

# npcurrent

Canadian Journal for Nurse Practitioners

2020  
ISSUE 5

## **Wound Management**

Literature review

## **Allergic Rhinitis**

Prescription antihistamines

## **Chronic Musculoskeletal Pain**

The SPACE trial

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Christopher Wilson-Steele

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## A Canadian Journal for Nurse Practitioners

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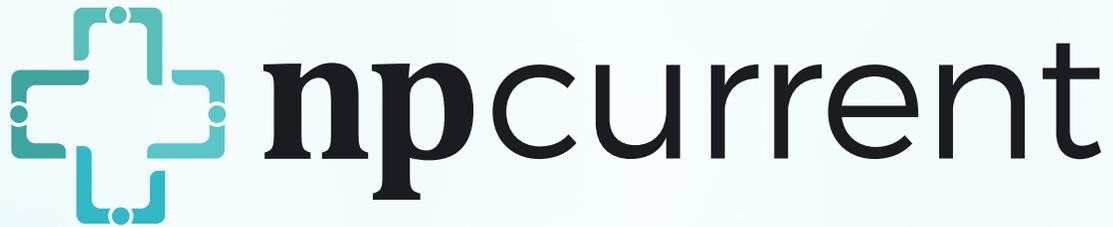
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## Canada's Journal for Nurse Practitioners

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Some of you may be looking at our table of contents and wondering why there is no information on Covid-19 in this issue. It's certainly in the forefront of everyone's minds right now, especially for frontline healthcare providers. As you can appreciate, content for the NP Current begins to come together well before the publication date, so much of what you'll find in this issue was in the works long before.

This novel coronavirus has had a tremendous impact on Canadian society and will no doubt influence future content in the NP Current. In future issues we look forward to talking about positive changes in the Canadian healthcare system and success stories in the treatment of Covid-19. In the meantime, we hope that you find this issue interesting and informative!

Melissa Lamont  
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# Wound management provided by nurse practitioners: a literature review

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## Introduction

Improving healthcare systems around the world requires innovative strategies to address the many challenges that exist. Given that many current models of care struggle to meet the needs of their populations, alternate models of care must be explored. Nurse practitioners (NPs) scope of practice and professional regulation make them an ideal choice to provide wound care. The provision of wound care by NPs can be independent or in collaboration with other healthcare providers.

## Review Objective

The objective of this literature review is to explore the state of knowledge regarding wound care provided by NPs or Advanced Practice Nurses (APN) in countries without a defined NP role. The concept of interest is the global participation of NPs in the provision of wound management, whether independently or as a part of a team.

## Background

The role of the NP is recognized by many countries across the world. NPs practice in countries such as the United States (U.S.), United Kingdom (U.K.), Australia, New Zealand, Hungary, Canada, Ireland, Israel, and Jamaica.<sup>1-3</sup>

Although the NP role varies from country to country, the majority of countries recognize NP as a protected title. In fact, most countries require graduate-level education, registration, certification and credentialing for NPs.<sup>1,4,5</sup>

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# Wound management provided by nurse practitioners: a literature review

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Some countries do not require protected titles while others have APNs without a defined NP role.<sup>1</sup> In countries that have NPs, advanced health assessments, diagnostic testing, screenings, and the prescription of medications is performed by NPs.<sup>3</sup> In these countries, the role of the NP is directed towards prevention, health education, monitoring chronic disease, and coordination of care.<sup>3</sup> NPs work autonomously with client populations in a variety of healthcare settings such as clinics, primary and acute care facilities, rehab, curative and palliative care settings, private physician practices, nursing homes, schools, colleges, and public health departments.<sup>1,6,7</sup>

Registration through a regulatory body provides the NP with the authority to practice at an advanced level. However, the authority granted by regulatory bodies varies by country. In Australia and Canada, NPs have been granted the authority to diagnose conditions, order and interpret diagnostic tests, prescribe medications (including controlled substances), provide treatments, consult or refer to specialists, and provide ongoing patient management.<sup>8,9</sup> Practice regulation in the U.S. varies by state and falls into one of the following practice regulations: 1) full practice, which allows NPs to evaluate patients, diagnose conditions, provide treatments, prescribe medications (including controlled substances), order and interpret diagnostic tests; 2) reduced practice, requiring a career-long collaborative agreement with a health care provider, or limits one or more elements of practice and 3) restricted practice, which restricts the ability of NPs in at least one area of practice, with

requirements of career-long supervision.<sup>10</sup> In Ireland, NPs manage and treat chronic diseases, prescribe medications, and order diagnostic and laboratory tests. The U.K. authorizes NPs to diagnose conditions, manage care, and order diagnostic tests.<sup>11</sup> Standards of practice and controlled acts, developed through regulatory bodies in each country, allow NPs to provide collaborative wound management.

## Literature Review

A literature review using Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Ovid MEDLINE was undertaken using the key words nurse practitioner, registered nurse extended class, advanced practice nurse, wound care, and wound management. The keywords were searched in the title, abstract, and keywords. Limitations were not placed on publication dates as there are variations in the historical development of NP roles globally. The search was limited to articles published in English. The search yielded a total of 193 articles which were reviewed for appropriateness and findings are reported.

## Wound Management Provided by Nurse Practitioners Findings

Globally, NPs provide wound care in a variety of settings such as emergency departments (EDs),<sup>12-14</sup> acute care,<sup>15,16</sup> and long-term care facilities,<sup>17</sup> military,<sup>18</sup> urology clinics,<sup>19</sup> primary care,<sup>20</sup> and community settings.<sup>21-24</sup> However, most articles regarding NPs and wound management originate in Australia.

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# Wound management provided by nurse practitioners: a literature review

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Research by MacLellan et al examined a ten-month trial of the NP-funded wound care model in 2001, by the Australian Capital Territory (ACT). This study took place in a tertiary institution in the ACT health care system.<sup>25</sup> The purpose of the ACT Nurse Practitioner Trial was to examine the feasibility of a wound care NP role in a tertiary environment. Outcomes measured included defining the scope of practice, patient demographics, and efficacy of the NP service. Results demonstrated that at-risk patients received expert wound management. This study was instrumental in the development of protocols to define the Wound Care Nurse Practitioners' scope in a tertiary environment in the Australian healthcare system today.

