CASE STUDY

IMOLCET™ DETAIL AID

A MEDICAL COPYWRITING SAMPLE FOR THE PHARMACEUTICAL INDUSTRY

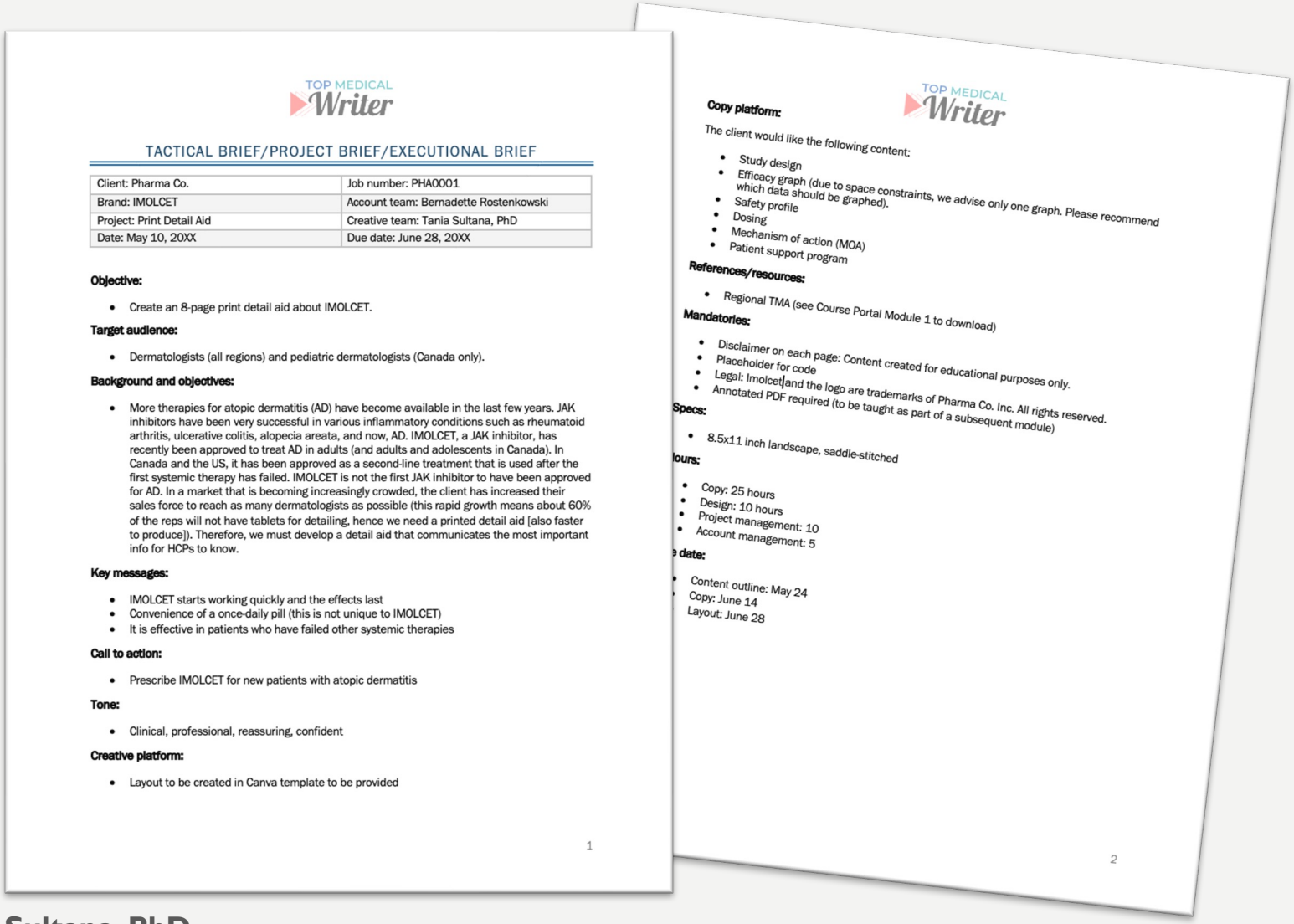
Tania Sultana, PhD

- ✓ CREATIVE BRIEF
- ✓ CONTENT OUTLINE
- ✓ COPY DEVELOPMENT
- ✓ LAYOUT
- ✓ ANNOTATED LAYOUT

A DETAIL AID FROM BRIEF TO LAYOUT

Tania Sultana, PhD

TACTICAL BRIEFING



TOP MEDICAL Writer

TACTICAL BRIEF/PROJECT BRIEF/EXECUTIONAL BRIEF

Client: Pharma Co.	Job number: PHA0001
Brand: IMOLCET	Account team: Bernadette Rostenkowski
Project: Print Detail Aid	Creative team: Tania Sultana, PhD
Date: May 10, 20XX	Due date: June 28, 20XX

Objective:

- Create an 8-page print detail aid about IMOLCET.

