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CLINICAL CHARACTERISTICS AND TREATMENT OUTCOMES OF STEPWISE BILASTINE UP-DOSING IN CHRONIC SPONTANEOUS URTICARIA AT THANH HOA DERMATOLOGY HOSPITAL

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ABSTRACT

Objective: To describe the clinical characteristics and evaluate the treatment outcomes and safety of stepwise bilastine up-dosing in patients with chronic spontaneous urticaria (CSU). **Methods:** This prospective, single-arm interventional study included 93 patients with CSU aged ≥12 years who were treated at Thanh Hoa Dermatology Hospital in 2026. Bilastine was initiated at 20 mg/day; in patients with uncontrolled disease (UAS7 >6), the dose was increased to 40 mg/day at week 2 and to a maximum of 80 mg/day at week 4. **Results:** The mean age was 37.6 ± 18.7 years, and 61.3% of patients were female. Wheals were present in 100.0%, pruritus in 97.8%, and angioedema in 26.9%. At baseline, 78.5% had moderate-to-severe disease activity according to UAS7 and 94.6% had UCT <12. Median UAS7 decreased from 22 (17–31) at baseline to 0 (0–3) at week 6, whereas mean UCT increased from 5.31 ± 2.61 to 15.19 ± 0.95 (p<0.001). Cumulative disease-control rates were 45.2% after the 20-mg step, 93.5% after the 40-mg step, and 97.8% after the 80-mg step; 62.4% achieved UAS7=0 at week 6. Overall, 54.8% required ≥40 mg/day and 6.5% required 80 mg/day. Higher baseline UAS7 was independently associated with the need for dose escalation (aOR=1.15; 95% CI: 1.06–1.25; p=0.001). The most frequently reported adverse events were headache (5.4%) and somnolence (4.3%); no patient discontinued treatment because of adverse events. **Conclusion:** In this cohort, stepwise bilastine up-dosing was accompanied by reduced disease activity and improved disease control over 6 weeks. Higher baseline UAS7 was associated with the need for dose escalation to ≥40 mg/day.

Key words: Chronic spontaneous urticaria; Bilastine; Up-dosing; UAS7; UCT.

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1. Introduction

Chronic spontaneous urticaria (CSU) is a mast cell-driven disease characterized by recurrent wheals, angioedema, or both for more than 6 weeks in the absence of a specific identifiable trigger. Its fluctuating course can substantially impair sleep, daily activities, and quality of life [1], [2]. The Urticaria Activity Score over 7 days (UAS7) and Urticaria Control Test (UCT) allow standardized assessment of disease activity and disease control, respectively, and support treatment decisions [3], [4].

Second-generation H1-antihistamines are the first-line treatment for CSU. In patients whose disease remains uncontrolled at the standard dose, international guidelines recommend up-dosing a second-generation H1-antihistamine to as much as fourfold the standard dose before proceeding to subsequent treatment steps [5]. Bilastine is a highly selective H1-receptor antagonist with low sedative potential; studies have demonstrated efficacy at the standard dose and support dose escalation in patients with inadequately controlled disease [6], [7].

In Vietnam, Nguyen Thi Tra My et al. investigated the efficacy of bilastine in patients with autoimmune CSU and reported a complete response rate of 82.4% following treatment with a stepwise up-dosing regimen [8]. These findings provide preliminary evidence supporting bilastine up-dosing in Vietnamese patients with CSU. Nevertheless, data on stepwise bilastine up-dosing and factors associated with the need for dose escalation in broader CSU populations in Vietnam remain limited. This study aimed to describe the clinical characteristics of patients with CSU and to evaluate the treatment outcomes and safety of stepwise bilastine up-dosing at Thanh Hoa Dermatology Hospital.

2. Subjects and Methods

2.1. Subjects

The study included 93 patients aged ≥12 years who were diagnosed with CSU and attended the Outpatient Department of Thanh Hoa Dermatology Hospital between March and September 2026.

Inclusion criteria

• Diagnosis of CSU, defined by recurrent spontaneous wheals and/or angioedema lasting for more than 6 weeks without an identifiable specific trigger.

• Typical clinical manifestations of chronic urticaria, including transient wheals and pruritus, with or without angioedema.