Research by Gibb et al<sup>26</sup> surveyed twenty-one NP respondents (71% response rate), to examine Wound Management Nurse Practitioner models of service in Australia. NPs in this model provided the following: patient and family education; ankle brachial pressure indexes (ABPI); sharp debridement; counselling, ordering medication and hospital admissions. Wound etiologies included leg ulcers, diabetic foot ulcers, pressure injuries, malignant, and complicated wounds. NP-led wound clinics provide not only inpatient care, but also provide interventions in the community setting. The NPs were responsible for assessments, diagnosis, treatments, diagnostic procedures, referrals, and education on wound management and prevention.

Additionally, there is literature examining NPs in various settings. A quantitative study by Lutze et al., examined the practice patterns of transitional NPs (students progressing to NP) in

two urban EDs.<sup>27</sup> Study results indicated that patients were evaluated for wound related concerns, follow-up, dressing changes, wound review, and minor wound suturing. Another paper by Asimus et al reviewed an NP wound management (NPWM) led Pressure Ulcer Prevention Program in New South Wales, Australia.<sup>15</sup> They found that the prevalence of pressure ulcers decreased from 29.4% to 13.0% over a three-year period, with the introduction of the NPWM program.

In 1997, Flanders Medical Centre in Australia was the first hospital to develop and support the NP role as a wound management consultant.<sup>21</sup> At Flanders, NPs provided wound care to inpatients throughout the hospital, and to outpatients (with consultation) throughout the community. NPs provided assessments, diagnosis, treatments diagnostic procedures, referrals, and education on wound management and prevention. A multidisciplinary approach was used to meet the complex wound care needs of these patients. In March 1999, 11 NP models including wound care were funded by the Victorian Minister for Health, followed in 2001 by the ACT funding a trial for a wound care NP model of care.<sup>28</sup>

An NP-led service clinic in Brisbane, Queensland began seeing patients in 2008. The NP provided evidence-based wound healing and education to improve wound healing outcomes.<sup>24</sup> To reduce wait times and increase access to care, patients without access to health services were not required to have referrals. Results showed that 90% of leg ulcers healed within 24 weeks compared to an average of 26 weeks prior to admission. This outreach service also

provided education and clinical support to clinicians and students to help improve care. This NP-led wound care service demonstrated improved healing outcomes for patients with complex wounds.

In the United States Irvin et al performed a retrospective chart review at a community hospital to determine if there was a difference in hospital acquired pressure injury rates after NPs became wound care consultants. Results of the audit indicated that pressure injury rates were lower, suggesting that the chance of occurrence after the NPs became consultants was much less likely.<sup>16</sup>

## Implications for Practice

Evidence demonstrates that NPs provide accessible,<sup>29</sup> cost-effective,<sup>26,29</sup> evidenced-based, safe, and effective wound care.<sup>30</sup> They practice collaboratively within a healthcare team,<sup>31</sup> and have the skill set to evaluate and treat wounds, while managing the overall care of the patient including specialist referral as appropriate.<sup>32,33</sup> As such, NPs are an excellent choice to provide wound care. Furthermore, NPs can act as coordinators of patient care from acute settings to community care.<sup>34</sup> They function as consultants, educators, and researchers,<sup>26</sup> thereby making NPs vital members of multidisciplinary wound care teams.<sup>35</sup> Improving healthcare systems globally requires innovations in the delivery of healthcare, including increased utilization of NPs.<sup>36</sup> Based on the limited research available regarding nurse practitioners and wound care, future studies should focus on this important and timely topic.

## Conclusion

The purpose of this review was to explore the global state of knowledge regarding wound care provided by NPs. It is clear from the literature reviewed that NPs are competent and educated in the provision of wound care, often improving patient outcomes in both

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It is clear from the literature reviewed that NPs are competent and educated in the provision of wound care.

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community and acute care settings. It is clear that the utilization of NPs in multidisciplinary health care teams would be beneficial for team members and patients. Research is lacking regarding this very important topic. Given that wound care and wound prevention could have substantial financial effects on health care systems globally, future research should be conducted in this area.

## Conflicts of interest

The authors declare no conflicts of interest.

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# The move away from 1<sup>st</sup> generation antihistamines

Dr. Nina Jindal MD, FRCPC

Allergy and Clinical Immunology

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First generation antihistamines are widely available over-the-counter in Canada and have been for decades. Diphenhydramine (Benadryl®), a 1<sup>st</sup> generation antihistamine, was first approved for use in 1946. Concerns have been raised over the side effects of these antihistamines and their place in therapy.

The Canadian Society of Allergy and Clinical Immunology (CSACI) has recently released a position statement recommending against

the use of 1<sup>st</sup> generation antihistamines and published their key points.<sup>1</sup> (Figure 1) Similarly, the Allergic Rhinitis and Its Impact on Asthma (ARIA) Guidelines do not recommend 1<sup>st</sup> generation antihistamines for the treatment of allergic rhinitis in adults.<sup>2</sup>

We spoke with Dr. Nina Jindal, allergist and clinical immunologist at St Michael's Hospital in Toronto, ON for her perspective on the use of 1<sup>st</sup> generation antihistamines (AH) in therapy.

## Figure 1. CSACI Position Statement on 1<sup>st</sup> Generation AHs: Key Points<sup>1</sup>

1. First-generation AHs are associated with significant and, at times, serious adverse effects including fatal outcomes, and they should not be used as first-line treatment in allergic disease.
2. Despite package warnings, the level of CNS impairment caused by 1<sup>st</sup> generation AHs is not fully appreciated both by health care professionals and the public, which has resulted in preventable fatal injuries.
3. Newer generation AHs are proven to be much safer than 1<sup>st</sup> generation AHs, have a faster onset of action, and have superior potency, selectivity and efficacy.
4. Despite the widespread availability of newer generation AHs, older AHs remain over-utilized.
5. To encourage the cessation of the routine use of older AHs including diphenhydramine (Benadryl®), this class of medications should have eventual consideration for availability on a behind-the-counter basis only.
6. Further efforts are needed to disseminate this information to healthcare providers and patients to help change practice and improve patient health and safety.

