

CADTH COMMON DRUG REVIEW

# Patient Input

**HALOBETASOL PROPIONATE AND TAZAROTENE (Duobrii)**

(Bausch Health, Canada Inc.)

Indication: Psoriasis, moderate to severe plaque

CADTH received patient input from:

**Canadian Psoriasis Network (CPN), Canadian Skin Patient Alliance (CSPA) and the Canadian Association of Psoriasis Patients (CAPP) (Joint Submission)**

February 14, 2020

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CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

## Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	<b>Halobetasol propionate and tazarotene (Duobrii®)</b> for moderate to severe plaque psoriasis
Name of the Patient Group	Canadian Psoriasis Network (CPN), Canadian Skin Patient Alliance (CSPA) and the Canadian Association of Psoriasis Patients (CAPP)
Author of the Submission	[REDACTED]
Name of the Primary Contact for This Submission	[REDACTED]
Email	[REDACTED]
Telephone Number	[REDACTED]

### 1. About Your Patient Group

CPN is working in collaboration with CSPA and CAPP for the completion of this submission. The CSPA is a registered patient group with CADTH.

CPN is a national, not-for-profit organization dedicated to improving the quality of life of Canadians who live with psoriasis and psoriatic arthritis. We do this by providing current information on research and treatment options and by working with others to build awareness and advocacy about the complexities of these conditions.

CSPA is a national not-for-profit organization dedicated to educating, supporting and advocating on behalf of Canadians living with diseases, conditions and traumas that affect skin, hair and nails. Our mission is to promote skin health and improve the quality of life of Canadians living with skin disorders.

CAPP is a national, not-for-profit formed to better serve the needs of psoriasis patients across the country. CAPP is a partner organization of CSPA and strives to improve the quality of life for all Canadian psoriasis patients. CAPP's mission is to be a resource and advocate for psoriatic patients and their families to improve patient care and quality of life.

### 2. Information Gathering

There were no clinical trials for Duobrii® conducted in Canada, thus our reach to individuals who have experience with this product was limited.

The information in this submission has been gathered from the following sources:

- Survey about topical treatments run by CPN in English only from January 27 – February 15, 2019 that was promoted through CPN’s membership list and social media channels and resulted in 61 responses. A section for respondents who had experience with Duobrii<sup>®</sup> was included, but it did not elicit any responses. Just over half of survey respondents (51%) identified their condition as “well-controlled”, 30% said “poorly controlled” and 5% said “not controlled at all”. The rest indicated that they fall somewhere in between. Just over half had psoriasis for over 20 years (53%). Respondents were from British Columbia, Alberta, Manitoba, Saskatchewan, Ontario, Quebec, Newfoundland-Labrador and Nova Scotia.
- Survey about gaps in topical treatments for psoriasis led by CAPP in English only from January 24 – February 22, 2019. It was promoted on CAPP’s social media channels and resulted in 212 responses. Approximately half of the respondents were more than 55 years old (52.1%, n=110) while slightly less than half (46.0%, n=97) were between working age adults. All provinces were represented in the survey, with 35% from Ontario (n=74), 15.6% from Nova Scotia (n=33) and 14.2% from British Columbia (n=30).
- A second survey run by both CPN and CAPP from January 2 – February 10, 2020 targeting only people who had used Duobrii<sup>®</sup>. The survey was promoted through both organizations’ social media channels, featured on CPN’s website and included in an e-newsletter by the National Psoriasis Foundation in the US that launched with very limited time before this submission due date. We received three responses to this survey from people who live in the US.
- CPN and CAPP also heard extensively from the psoriasis population in Canada about the challenges of managing their psoriasis symptoms in our report [Journey to Stability](#).

### 3. Disease Experience

Plaque psoriasis is a chronic inflammatory skin condition that affects the regeneration of skin cells. Normal skin cell regeneration takes 28-30 days; with psoriasis, faulty signals in the body’s immune system trigger new skin cells to form in 3-4 days instead. Because the skin cells grow too quickly, they are not shed normally. Instead, they pile up on the skin’s surface, creating sores or lesions – commonly called plaques. Thick, silvery scales form atop these itchy and sometimes painful inflamed plaques.

Psoriasis usually affects the elbows, knees and scalp, but it can also occur on the palms of the hands, soles of the feet, nails, genitals and torso. Psoriasis is a persistent, chronic condition that may wax and wane – flare up then go into remission. During flare-ups, the inflamed skin is itchy and painful. Under this stress, the skin may crack and bleed.