• Age ≥12 years and eligibility for a bilastine up-dosing regimen with a second-generation H1-antihistamine.

• Provision of consent to participate and willingness to comply with follow-up and study assessments.

Exclusion criteria

• Acute urticaria (disease duration <6 weeks).

• Other dermatologic conditions mimicking urticaria, including urticarial vasculitis, contact dermatitis, drug eruptions, or other pruritic dermatoses.

• Severe or uncontrolled systemic diseases that could compromise treatment safety or interfere with outcome assessment, including decompensated cardiovascular disease, severe hepatic or renal impairment, and other clinically significant unstable conditions.

• Concomitant use of medications that could interfere with treatment assessment and could not be discontinued according to the study protocol.

• Pregnancy or breastfeeding.

• Refusal to participate or failure to complete the required follow-up and assessments.

Study setting and period: The study was conducted at the Outpatient Department of Thanh Hoa Dermatology Hospital from March to September 2026.

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2.2. Methods

Study design

: Prospective, single-arm, uncontrolled interventional study with pre- and post-treatment follow-up.

Sample size

The sample size for a single proportion was calculated using the following formula:

$$n = \frac{Z^2_{1-\alpha/2}\, p(1-p)}{d^2}$$

In which:

- n: required sample size

- $Z_{1-\alpha/2} = 1.96$, corresponding to a 95% confidence level.

- p: estimated proportion achieving complete response after the 80-mg dose step; p=0.824 based on the study by Nguyen Thi Tra My et al. [8].

- d: allowable margin of error, set at 0.08.

The minimum required sample size was 88 patients. A total of 93 patients with CSU were enrolled.

Sampling method

Consecutive non-probability sampling was used. All patients with CSU presenting during the recruitment period who met the inclusion criteria, fulfilled none of the exclusion criteria, and agreed to participate were consecutively enrolled until recruitment ended. In total, 93 patients were included.

Stepwise bilastine up-dosing regimen

Bilastine was initiated at 20 mg/day. Treatment response was assessed every 2 weeks based on clinical symptoms, UAS7, and UCT. In patients with uncontrolled disease (UAS7 >6), bilastine was increased from 20 to 40 mg/day at week 2 (T2) and to a maximum of 80 mg/day at week 4 (T4), corresponding to twofold and fourfold the standard dose, respectively [5], [6]. Bilastine up-dosing to 40–80 mg/day was based on international CSU guidelines recommending up to fourfold doses of second-generation H1-antihistamines [5]. These doses constitute off-label use, and evidence regarding their safety in adolescents remains limited. Once disease control was achieved (UAS7 ≤6), the patient remained on the current dose through week 6 (T6); UAS7=0 was defined as complete response. Patients who remained uncontrolled on 80 mg/day were reassessed to consider the next treatment step in accordance with guideline recommendations [5].

Treatment outcomes were evaluated according to changes in wheals, pruritus, and angioedema; UAS7 and UCT scores; rates of disease control and complete response; the bilastine dose required; and time to disease control.

Study variables

Demographic and clinical characteristics: age, sex, disease duration; wheals, pruritus, angioedema, lesion distribution, symptom frequency, nocturnal worsening, and sleep disturbance.

Disease activity and control: UAS7 and UCT were assessed at baseline (T0), week 2 (T2), week 4 (T4), and week 6 (T6). UAS7 ≤6 was defined as disease control, whereas UAS7=0 was defined as complete response.

Treatment outcomes: changes in UAS7 and UCT over time; disease-control rates at bilastine doses of 20, 40, and 80 mg/day; cumulative disease-control rate; time to disease control; and the proportion of patients requiring dose escalation to ≥40 mg/day.

Safety: type and frequency of adverse events during treatment, adverse events by dose level, and treatment discontinuation due to adverse events.

Factors associated with the need for dose escalation: The dependent variable was the need for bilastine dose escalation to ≥40 mg/day (yes = 1; no = 0). Five baseline variables were selected based on their clinical relevance and potential association with disease severity and treatment response: age, disease duration >2 years, angioedema, baseline UAS7, and baseline UCT. All five variables were entered simultaneously into the multivariable logistic regression model.