“ Newer generation H<sub>1</sub>-antihistamines are safer than 1<sup>st</sup> generation H<sub>1</sub>-antihistamines and should be the first-line antihistamines for the treatment of allergic rhinitis and urticaria.”

”

– CSACI Position Statement<sup>1</sup>

### Q. Do you see a place in therapy for 1<sup>st</sup> generation AHs and do you use them in your practice?

In adults, truthfully, I do not. There are so many 2<sup>nd</sup> generation AH alternatives out there that are better medications – safer and effective, that I don't need to use 1<sup>st</sup> generation AHs.

Situations where parenteral administration is needed would be the exception (eg. laryngeal edema in the ER), as there are no 2<sup>nd</sup> generation antihistamines available in IV or IM forms and diphenhydramine is the only option for these situations.

### Q. What are the risks of 1<sup>st</sup> generation AHs?

Sedation is a common side effect of 1<sup>st</sup> generation AHs. There are good studies on the impairment caused by 1<sup>st</sup> generation AHs due to their ability to cross the blood brain barrier. Patients have been found, for example, to have impaired REM sleep and have a harder time driving in a straight line after using 1<sup>st</sup> generation AHs for several days in a row. These studies really highlight the real-world situations where patients will be getting in their cars, going to work or picking up their kids, and we

have to be cognizant of the impact of these side effects on peoples' lives.

In particular, the elderly is a population where it is really important to think twice before using a 1<sup>st</sup> generation AH. I have seen several elderly patients suffer adverse outcomes due to 1<sup>st</sup> generation sedating AHs including hip fractures from falling, and prolonged hospitalizations as a result.

Cardiac toxicity, specifically the risk of QT prolongation and torsade de pointes must also be considered, especially in the elderly with comorbidities and polypharmacy. Unlike 2<sup>nd</sup> generation AHs, where the risk was recognized and studied, this risk was not known when 1<sup>st</sup> generation AHs were approved and was therefore not studied. Health Canada did add a black box warning in 2016 for hydroxyzine's risk of QT prolongation and torsade de pointes.

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# Allergic rhinitis: prescription antihistamine treatments

Dr. Susan Wasserman MSc, MDCM, FRCPC

Professor of Medicine

Director

Division of Clinical Immunology and Allergy

McMaster University, Hamilton ON

## The Impact of Allergic Rhinitis

The prevalence of allergic rhinitis (AR) is estimated at 20% of the Canadian population and rising.<sup>1,2</sup> The symptoms of AR, typically nasal congestion, rhinorrhea, sneezing and nasal itching, negatively impact a patient's quality of life.<sup>2</sup> Additionally, AR is a risk factor for the development of asthma and untreated AR is associated with asthma exacerbations.<sup>2</sup>

## Comparing Second Generation Antihistamines

In light of the Canadian Society of Allergy and Clinical Immunology's (CSACI) recent position paper<sup>3</sup> against the routine use of 1<sup>st</sup> generation antihistamines and their recommendation for the use of 2<sup>nd</sup> generation as first-line treatment for AR, a review of the currently available prescription therapeutic options in Canada is timely.

Second generation antihistamines are available both over-the-counter and by prescription. Until as recently as 2017, the only available 2<sup>nd</sup> generation prescription strength AH was cetirizine (Reactine®). Two new 2<sup>nd</sup> generation prescriptions are now available, bilastine (Blexten®) and rupatadine (Rupall®).

The international Allergic Rhinitis and Its Impact on Asthma (ARIA) Guideline<sup>4</sup> classify 2<sup>nd</sup> generation antihistamines into 2 categories:

- 2<sup>nd</sup> generation antihistamines that do not cause sedation and do not interact with cytochrome P450
- 2<sup>nd</sup> generation antihistamines that cause some sedation and/or interact with cytochrome P450

## ASK THE EXPERT

### When should patients be referred to an allergist?

I recommend referring patients to an allergist for the following reasons:

- Patients have symptoms of AR that are not adequately responding to medical therapy
- To deal with other allergic comorbidities like asthma
- The patient or referring nurse practitioner (NP) would like to identify allergic triggers for proper allergen avoidance
- The patient is having side effects to medical therapy or does not wish to take medical therapy
- Consideration by the patient and/or NP of immunotherapy to treat AR

# Allergic rhinitis: prescription antihistamine treatments

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ARIA Guidelines recommend a 2<sup>nd</sup> generation AH that does not cause sedation and does not interact with the cytochrome P450 system as a first-line treatment option for all severities of intermittent AR and mild persistent AR.<sup>4</sup> (Figure 1)

## Sedation

The sedation rates from the product monographs of each of the available prescription 2<sup>nd</sup> generation AHs are shown in figure 2.<sup>5-7</sup> Both bilastine and rupatadine demonstrated a lower rate of somnolence than cetirizine, with bilastine’s rate of somnolence being comparable to placebo.<sup>5-7</sup>

## Interaction with cytochrome P450

Comparing the metabolism of the prescription antihistamines, rupatadine is metabolized by the cytochrome P450 system, cetirizine is less extensively metabolized and bilastine is not metabolized, meaning it does not interact with other drugs metabolized via the CYP450.<sup>5-7</sup> Bilastine can therefore be given to patients with kidney or liver impairment without dose adjustment whereas the dose of cetirizine needs to be adjusted and rupatadine is not recommended in patients with kidney or liver impairment.<sup>5-7</sup>