Psoriasis can range from a few dandruff-like scales to widespread patches that cover large areas of skin. For some people, psoriasis is manageable. For others, it’s a painful and disabling condition. Many oscillate between these experiences throughout the course of their lives with the condition.

Findings from a survey that informed CPN and CAPP’s “Journey to Stability” report, which examined patients’ efforts to achieve stability of symptoms, confirmed that many people with psoriasis perceive their condition to be uncontrolled. In fact, 38% (n=286) of English respondents have lived for 10 or more years feeling that their condition was not satisfactorily controlled. The length of time survey respondents’ lived with psoriasis ranged from 2-55 years.

Nearly half of the respondents to CAPP’s survey on the gaps in topical treatments responded that they lived with psoriasis for over 20 years (44.8%, n=94), while a quarter lived with the disease for between 10-20 years (25.2%, n=53), 16% (n=34) for between five to 10 years and nearly 14% (n=29) for fewer than five years.

The survey respondents that informed the “Journey to Stability” report identified lack of self-esteem, loss of sleep, anxiety, depression, fear of intimacy and avoidance of social activities as part of their experience living with this condition.

People with psoriasis are also at higher risk of certain health conditions than the general population. In CPN’s survey about topical treatments, for example, 46.7% (n=28) of respondents indicated that they experience joint pain; 23.3% (n=14) experience depression; 13.3% (n=8) live with heart disease; and 11.7% (n=7) reported having diabetes.

Respondents to this survey also highlighted the impact that psoriasis has on their family members. The top three concerns identified by respondents related to their family members included: worrying about their condition (61.2%, n=30), intimacy challenges (34.7%, n=17) and avoiding activities (24.5%, n=12). In terms of effects on their family and interpersonal relationships, several people living with psoriasis also shared that they experienced “stress and time issues” and “frustration”; that they had to “clean up plaques around the house after they fell off” and that they “didn’t want people to see or even know about the more private areas where [they] have psoriasis”.

#### 4. Experiences With Currently Available Treatments

Eight-five percent of the respondents to CAPP’s survey about gaps in topical treatments were using a topical treatment at the time of the survey (n=177). Respondents shared that they were using Dovobet (17.4%, n=26), betamethasone (14.8%, n=22), clobetasol (11.4%, n=17), Enstilar (7.4%, n=11), Dovonex (6%, n=9), cortisone (5.4%, n=8), as well as Diprosalic, Elidel, Lamisil, Lyderm, ultravate, Fucidin and tar. Responses also included non-prescription moisturizers, essential and coconut oils, Epsom salts baths, and other products. Several respondents also reported using or having tried multiple products. Notably, nearly 1 in 10 respondents came to their current topical treatment through their own trial and error (9.2%).

Respondents to CAPP’s survey on the gaps in topical treatments described the benefits and disadvantages of using topical treatments they were currently using: less than half were confident their topical treatment was working (46.7%) and one-fifth (21.1%) were not confident that this was the case. Slightly more than a third (37.1%) felt their treatment was effective, while nearly the same number (31.8%) felt their topical treatment was ineffective. Half of respondents (50.3%) felt that their topical treatment took too long to work and a quarter disagreed (26.5%).

In a separate question, when asked to identify why they stopped using a topical treatment in the past, more than half (56.4%) of CAPP survey respondents said the treatment did not work or was ineffective and 7.7% said it stopped working. Other reasons for discontinuing a previously used topical included: change of treatment (2.6%), side effects (13.7%), difficulty of use (8.5%), cost (6%), and unavailability of the product (3.4%).

Half of respondents felt their topical was safe to use (50.3%), however nearly half (44.74%) worried about side effects. Nearly half of respondents felt their topical was expensive (46.6%); one-third (32.5%) felt their topical was good value while one-quarter (25.2%) did not. Three-quarters of respondents (78.4%) felt that their

topical was easy to use while roughly one-tenth (10.9%) disagreed. Nearly half of respondents found their topical to be messy (48%) and slightly over half (55.9%) agreed it was pleasant to use, in terms of odour and texture.

Of the 56 respondents to a question in CPN’s survey about what challenges (if any) they have had with using topical treatments, survey respondents identified the following: inconvenient (e.g., greasy, time-consuming) (78.6%), side effects (e.g., redness, soreness, thinning skin, pain/burning) (46.4%) and stopped working after some time (46.4%).