2.3. Statistic

Data were analyzed using SPSS version 26.0. Categorical variables are presented as frequencies and percentages, and continuous variables as mean ± standard deviation or median (Q1–Q3), depending on their distribution. Changes in UAS7 and UCT scores between baseline (T0) and follow-up assessments (weeks 2, 4, and 6) were evaluated using the Wilcoxon signed-rank test for paired observations. A p-value <0.05 was considered statistically significant. Logistic regression was used to investigate factors associated with the need for bilastine dose escalation to ≥40 mg/day; variables entered into the model were age, disease duration >2 years, angioedema, baseline UAS7, and baseline UCT. Multicollinearity among independent variables was assessed using the variance inflation factor (VIF) and tolerance. VIF <5 and tolerance >0.2 were considered indicative of no substantial multicollinearity.

2.4. Research Ethics

The study was conducted following approval by the Scientific Research Council and the leadership of Thanh Hoa Dermatology Hospital. Although the eligibility criteria included patients aged 12 years and older, all enrolled participants were adults aged 19–39 years. Informed consent was obtained from all participants before enrolment. Participation was voluntary, and participants were informed of the study objectives, treatment procedures, potential benefits, and risks associated with bilastine up-dosing. All patient information was coded, kept confidential, and used exclusively for research purposes.

Bilastine up-dosing to 40–80 mg/day was considered off-label and was implemented based on clinical assessment and relevant treatment guidelines. Participants were monitored throughout the treatment and follow-up periods for potential adverse events. No adverse effects attributable to bilastine up-dosing were observed during the study. Participants had the right to withdraw at any time without affecting their access to routine medical care.

The authors declare no conflicts of interest related to this study.

3. Results

Among the 93 patients, the mean age was 37.6 ± 18.7 years (range, 12–92), and 61.3% were female. Patients aged 19–39 years constituted the largest age group (41.9%). Disease duration from 6 weeks to <1 year was observed in 44.1%, while 30.1% had disease for >2 years.

Table 1. Baseline clinical characteristics and disease activity (N=93)

Characteristic	n	%
Wheals	93	100.0
Pruritus	91	97.8
Angioedema	25	26.9
Nocturnal worsening	43	46.2
Sleep disturbance	38	40.9
Symptoms ≥5 days/week	64	68.8
Moderate/severe UAS7	73	78.5
UCT <12	88	94.6

Wheals (100.0%) and pruritus (97.8%) were the most common clinical manifestations, while angioedema was observed in 26.9% of patients. Nocturnal worsening and sleep disturbance were reported in 46.2% and 40.9% of patients, respectively. Symptoms occurring on at least 5 days per week were reported by 68.8% of patients. At baseline, 78.5% had moderate-to-severe disease activity according to UAS7, and 94.6% had uncontrolled disease (UCT <12).

Table 2. Changes in UAS7 and UCT during treatment

Time point	UAS7, median (Q1–Q3)	UCT, mean ± SD
T0	22 (17–31)	5.31 ± 2.61
Week 2	11 (6–16)	12.83 ± 1.66
Week 4	5 (3–8)	14.11 ± 1.46
Week 6	0 (0–3)	15.19 ± 0.95
P_{0-2}*	<0.001	<0.001
P_{0-4}*	<0.001	<0.001
P_{0-6}*	<0.001	<0.001

** Wilcoxon signed-rank test versus T0*

Compared with baseline, UAS7 decreased and UCT increased at follow-up assessments (p<0.001). At week 6, 58/93 patients (62.4%) achieved complete response (UAS7=0), 33/93 (35.5%) had UAS7 scores of 1–6, and 2/93 (2.2%) remained uncontrolled (UAS7>6).

Table 3. Disease control according to stepwise bilastine up-dosing

Dose	Patients entering dose step	Controlled, n (%)	Uncontrolled, n (%)	Time to disease control	Cumulative disease-control rate (%)
20 mg/day	93	42 (45.2)	51 (54.8)	≤2 weeks	45.2
40 mg/day	51	45 (88.2)	6 (11.8)	>2–4 weeks	93.5
80 mg/day	6	4 (66.7)	2 (33.3)	>4–6 weeks	97.8

The proportions controlled/uncontrolled at each dose step were calculated using the number of patients who actually entered that dose step as the denominator.