**Figure 1. ARIA 2010 Treatment Recommendations for Allergic Rhinitis in Adults<sup>4</sup>**

	Recommended	Suggested	Not Suggested
<b>Allergen avoidance</b>			
Animal dander	●		
Indoor moulds		●	
Occupational allergens	●		
<b>First generation oral H<sub>1</sub>-antihistamines</b>			
			●
<b>Second generation oral H<sub>1</sub>-antihistamines</b>			
New generation H <sub>1</sub> -antihistamines that do not cause sedation and do not interact with cytochrome P450	●		
New generation H <sub>1</sub> -antihistamines that cause some sedation and/or interact with cytochrome P450		●	

## Pharmacodynamics

Bilastine's onset of action is 1 hour post-dose and lasts for 26 hours.<sup>5</sup> Cetirizine's onset is within 20-60 minutes and lasts for at least 24 hours post-dose.<sup>6</sup> Similarly, onset of action of rupatadine occurs within 1-2 hours post-dose.<sup>7</sup>

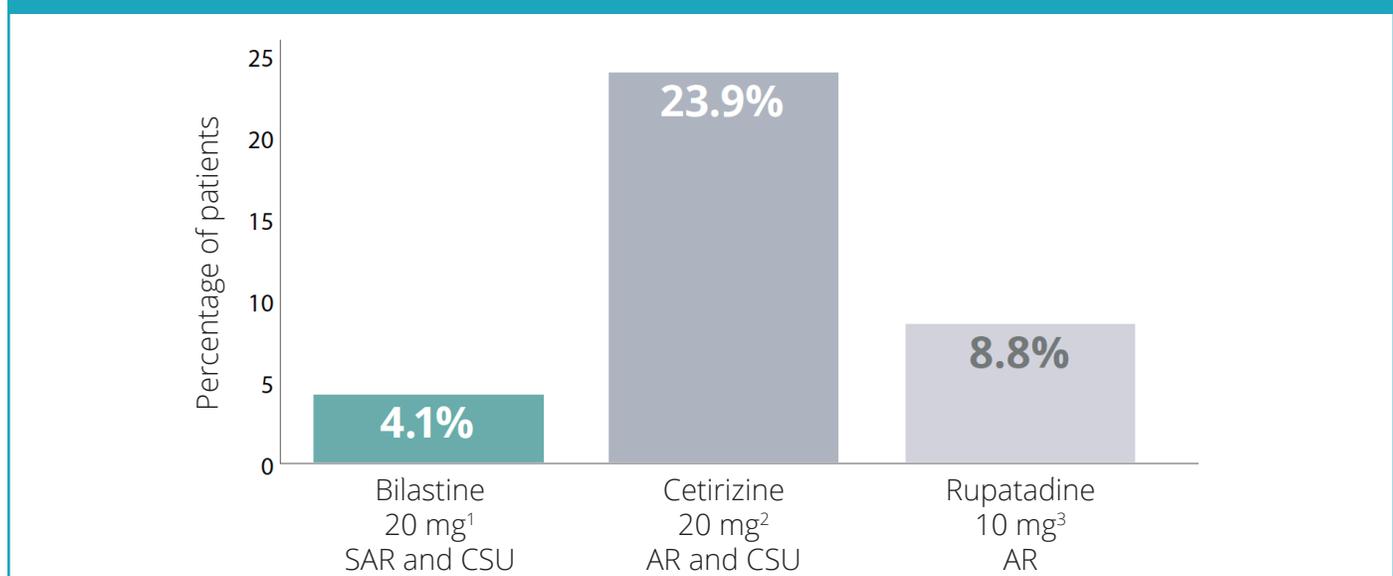
## QT prolongation

The potential for QT prolongation is a class effect of all antihistamines. As such, all 2<sup>nd</sup> generation AHs are contraindicated in patients with a history of QT prolongation including congenital long QT syndromes, and/or torsade de pointes.<sup>5-7</sup>

## Indications and Contraindications of Prescription 2<sup>nd</sup> Generation Antihistamines<sup>5-7</sup>

Indications	
	<b>Allergic Rhinitis</b>
OD Bilastine 20 mg	Seasonal allergic rhinitis ≥ 12 yrs
OD Cetirizine 20 mg	Seasonal allergic rhinitis & perennial allergic rhinitis ≥ 12 yrs
OD Rupatadine* 10 mg	Seasonal allergic rhinitis & perennial allergic rhinitis ≥ 12 yrs
* Children 2-11 years of age, dosage based on weight	
Contraindications*	
Bilastine	• History of QT prolongation and/or torsade de pointes
Cetirizine	• Renal impairment: CrCl < 10 ml/min
Rupatadine	• History of QT prolongation and/or torsade de pointes • Use with CYP3A4 inhibitors • Use with other QTc-prolonging drugs
* All are contraindicated in patients with a hypersensitivity to the drug or to any ingredient in the formulation or component of the container.	

Figure 2. Somnolence rates of the prescription 2<sup>nd</sup> generation AHs from product monographs<sup>5-7</sup>



# Allergic rhinitis: prescription antihistamine treatments

Continued from page 15

## Metabolism

Bilastine <sup>5</sup>	Cetirizine <sup>6</sup>	Rupatadine <sup>7</sup>
<ul style="list-style-type: none"> <li>Not metabolized</li> </ul>	<ul style="list-style-type: none"> <li>Less extensively metabolized than other antihistamines</li> </ul>	<ul style="list-style-type: none"> <li>Metabolized by cytochrome P450 (CYP 3A4)</li> <li>Metabolites include desloratadine</li> </ul>

## Dosing in kidney and liver disease

Bilastine <sup>5</sup>	Cetirizine <sup>6</sup>	Rupatadine <sup>7</sup>
<ul style="list-style-type: none"> <li>No dose adjustment for patients with kidney or liver impairment</li> </ul>	<ul style="list-style-type: none"> <li>Dose adjustment in patients with moderate kidney or liver impairment</li> </ul>	<ul style="list-style-type: none"> <li>Not recommended in patients with kidney or liver impairment</li> </ul>

## Overview of Bilastine: a novel 2<sup>nd</sup> generation antihistamine

Bilastine is a novel 2<sup>nd</sup> generation antihistamine used by over 113 million patients in over 118 countries around the world. Bilastine has been available in Canada since January 2017 and is also approved in Europe for children 6 to 11 years age for seasonal and perennial allergic rhino-conjunctivitis.