Treatment options that can effectively reduce symptoms and that are well-tolerated are welcome, especially because people report building a tolerance to treatments over time.

Of the 55 patients who responded to a question about other psoriasis treatments that they have tried, 42.3% said they have used over-the-counter topicals, phototherapy (49.1%), oral medications (41.8%), and biologics (41.8%). When asked if they have needs that have not been met by treatments they have used, we heard the following highlights:

- “None of the treatments last for very long.”
- “As a cancer survivor, I can’t take any biologics so my options are limited. As well [I] don’t have a dermatologist [and] I have to rely on a family doctor.”
- “The closest phototherapy is over an hour away from where I live (in rural Manitoba) and I cannot afford the gas to go there the two or three times a week that I would need to – phototherapy worked best for me. I am trying to get some benefit from [the] tanning bed in town and there is some improvement...[I] see [my] doctor again in a few weeks for [an]8 month follow up.”
- “I am still trying to cope with my skin not [being] completely healed and another summer to cover up.”
- “Psoriasis is spreading throughout my body. The ointments/shampoo clear up one area but it breaks out in a new area. When I stop using a product for a while the psoriasis returns.”
- “Would like to try some of the drugs from the states.”
- “The flaking/scaling and redness/itchiness never actually goes away – particularly on my face.”
- “Plaques not going away, finger nails discoloring and at times nails crumble, bottom of feet are peeling and at times are tender to walk on.”
- “Currently not cleared up.”

Notably, 10 respondents indicated “no” or “not really” in answer to this question. There does not seem to be an obvious difference in the types of treatments respondents who answered “no” have tried compared to respondents who have indicated significant unmet needs. The variety of responses may reflect the heterogeneity of people with psoriasis. How people respond to treatment, how they view their condition and how well current treatments are meeting peoples’ needs vary across individuals and across the course of one’s condition.

## 5. Improved Outcomes

When asked, “What aspects of psoriasis are the most important to control in your opinion?” of the 60 people who responded to this question in CPN’s survey about topicals, the majority (88.3%) selected “appearance of plaques”, 76.7% selected “itching”, 41.7% selected “joint pain” (specifically), 26.7% chose “pain” (generally) and 30% selected “depression/anxiety”. Other selections included “stigma”

(35%), bleeding (25%) and related conditions (e.g., diabetes, heart disease) (23.3%). Patients also identified other aspects including “flaking of scalp”, “sleep interruption” and a “burning sensation”.

CAPP survey respondents indicated that they were looking for topical treatments to address the itch (86.1%), the redness (81.5%), the burning sensation (75%) and the pain (64.1%) from their psoriasis. Three-fifths of survey respondents wanted topical treatments to address all their symptoms (61.2%).

Respondents to CAPP’s survey also indicated that they would like a cure or a product that controlled all symptoms of psoriasis. In terms of specific outcomes and factors affecting their use of topical treatment, respondents indicated they would like to see a treatment that relieves symptoms faster; is “a more effective natural approach”; “works better on scalps”; reduces scales; reduces scars; doesn’t thin the skin; controls psoriasis while in remission but does not include a steroid; works for both the rash and the pain associated with psoriasis; has a better applicator, is not as messy when used on the scalp, and is not greasy or smelly; treats nail psoriasis; and is more affordable, especially when treating large parts of the body.

## 6. Experience With Drug Under Review

As mentioned at the beginning of this submission, we received three survey responses from individuals in the US who have used Duobrii<sup>®</sup>. Because there were so few responses, we have provided a snapshot of each of the survey respondents:

Respondent 1 is age 45-54, has had psoriasis for over 20 years and considers their condition to be well-controlled. They experience psoriasis on their arms/elbows and legs/knees. They think that itching and appearance of plaques (in no particular order) are the most important aspects of psoriasis to control. Respondent 1 has had to miss social events, not wear certain types of clothing and has had trouble sleeping due to symptoms of psoriasis. They think that Duobrii<sup>®</sup> does a better job of managing their itchiness and controlling appearances of plaques (number, size, thickness, scaling) than previous treatments they have used. They did not identify any symptoms that Duobrii<sup>®</sup> *does not* manage as well as previous treatments they have used. When asked, “did you experience any side effects when using Duobrii<sup>®</sup>?” they selected skin thinning. Respondent 1 indicated that Duobrii<sup>®</sup> is “very good” compared to previous treatments they have tried and that it “works fast”.

