiority between bilastine 10 mg ODT once daily and placebo with regard to safety and tolerability (Novák *et al*., 2016). A previous case study from the Original Real-world cases of Bilastine in Treatment (ORBIT) study, reported that bilastine 10 mg once daily was effective and well-tolerated in a 10-year-old male patient with chronic spontaneous urticaria and recurrent hives (Cheong *et al*., 2022).

Medication taste is a key barrier to treatment adherence, especially for paediatric patients, as children are often more sensitive to bitter tastes than adults (Mennella *et al*., 2013). In one of the presented cases, the child failed to adhere to a previous treatment due to its bitter taste. A taste test showed that the child liked the taste of bilastine 10 mg ODT, and there were no further adherence issues. Furthermore, the taste of bilastine was not a reported as a concern in any of the case studies, suggesting that all patients found the taste pleasant or acceptable.

Some children may struggle to take common oral dosage forms at home, such as tablets or capsules, due to choking hazards or fear (Kean and Adeleke, 2023). While syrups are widely available, they have some drawbacks; they are more difficult to carry, there is a risk of spillage during administration, they can be less stable than tablets, and the wrong dose may be administered, and susceptible to dosing errors. The ODT formulation of bilastine 10 mg allows children to easily self-administer the treatment. The water-free administration also enables use on the go, which may further support treatment adherence. This was reflected in Case 3, where the 8-year-old patient identified ease of administration as a key benefit of switching to bilastine 10 mg ODT once daily. Furthermore, the fixed dosage of bilastine 10 mg ODT allows for more precise dosing, reducing the risk of dosing errors.

In our cases, bilastine 10 mg ODT once daily improved patients' quality of life across multiple domains: physical wellbeing through resolution of sleep problems (Cases 1, 5, 6, 8, 10) and bothersome symptoms; mental/cognitive wellbeing through elimination of daytime somnolence and drowsiness (Cases 1, 3, 12, 13); and social wellbeing through restored school attendance/performance (Cases 1, 2, 10) and participation in daily activities (Case 2).

We present a small number of retrospectively collected data from cases from real-world clinical practice, which are based on individual clinical experiences. They were not part of a clinical trial or case series and may not be generalizable to the broader patient population. The reported outcomes may be

influenced by patient-specific factors, clinician judgment, and contextual variables and should be interpreted with caution.

Conclusion

Our findings from a diverse range of case studies in AR and CU, involving school-going children with different clinical aetiologies and symptoms, demonstrate that bilastine 10 mg ODT once daily is both effective and well tolerated in managing these conditions in children aged 6–11 years, improving symptom control compared with other antihistamines, without any sedative effects or other adverse events. The palatability and ease of administration of the ODT formulation may support treatment compliance in paediatric patients.

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