### Efficacy in AR

Two phase III studies investigated the efficacy and safety of bilastine compared to cetirizine and desloratadine.<sup>8-9</sup> There was no significant difference in the change in total symptom score between the bilastine and cetirizine treatment arms or bilastine and desloratadine arms. However, bilastine demonstrated a significantly lower incidence of somnolence and fatigue compared to cetirizine.

### Safety and Tolerability

At the recommended dose of 20 mg once daily, bilastine's treatment-emergent adverse reactions, including somnolence, were equal to placebo.<sup>5</sup> At doses up to double the recommended dose (40 mg), bilastine, did not affect psychomotor performance and did not affect driving performance in a standard car driving test.<sup>5</sup>

Bilastine's cardiac safety was assessed in a robust QT study and showed no clinically significant impact on the QTc interval at both therapeutic and suprathreshold doses.<sup>5</sup>

## Conclusion

The use of 1<sup>st</sup> generation AHs is no longer recommended by the CSACI and ARIA guidelines.<sup>2,3</sup> In their place, ARIA guidelines recommend a 2<sup>nd</sup> generation AH that is non-sedating and does not interact with the cytochrome P450 system.<sup>4</sup>

Bilastine is the only prescription 2<sup>nd</sup> generation antihistamine available in Canada that meets both these criteria.

Bilastine has shown comparable efficacy to other 2<sup>nd</sup> generation AHs with sedation less than cetirizine and comparable to placebo.<sup>5</sup>

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2. Brozek JL et al. Allergic Rhinitis and its Impact on Asthma (ARIA) Guidelines - 2016 Revisions. *J Allergy Clin Immunol* 2017;140:930-958.
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7. PEDIAPHARM INC., Rupall (rupatadine) product monograph, January 2017.
8. Bachert C, et al. Comparison of the efficacy and safety of bilastine 20 mg vs desloratadine 5 mg in seasonal allergic rhinitis patients. *Allergy.* 2009;64(1):158-65.
9. Kuna P et al. Bilastine International Working Group. Efficacy and safety of bilastine 20 mg compared with cetirizine 10 mg and placebo for the symptomatic treatment of seasonal allergic rhinitis: a randomized, double-blind, parallel-group study. *Clin Exp Allergy.* 2009;39(9):1338-47.

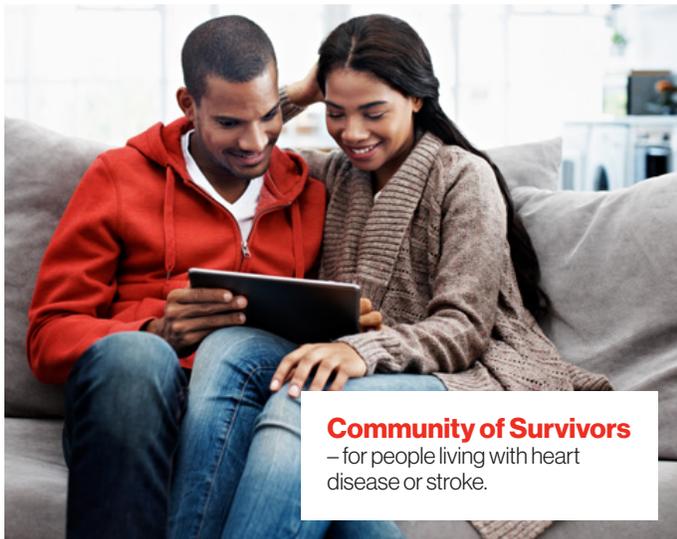


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# Chronic musculoskeletal pain – the SPACE trial

Chronic musculoskeletal pain is an unfortunately common concern seen in primary care clinics. Chronic pain is often difficult to treat and opioids have become common to help patients manage pain. In the midst of an opioid crisis, many in Canada are questioning whether opioids are in fact the best way to manage chronic pain and their use/overuse. The SPACE trial set out to compare the effects of opioid analgesia to non-opioid analgesia in a population of moderate to severe musculoskeletal chronic pain sufferers over a 12-month period. The authors hypothesized that opioids would provide better pain management but with increased medication side effects.

## Trial design

In order to more closely represent a primary care population, the researchers chose a pragmatic trial design. Thus, participant eligibility was broadened to encourage a diversity of patients. There was flexibility in intervention selection and participants were also able to continue to participate in non-pharmacologic treatment modalities.

## Participants

Patients with chronic back, knee or hip osteoarthritis pain, rated as moderate to severe despite analgesia use, were eligible. Participants met the criteria for chronic pain as defined if they had daily pain for 6 months or longer with a score of 5 or greater on the 3-item pain

intensity scale, interference with enjoyment of life, and interference with general activity. Patients on long term opioid therapy were excluded as well as those who were unable to tolerate or were allergic to the medications prescribed in the trial.

“

The trial set out to examine the effectiveness of opioid compared to non-opioid analgesia on chronic musculoskeletal pain in a primary care setting.

”

## Setting

Participants were recruited from Veterans Affairs primary care clinicians in Minnesota, USA (n=62). Participants were initially identified by electronic health record query for diagnosis of low back, knee or hip pain in the prior month and then screened by telephone for eligibility and consent.

## Participants

In total, 240 participants were randomized and 119 participants in each arm of the trial were included in the final analysis. Participants were also stratified in order to have an even representation of back pain and osteoarthritis pain in each arm of the trial.