Target audience:

- Dermatologists (all regions) and pediatric dermatologists (Canada only).

Background and objectives:

- More therapies for atopic dermatitis (AD) have become available in the last few years. JAK inhibitors have been very successful in various inflammatory conditions such as rheumatoid arthritis, ulcerative colitis, alopecia areata, and now, AD. IMOLCET, a JAK inhibitor, has recently been approved to treat AD in adults (and adults and adolescents in Canada). In Canada and the US, it has been approved as a second-line treatment that is used after the first systemic therapy has failed. IMOLCET is not the first JAK inhibitor to have been approved for AD. In a market that is becoming increasingly crowded, the client has increased their sales force to reach as many dermatologists as possible (this rapid growth means about 60% of the reps will not have tablets for detailing, hence we need a printed detail aid [also faster to produce]). Therefore, we must develop a detail aid that communicates the most important info for HCPs to know.

Key messages:

- IMOLCET starts working quickly and the effects last
- Convenience of a once-daily pill (this is not unique to IMOLCET)
- It is effective in patients who have failed other systemic therapies

Call to action:

- Prescribe IMOLCET for new patients with atopic dermatitis

Tone:

- Clinical, professional, reassuring, confident

Creative platform:

- Layout to be created in Canva template to be provided

1

TOP MEDICAL Writer

Copy platform:

The client would like the following content:

- Study design
- Efficacy graph (due to space constraints, we advise only one graph. Please recommend which data should be graphed).
- Safety profile
- Dosing
- Mechanism of action (MOA)
- Patient support program

References/resources:

- Regional TMA (see Course Portal Module 1 to download)

Mandatories:

- Disclaimer on each page: Content created for educational purposes only.
- Placeholder for code
- Legal: Imolcet and the logo are trademarks of Pharma Co. Inc. All rights reserved.
- Annotated PDF required (to be taught as part of a subsequent module)

Specs:

- 8.5x11 inch landscape, saddle-stitched

lours:

- Copy: 25 hours
- Design: 10 hours
- Project management: 10
- Account management: 5

e date:

- Content outline: May 24
- Copy: June 14
- Layout: June 28

2

Creative brief developed based on market and product insights resulting from a landscape analysis.

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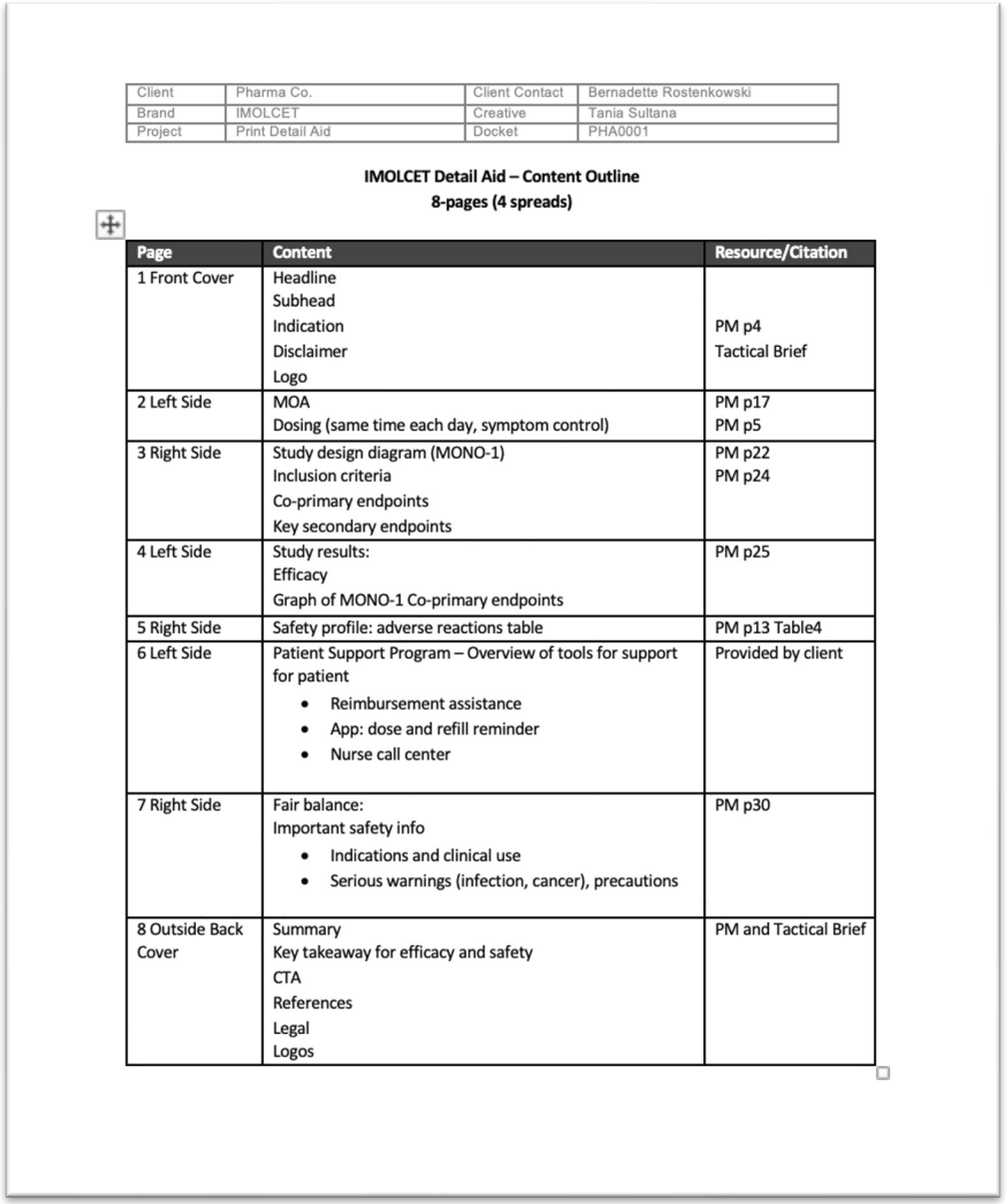
CONTENT OUTLINE