Among 93 patients initially treated with bilastine 20 mg/day, 42 (45.2%) achieved disease control by week 2. Of the 51 patients requiring dose escalation to 40 mg/day, 45 (88.2%) achieved disease control by week 4. Among the remaining six patients receiving 80 mg/day, four (66.7%) achieved disease control by week 6. Cumulative disease-control rates increased from 45.2% at week 2 to 93.5% at week 4 and 97.8% at week 6. Overall, 51/93 patients (54.8%) required dose escalation to ≥40 mg/day, including six (6.5%) who received 80 mg/day. At week 6, two patients (2.2%) remained uncontrolled.

Table 4. Factors associated with the need for bilastine dose escalation to ≥40 mg/day

Factor	Crude OR (95% CI)	p	aOR (95% CI)	p
Age, per 10 years	1.17 (0.95–1.44)	0.150	1.14 (0.87–1.49)	0.339
Disease duration >2 years	2.74 (1.06–7.11)	0.038	2.75 (0.79–9.55)	0.111
Angioedema	3.56 (1.27–10.02)	0.016	2.78 (0.82–9.47)	0.101
Baseline UAS7, per 1 point	1.18 (1.10–1.27)	<0.001	1.15 (1.06–1.25)	0.001
Baseline UCT, per 1 point	0.63 (0.49–0.82)	0.001	0.78 (0.57–1.08)	0.136

OR, odds ratio; aOR, adjusted odds ratio; CI, confidence interval.

In univariable logistic regression analyses, disease duration >2 years, angioedema, higher baseline UAS7 scores, and lower baseline UCT scores were significantly associated with the need for bilastine dose escalation to ≥40 mg/day. In the multivariable model, baseline UAS7 was the only variable that remained statistically significantly associated with dose escalation (aOR = 1.15; 95% CI: 1.06–1.25; p = 0.001). Each 1-point increase in baseline UAS7 was associated with approximately 15% higher adjusted odds of requiring dose escalation, holding the other variables in the model constant.

Table 5. Adverse events during treatment (N=93)

Adverse event	n	%
Patients experiencing ≥1 adverse event	**11**	**11.8**
Types of adverse events		
Headache	5	5.4
Somnolence	4	4.3
Dizziness/fatigue	3	3.2
Gastrointestinal disturbance	2	2.2
Other	1	1.1
Discontinuation due to adverse events	0	0
Number of adverse-event types per patient		
One	7	7.5
Two	4	4.3
Three or more	0	0.0

Patients could experience more than one adverse event.

A total of 11/93 patients (11.8%) experienced at least one adverse event during treatment. The most frequently reported events were headache (5.4%), somnolence (4.3%), dizziness/fatigue (3.2%), and gastrointestinal disturbances (2.2%). Some patients experienced more than one type of adverse event. No patient discontinued treatment because of an adverse event.

4. Discussion

4.1. Clinical characteristics of the study population

The mean age was 37.6 ± 18.7 years, and 61.3% of patients were female. This distribution is consistent with the epidemiology of CSU, which predominantly affects adults and is more common in women than in men [2]. Wheals were present in all patients, pruritus in 97.8%, and angioedema in 26.9%. These findings are consistent with the typical clinical manifestations of CSU, with wheals and pruritus directly captured by the UAS7. The prevalence of angioedema in our cohort was lower than that reported in some Vietnamese CSU cohorts and pooled international data, but it nevertheless highlights angioedema as an important concomitant manifestation [2], [9].

At baseline, 78.5% of patients had moderate-to-severe disease activity and 94.6% had UCT <12. These findings are clinically concordant because UAS7 captures disease activity over 7 days, whereas UCT assesses disease control; higher UAS7 scores generally correspond to poorer control and lower UCT scores [3], [4]. Thus, the study population predominantly comprised patients with frequent symptoms and inadequately controlled disease at enrollment.