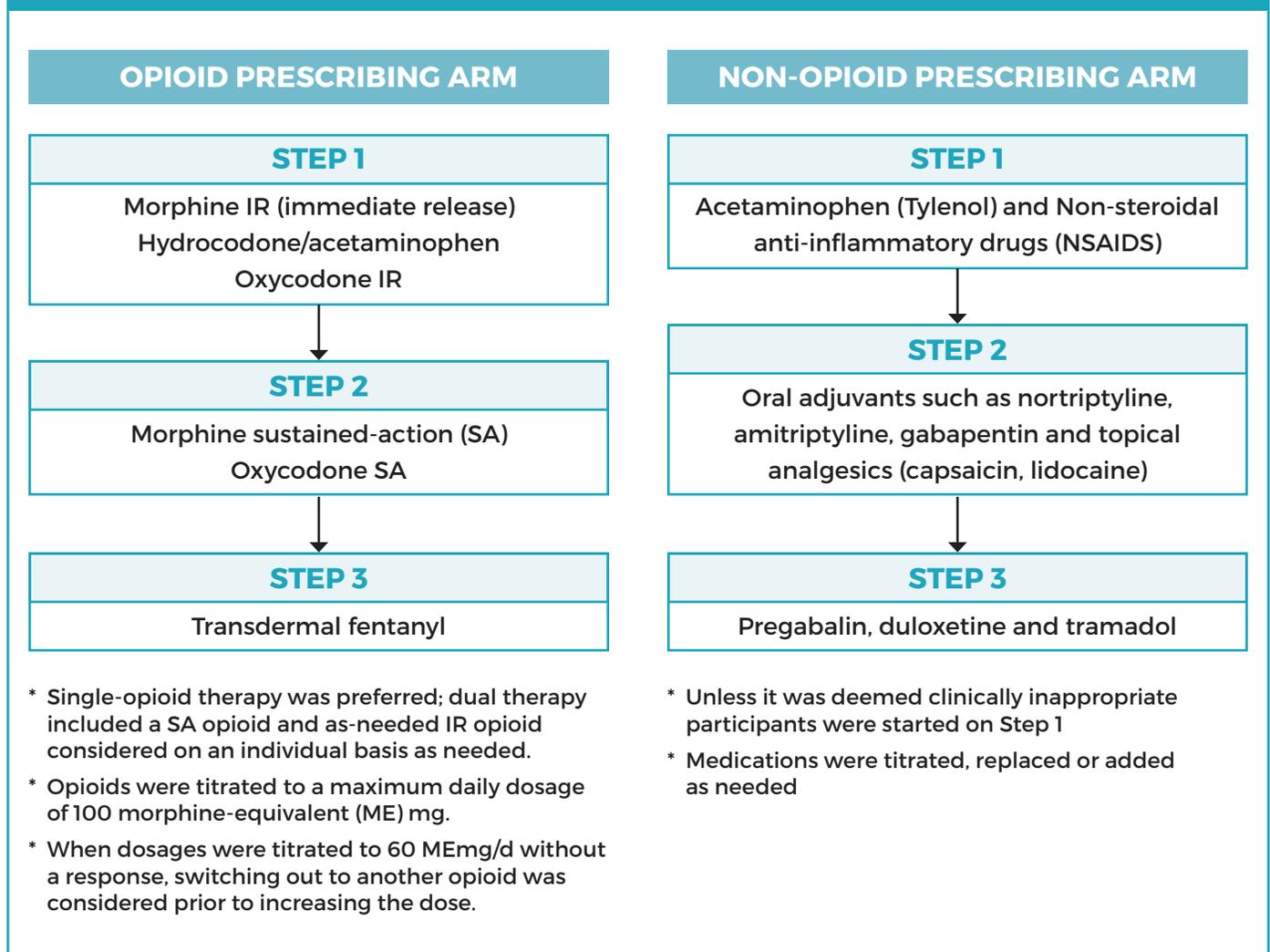
## Intervention

The trial consisted of two intervention arms; opioid analgesia and non-opioid analgesia (Figure 1). Each arm included a 3-step prescribing approach done primarily by a single pharmacist. All participants reviewed their

medication history and functional goals with the pharmacists and received information about how to monitor symptoms. The pharmacist held monthly visits with participants until symptoms were stabilized with follow-ups every 1 to 3 months, many conducted over the phone. All participants received in-person follow-up at 6 and 12 months.

Medication adherence was documented through follow up calls with patients and through the state pharmacy registry. Participants were also advised to only use medication provided by the study pharmacy for their back, knee, or hip pain.

**Figure 1.** Intervention arms of SPACE trial



Continued on page 20

# Chronic musculoskeletal pain – the SPACE trial

Continued from page 19



## Outcomes

The main outcomes were pain related function and pain intensity. Pain related function was assessed using the 7-item Brief Pain Inventory (BPI) scale and intensity was measured using the 4-item BPI Severity scale. These two scales each result in a 0-10 score with the higher the score the greater the pain or intensity. Drawing on previous chronic pain research the minimal clinically important difference (MCID) in the BPI scores would need to be 0.7. The SPACE group determined they would use a 1 point MCID in both intensity and severity and a 30% reduction in BPI scores from baseline to indicate moderate improvement.

The primary adverse outcome assessed was a 19-item self-report of medication adverse outcomes, including common side effects common to analgesics.

Secondary health outcomes included measures of mental health, quality of life, substance use, sleep and general health.

Prior to being randomized participants were also asked about their preference for treatment and this was recorded and included in the final analysis.

## Adverse Outcomes

Adverse outcomes were monitored through electronic health records (EHRs). EHRs were reviewed for emergency department visits and hospitalizations and these events were then assessed to determine if they were related to the analgesia use. State pharmacy databases were also reviewed to assess for medication misuse or overuse. Furthermore, patients were asked substance misuse screening questions at follow ups and drug tests were performed at 6 and 12 month visits.

## Summary of Results

Over the 12 months of the study there was no statistical difference in the pain-related function between the two groups ( $p = 0.58$ ). Pain intensity was significantly improved in the non-opioid treatment arm vs opioid arm ( $p=0.03$ ). A significant number of participants in the non-opioid group also showed a  $\geq 30\%$  improvement from baseline in pain severity ( $p=0.05$  vs. opioid group).