OBJECTIVE

Inform dermatologists and pediatric dermatologists in Canada about the availability of IMOLCET, which can be used as a second line of treatment for patients with moderate to severe atopic dermatitis.

- I chose to include the Monotherapy-1 trial because the efficacy data are aligned with the messages the client wants to emphasize.
- The dosing section highlights that doses can be reduced after symptom control is achieved by week 12.
- I have placed the efficacy data on the left side (p4) and the safety profile on the right (p5) to help physicians weigh faster the benefits vs risks for their patients.



Client	Pharma Co.	Client Contact	Bernadette Rostenkowski
Brand	IMOLCET	Creative	Tania Sultana
Project	Print Detail Aid	Docket	PHA0001

IMOLCET Detail Aid – Content Outline
8-pages (4 spreads)

Page	Content	Resource/Citation
1 Front Cover	Headline Subhead Indication Disclaimer Logo	 PM p4 Tactical Brief
2 Left Side	MOA Dosing (same time each day, symptom control)	PM p17 PM p5
3 Right Side	Study design diagram (MONO-1) Inclusion criteria Co-primary endpoints Key secondary endpoints	PM p22 PM p24
4 Left Side	Study results: Efficacy Graph of MONO-1 Co-primary endpoints	PM p25
5 Right Side	Safety profile: adverse reactions table	PM p13 Table4
6 Left Side	Patient Support Program – Overview of tools for support for patient • Reimbursement assistance • App: dose and refill reminder • Nurse call center	Provided by client
7 Right Side	Fair balance: Important safety info • Indications and clinical use • Serious warnings (infection, cancer), precautions	PM p30
8 Outside Back Cover	Summary Key takeaway for efficacy and safety CTA References Legal Logos	PM and Tactical Brief

COPY DEVELOPMENT

Project Details		
Client	Pharma Co.	Clie
Brand	IMOLCET	Cre
Project	8-page Detail Aid	Doc

[blue text]: Paragraph styles or design notes
[red text]: Reference paths
[pink text]: Variable copy
[green text]: Links or functionality notes

Version	Date	Comment
1	27Jun 20XX	Initial copy de
2	7 Aug 20XX	Internal Revis

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[PAGE 1 – FRONT COVER]

[Logos]
<PrIMOLCET® Imocitinib tablets>

[Headline]
Demonstrated efficacy in treating refractory atop

[Subhead]
With 62.7% EASI-75 responders compared to th
24B]

[Indication and boxed warning]
IMOLCET is indicated for the treatment of patien
atopic dermatitis, including the relief of pruritus,
systemic drugs (e.g., steroid or biologic), or for
4A]
IMOLCET can be used with or without medicate

[Abbreviations]
EASI, Eczema Area and Severity Index; IGA, In
Pruritus Numerical Rating Scale; PSAAD, Prurit
Dermatitis.