4.2. Outcomes of stepwise bilastine up-dosing

Median UAS7 decreased from 22 at baseline to 11 at week 2, 5 at week 4, and 0 at week 6, while mean UCT increased from 5.31 ± 2.61 to 15.19 ± 0.95. The concordant changes in these two measures indicate a reduction in disease activity alongside improved disease control during treatment. Previous trials of standard-dose bilastine and pooled evidence have likewise demonstrated improvements in UAS7, total symptom scores, and quality of life [6], [10], [11]. However, because the present study had no control group, the observed improvement cannot be attributed entirely to bilastine; the natural fluctuation of CSU and other factors may also have contributed to changes over time.

At 20 mg/day, 42/93 patients (45.2%) achieved disease control. Of the 51 patients escalated to 40 mg/day, 45 (88.2%) achieved control; only 6 required further escalation to 80 mg/day, of whom 4 achieved control at this step. Cumulative disease-control rates reached 93.5% after the 40-mg step and 97.8% after the 80-mg step. These findings suggest that most patients who remained uncontrolled on the standard dose achieved control after escalation to 40 mg/day, whereas relatively few required 80 mg/day. This is consistent with the recommendation to increase second-generation H1-antihistamines up to fourfold the standard dose in patients with uncontrolled CSU [5]. Sneha et al. (2024) also reported improvement in UAS7 over 6 weeks among patients whose bilastine dose was increased to 40 mg/day, providing further evidence for bilastine up-dosing in patients inadequately controlled on the standard dose [12]. In our study, dose escalation was sequential and guided by disease control at each assessment; therefore, response rates at individual dose steps reflect the outcomes of the stepwise treatment strategy rather than direct comparative efficacy among 20, 40, and 80 mg/day.

At week 6, 62.4% of patients achieved complete response (UAS7=0), while 97.8% achieved disease control (UAS7 ≤6). Thus, most patients had minimal or no disease activity after 6 weeks of treatment. Response rates may differ across studies because outcome definitions are not uniform; some studies use UAS7=0 to define complete response, whereas we used UAS7 ≤6 to define disease control. Differences in assessment time points and patient characteristics may also contribute to variation in reported response rates.

Overall, 54.8% of patients required dose escalation to ≥40 mg/day. In the multivariable model, baseline UAS7 remained independently associated with the need for dose escalation (aOR=1.15; 95% CI: 1.06–1.25; p=0.001), whereas age, disease duration >2 years, angioedema, and baseline UCT were no longer statistically significant after adjustment. This finding is consistent with the study by Wongjirattikarn et al. (2022) in 182 patients with CSU, in which baseline UAS7 was the only factor independently associated with refractoriness to second-generation H1-antihistamines at doses up to fourfold the standard dose (OR=1.14; 95% CI: 1.01–1.28; p=0.03) [13]. The concordance between the two studies suggests that baseline disease activity may be clinically relevant when assessing antihistamine treatment requirements. In our cohort, patients with higher baseline UAS7 were more likely to require bilastine dose escalation during treatment. UAS7 may therefore provide useful information not only for quantifying disease activity but also for guiding follow-up and treatment adjustment. This potential role should be further evaluated in larger studies.

4.3. Safety and study limitations

Bilastine was generally well tolerated during follow-up. Headache and somnolence were the most frequently reported adverse events, and no patient discontinued treatment because of an adverse event. These findings are consistent with the reported safety profile of bilastine and systematic evidence on up-dosing second-generation H1-antihistamines [7], [10]. Adverse events were reported in 5/93 patients receiving 20 mg/day, 5/51 receiving 40 mg/day, and 1/6 receiving 80 mg/day. Because dose levels were administered sequentially to the same patients and only six patients received 80 mg/day, the study was not designed to establish differences in safety across dose levels. The absence of treatment discontinuation during dose escalation is noteworthy; nevertheless, the safety of higher-dose bilastine warrants further evaluation in larger cohorts with longer follow-up.

This study has several limitations. It was conducted in a single hospital department, included 93 patients, had no control group, and had a follow-up duration of only 6 weeks, limiting generalizability and the assessment of long-term effectiveness and safety. Previous use of H1-antihistamines, particularly bilastine, was not systematically documented, preventing evaluation of its potential influence on treatment response and dose escalation. Because the UCT reflects disease control over the preceding 4 weeks, the week-2 result should be interpreted cautiously. Bilastine dose levels were administered sequentially to the same patients; therefore, dose-exposure groups were not independent. In addition, only six patients received 80 mg/day and only two remained uncontrolled at week 6, precluding reliable analysis of factors associated with failure to achieve control at the end of follow-up or meaningful comparisons of safety across dose levels.