Overall, opioids did not demonstrate any advantage over non-opioid medications that could potentially outweigh their greater risk of harms.



There were no statistically significant differences in the measures of physical health, quality of life or overall mental health though the subscale for anxiety did show a difference in favour of the opioid group ( $p=0.02$ ). This is not surprising given the profile of the opioids; also important to note that only 9% of the study participants exhibited anxiety.

Primary adverse outcome as recorded through self reports indicated significantly fewer medication related symptoms in the non-opioid group at 12 months ( $p=0.03$ ).

There were no differences in incidence of adverse outcomes, nor was there any significant difference in medication overuse or misuse. The study was not powered to identify opioid use disorder or opioid related death.

Medication adherence was equivalent between the groups and a strength of the study was the pragmatic design which meant that strict adherence wasn't required, there was flexibility in choosing, adding or changing medications and doses were adjusted in a "treat to target" approach, all of which are reflective of primary care.

The authors conclude that non-opioid analgesia is a reasonable route for most patients and that given the increased medical related symptoms patients in the opioid arm of the study experienced, initiating opioid therapy is not supported.

“

Treatment with opioids was not superior to treatment with non-opioid medications for improving pain-related function over 12 months. Results do not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain.

”

### Limitations

The authors clearly point to the lack of gender diversity in the study participants; though this is reflective of the Veterans population it does not reflect the general population. Another limitation for clinicians to be mindful of is that those who were previously on long-term opioids were excluded from the study and so the findings here cannot be generalized to that group.



### Call for Contributions

At NP Current we want to reflect the needs and interests of nurse practitioners across Canada. We are seeking your ideas and contributions on any topics that would be of interest to the NP community. In each issue we will strive for a mix of content that addresses diagnosis, treatment, prevention and management of patients from the NP perspective.

We invite you to submit your ideas for new articles such as case studies, research, reports or newsworthy information from your practice or area of expertise or interest. Contact NP Current at [info@npcurrent.ca](mailto:info@npcurrent.ca) and your contributions can help to inform and educate your peers.

# The ComPARE Study: implications for cancer prevention

An estimated 226,000 Canadians will be diagnosed with cancer in 2020, and it is the leading cause of death, with a projected 83,300 deaths from cancer this year.<sup>1</sup> Cancer accounts for 30% of all deaths in Canada, almost 50% more deaths than heart disease. Research into modifiable or preventable risk factors that contribute to cancer incidence is the key to developing effective public health policies and cancer risk reduction programs that will have the greatest impact on cancer incidence and mortality.

The results of the Canadian Population Attributable Risk of Cancer (ComPARE) Study<sup>2</sup> highlight the potential for cancer prevention in reducing the overall burden of disease, with implications for nurse practitioners as promoters of health in their practices. A collaboration between the Canadian Cancer Society and a team of Canadian researchers, the ComPARE Study examined 30 cancer types and identified their preventable risk factors. In doing so, the

authors hoped to identify the factors that drive cancer incidence so that cancer prevention initiatives can be most effectively targeted, designed and implemented.

The ComPARE Study is the first Canadian comprehensive estimate of cancers with modifiable risk factors. Overall, the results showed that, in 2015, between 33% and 37% of all incident cancers in Canada, roughly 70,000 cases, could be attributed to preventable risk factors (Table 1). The three most prevalent cancer types with the highest number of preventable cases were lung, colorectal and breast cancers.

Of the twenty preventable risk factors examined in the study, the top 3 risk factors contributing to cancer incidence were:

- Tobacco smoking (17.5%)
- Lack of physical exercise (4.9%)
- Excess body weight (3.1%)

**Table 1.** Preventable risk factors

Cancer type	Number of incident cases attributable to modifiable risk factors	Percent attributable to modifiable risk factors
Lung	20,100	80%
Colorectal	9,800	43%
Breast	5,300	21%

## What do these numbers mean for the future cancer burden?

The ComPARE Study projected future cancer burden in 2042, based on their results and current trends in exposure prevalence. Of the estimated 102,000 future incident cases of cancer in 2042, roughly 11,000 cases could be prevented with relatively modest modifications to risk factors including:

- reduction of excess weight by 5%;
- reducing average daily intake of processed meat and red meat by 0.2 and 0.5 servings;
- maintaining current HPV vaccination direct coverage of 72.4%;
- a reduction of 10% for active and passive smoking, alcohol consumption, inadequate physical activity, sedentary behavior, low fruit and vegetable consumption, and UV radiation exposure,
- 10% population-wide reduction in the current prevalence of HBV, HCV, and *Helicobacter pylori*.

The projected future cancer burden might be reduced by as many as 40,000 incident cases with ambitious increased impacts on preventable risk factors, including reducing excess weight estimates by 25%, increasing HPV vaccination coverage to 80%, and reducing the risk factors mentioned above by 50% rather than 10% at the population level.

The results of the ComPARE Study highlight the potential impact of health promotion on cancer risk factors at the population level to reduce the overall cancer burden in Canada. The study identifies and emphasizes the role of preventable or modifiable risk factors, especially smoking, excess weight and inactivity. Strategies to reduce the impact of these three factors can make a large impact on the health of Canadians.