Respondent 2 is age 45-54, has had psoriasis for over 20 years and considers their condition to be well-controlled. They experience symptoms on their arms/elbows, scalp, feet and palms. They think that pain, itchiness and appearance of plaques (in no particular order) are the most important aspects of psoriasis to control. They indicated that Duobrii<sup>®</sup> does a better job of managing the appearance of plaques (number, size, thickness, scaling) compared to previous treatments they have used. They did not identify any symptoms that Duobrii<sup>®</sup> *does not* manage as well as previous treatments they have used. When asked, “did you experience any side effects when using Duobrii<sup>®</sup>?” they selected skin thinning.

Respondent 3 is age 19-24, has had psoriasis for under one year and considers their psoriasis to be poorly controlled. Their arms/elbows, legs/knees, scalp, back and face are affected. They identified itching, appearance of plaques, depression/anxiety and stigma (in no particular order) as the most important aspects

of psoriasis to control. Respondent 3 has had to miss social events and refrained from wearing certain types of clothing due to symptoms of their psoriasis. They indicated that Duobrii<sup>®</sup> manages their itchiness better than previous treatments they have tried and they noted that Duobrii<sup>®</sup> is easier to apply, though it took more time for their plaques to disappear compared to other steroids. When asked, “did you experience any side effects when using Duobrii<sup>®</sup>?” they selected appearance of stretch marks, skin irritation and dryness.

All respondents identified the following general challenges with past use of topical treatments for psoriasis: cost (100%), side effects (e.g., redness, soreness, thinning skin, pain/burning) (100%), inconvenience (e.g., greasy, time-consuming) (100%) and stopped working after some time (100%). Respondent 3 who has had psoriasis for less than one year also identified “uncertainty that they are using it properly” as a challenge.

## 7. Companion Diagnostic Test

**Not applicable**

## 8. Anything Else?

Psoriasis is complicated, frustrating condition that can be debilitating without access to appropriate treatments. Patients vary in their responses to lifestyle choices, to topical treatments and to other therapies. What works for one patient, may not work for the other, even if their symptoms are very similar. Moreover, a person’s condition and needs can change over time and throughout the course of their lives.

As such, having access to treatment options is fundamentally important to our organizations. We believe that access to a range of safe, effective and affordable treatments is key to effectively treat psoriasis patients.

Psoriasis is much more than “just” a skin disease. It is estimated that up to 30 percent of people with psoriasis develop psoriatic arthritis. People with psoriatic disease also are at greater risk of developing cardiovascular disease, depression and other health conditions such as [cancer](#), [diabetes](#) and [cardiovascular disease](#).

For more information about the challenges of living with psoriasis, please see CAPP’s recent report called “[Pso Serious 2018: A Report on Access to Care and Treatment for Psoriasis Patients in Canada](#)”. You can also visit our websites: [cpn-rcp.com](#) and [canadianpsoriasis.ca](#) for resources and information about living with this condition.

Ultimately, patients want a cure. Psoriasis patients must constantly manage a range of visible and invisible symptoms. There is a need for new medicines to better treat itchiness, redness, flaking and other symptoms of psoriasis. For those living with both psoriasis and psoriatic arthritis, multiple options need to be available to address the distinct symptoms of both diseases.



## Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

**Not applicable to this submission**

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

**Not applicable to this submission**

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
AbbVie				X
Janssen	X			
Pfizer				X
Merck			X	
Novartis			X	
Galderma			X	
Celgene				X
Leo Pharma	X			
UCB	X			
Bausch Health	X			

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Rachael Marion  
 Position: Executive Director  
 Patient Group: Canadian Skin Patient Alliance  
 Date: February 13, 2020

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
AbbVie			X	
Janssen			X	
Amgen		X		
Novartis			X	
Eli Lilly			X	
UCB			X	
Bausch Health (incl. Valeant)			X	
Leo Pharma			X	
Celgene			X	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Rachael Manion  
 Position: Executive Director  
 Patient Group: Canadian Association of Psoriasis Patients  
 Date: February 13, 2020

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Abbvie				X
Janssen				X
Amgen			X	
Novartis			X	
Leo			X	
Pfizer			X	
Bausch Health			X	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Antonella Scali  
 Position: Executive Director  
 Patient Group: Canadian Psoriasis Network  
 Date: February 13, 2020