5. Conclusion

Among 93 patients with CSU followed for 6 weeks, UAS7 disease activity decreased and UCT-assessed disease control improved during stepwise bilastine up-dosing. Cumulative disease-control rates were 45.2% after the 20-mg step, 93.5% after the 40-mg step, and 97.8% after the 80-mg step; 62.4% achieved complete response at week 6. Overall, 54.8% required dose escalation to ≥40 mg/day and 6.5% required 80 mg/day. Higher baseline UAS7 was independently associated with the need for dose escalation to ≥40 mg/day. Adverse events were infrequent, and no patient discontinued treatment because of an adverse event. Given the uncontrolled single-arm design and short follow-up, multicenter controlled studies with longer follow-up are needed to confirm longer-term effectiveness and safety.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Declaration of Generative AI and AI-Assisted Technologies

Artificial intelligence (AI) tools were used to assist with language editing and improving the clarity of the manuscript. All AI-assisted revisions were reviewed and verified by the authors, who take full responsibility for the final content.

Author Contributions

Identify authors who participated in the research in the following roles: Conceptualization and study design, performing experiments, data analysis, interpretation of results, preparing figures, drafting the manuscript, editing and critical review of the manuscript, and final approval of the manuscript.

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ĐẶC ĐIỂM LÂM SÀNG & KẾT QUẢ ĐIỀU TRỊ MÀY ĐAY MẠN TÍNH TỰ PHÁT BẰNG BILASTINE LIỀU TĂNG DẦN TẠI BỆNH VIỆN DA LIỄU THANH HÓA NĂM 2026

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[2] Bệnh viện Quân y 103

TÓM TẮT

Mục tiêu: Mô tả đặc điểm lâm sàng và đánh giá kết quả, tính an toàn của bilastine liều tăng dần ở người bệnh mày đay mạn tính tự phát (CSU). **Đối tượng và phương pháp:** Nghiên cứu can thiệp tiến cứu, một nhóm trên 93 người bệnh CSU từ 12 tuổi trở lên điều trị tại Bệnh viện Da liễu Thanh Hóa năm 2026. Bilastine được dùng khởi đầu 20 mg/ngày; người bệnh chưa đạt kiểm soát (UAS7 >6) được tăng lên 40 mg/ngày tại tuần 2 và tối đa 80 mg/ngày tại tuần 4. **Kết quả:** Tuổi trung bình 37,6 ± 18,7; nữ chiếm 61,3%. Sẩn phù gặp ở 100%, ngứa 97,8% và phù mạch 26,9%. Trước điều trị, 78,5% có UAS7 mức trung bình hoặc nặng và 94,6% có UCT <12. Trung vị UAS7 giảm từ 22 (17–31) xuống 0 (0–3) ở tuần 6; UCT tăng từ 5,31 ± 2,61 lên 15,19 ± 0,95 (p<0,001). Tỷ lệ kiểm soát tích lũy đạt 45,2% sau bước 20 mg, 93,5% sau bước 40 mg và 97,8% sau bước 80 mg; 62,4% đạt UAS7=0 tại tuần 6. Có 54,8% cần liều ≥40 mg và 6,5% cần dùng 80 mg. UAS7 ban đầu liên quan độc lập với nhu cầu tăng liều (aOR=1,15; KTC 95%: 1,06–1,25; p=0,001). Tác dụng không mong muốn thường gặp nhất là đau đầu (5,4%) và buồn ngủ (4,3%); không có trường hợp ngừng thuốc do tác dụng không mong muốn. **Kết luận:** Trong nhóm nghiên cứu, chiến lược bilastine tăng liều từng bước đi kèm với giảm hoạt động bệnh và tăng tỷ lệ kiểm soát sau 6 tuần. UAS7 ban đầu cao hơn liên quan với nhu cầu tăng liều ≥40 mg/ngày.

Từ khóa: Mày đay mạn tính tự phát; Bilastine; Tăng liều; UAS7; UCT.