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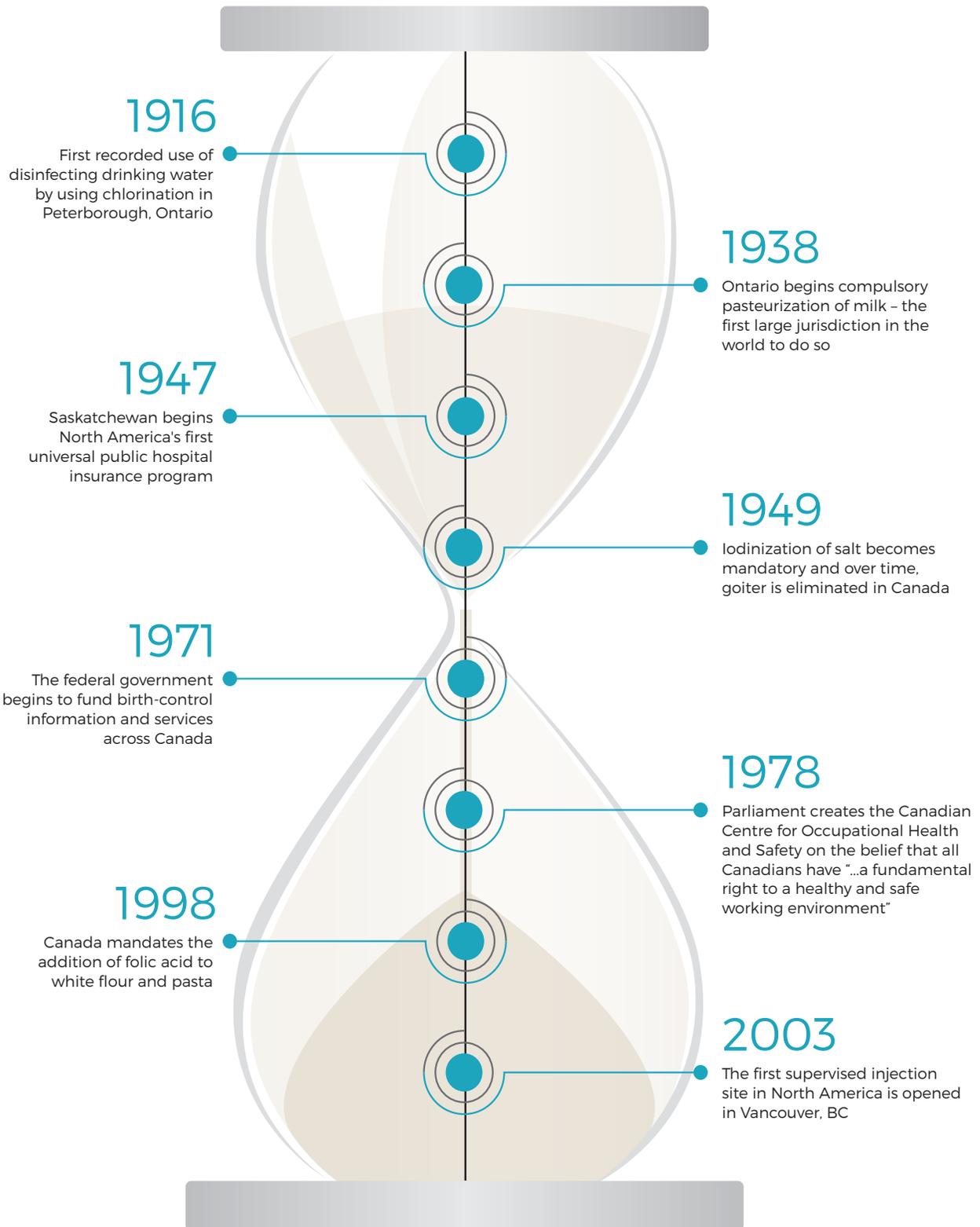
## RESOURCE FOR PATIENTS

### Its My Life

- Website developed by the Canadian Cancer Society in partnership with Desjardins
- Useful resource for Canadians to learn about what causes cancer and how they can reduce their risk with practical information

[itsmylife.cancer.ca](http://itsmylife.cancer.ca)

# Milestones: Public health in Canada<sup>1</sup>



1. Canadian Public Health Association, <https://www.cpha.ca/milestones-acting-social-determinants-health>

Pr **BLEXTEN**<sup>®</sup>



A study was performed to assess the effects of BLEXTEN<sup>®</sup> and bilastine 40 mg on real time driving performance compared to placebo and hydroxyzine 50 mg. Bilastine did not affect driving performance differently than placebo following day one or after one week of treatment. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.<sup>1</sup> BLEXTEN<sup>®</sup> is only indicated for use at 20 mg once daily.<sup>1\*</sup> Note: Hydroxyzine is not indicated for the treatment of allergic rhinitis.

#### **Indication**

BLEXTEN<sup>®</sup> (bilastine) is indicated for the symptomatic relief of nasal and non-nasal symptoms of seasonal allergic rhinitis (SAR) in patients 12 years of age and older and for the relief of the symptoms associated with chronic spontaneous urticaria (CSU) (e.g. pruritus and hives), in patients 18 years of age and older.

#### **Contraindication**

- History of QT prolongation and/or torsade de pointes, including congenital long QT syndromes

#### **Relevant warnings and precautions**

- QTc interval prolongation, which may increase the risk of torsade de pointes
- Use with caution in patients with a history of cardiac arrhythmias; hypokalemia, hypomagnesaemia; significant

- bradycardia; family history of sudden cardiac death; concomitant use of other QT/QTc-prolonging drugs
- P-glycoprotein inhibitors may increase plasma levels of BLEXTEN<sup>®</sup> in patients with moderate or severe renal impairment; co-administration should be avoided
- BLEXTEN<sup>®</sup> should be avoided during pregnancy unless advised otherwise by a physician

#### **For more information**

Please consult the product monograph at <https://aralez.com/wp-content/uploads/2018/12/Blexten-PM-ENG-13-Dec-2018.pdf> for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.

The product monograph is also available by calling 1-866-391-4503.

<sup>‡</sup> As of March 2018, the estimate of patient exposure is based on units sold, the defined daily dose (DDD) of 20 mg for bilastine and the mean treatment duration of 3 weeks.

\* Clinical significance has not been established.

#### **Reference:**

1. Blexten<sup>®</sup> Product Monograph. Aralez Pharmaceuticals Trading DAC. December 13, 2018.

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**References:** 1. TYLENOL® Prescribing Information. McNeil Consumer Healthcare. May 10, 2017. 2. Instar research, physician analgesic claims, 2015. 3. *The Medical Post and Profession Santé* 2018 Survey on OTC Counselling and Recommendations.

\* Please note that this content is not intended as professional medical or healthcare advice.

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