[Footnotes]
* A double-blind, placebo-controlled Phase 3 tria
safety of IMOLCET in patients ≥12 years of age
patients complying with the inclusion criteria wer
mg (n=146), 220 mg (n=154), or placebo (n=71)
endpoints were IGA 0/1 and EASI-75 responses
were PP-NRS4 and PSAAD change at week 12.
responders were patients with IGA scores of cle
and a reduction from baseline of ≥2 points. EAS
improvement in EASI, from baseline at week 12.
point improvement in PP-NRS from baseline. [P

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[PAGE 2 – MOA and Dosing]

[Eyebrow/Tab]
Dosing

[Headline]
Simple once daily dose [PM 6A]

[Subhead]
For adolescents and adults [PM 6A]

[Copy]
- The recommended dose is 110 mg or 220
potential risk for adverse reactions [PM 6A
- For patients using the 220 mg dosage, aft
consider a dose reduction to 110 mg [PM

[Icon/Copy]

<Insert icon>	<In
Once daily, same time each day [PM 7B]	With or wit

[Call out]
IMOLCET can be used with or without other medi
[PM 6B]

[Eyebrow/Tab]
Mechanism

[Headline]
IMOLCET is a highly selective JAK1/STAT signal

[Copy]
JAK inhibitors are used to treat inflammatory con
- JAKs transmit cytokine signals from cell m
[PM 17A]
- IMOLCET reversibly and selectively binds
inhibit it [PM 18B]

[Abbreviations]
ATP, adenosine triphosphate; JAK1, Janus kinas
transcription.

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[PAGE 3 – STUDY DESIGN]

[Eyebrow/Tab]
Monotherapy-1 trial

[Headline]
IMOLCET was studied in a phase 3, randomized, double-blind, placebo-controlled trial[1] [PM 22A]

[Subhead]
In adults and adolescents (≥12 years of age) with moderate-to-severe atopic dermatitis[1]* [PM 24A]

[Copy] [PM 24A]
387 patients complying with the following criteria were randomized 2:2:1 into IMOLCET 110 mg, 220 mg, and placebo:
- 12 - 65 years of age
- Moderate-to-severe AD*
- Inadequate response to AD topical medication
- Inadvisable topical treatments for AD
- Received systemic therapies for AD

[Visual-FPO] [PM 22A, 24A]

<insert icon>

<insert icon>

Treatments
[PM 22A]

- IMOLCET 110 mg (n=146)
- IMOLCET 220 mg (n=154)
- Placebo (n=71)

12 Weeks

Efficacy evaluation

Co-primary endpoint:
- IGA response at week 12
- EASI-75* response at week 12

Key secondary endpoints:
- PP-NRS4 at weeks 2, 4, 12
- PSAAD change from baseline at Week 12

[Copy near graph]
Adapted from product monograph

[Copy for visual-left to right]
Treatments
- IMOLCET 110 mg (n=146)
- IMOLCET 220 mg (n=154)
- Placebo (n=71)

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MedNarrate
SPOT-ON. ENGAGING CONTENT

COPY DEVELOPMENT

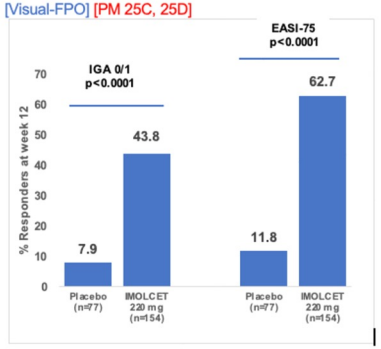
[PAGE 4 – STUDY RESULTS]

[Eyebrow/Tab]
Efficacy Data

[Headline]
Treatment with IMOLCET improved objective signs of atopic dermatitis[1] [P

[Graph title]
At week 12, significantly higher patient proportions achieved IGA 0/1‡ and/
in the IMOLCET 220 mg patient group ≥12 years compared to the placebo

[Visual-FPO] [PM 25C, 25D]



[Copy for graph]
[y-axis label] %Responders at week 12
[y-axis range] 0 10 20 30 40 50 60 70
[x-axis labels] Placebo (n=77) IMOLCET 110 mg (n=146) IMOLCET 220
[x-axis data labels] 7.9 43.8 11.8 62.7
[Label at the top] IGA 0/1 p<0.0001 EASI-75 p<0.0001

[Copy near graph]
Adapted from product monograph

[Copy]
- At week 12 in adolescents, compared to the placebo group, IMOLC group had clinically meaningful treatment effect shown by IGA [PM responders* [PM 28B]
- Significantly higher patient proportions achieved PP-NRS4#, obser 2 and persisted through Week 12 [PM 24C, 26A]

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MedNarrate
SPOT-ON. ENGAGING CONTENT

- Patients who achieved a response at Week 12 were enrolled in EXT assess long-term safety. The majority of them did not lose treatment 48 (70% for IGA 0/1 response, 87% for EASI-75, and 83% for PP-NR

[Abbreviations]
IGA, Investigator's Global Assessment; EASI, Eczema Area and Severity In Pruritus Numerical Rating Scale; PSAAD, Pruritus and Symptoms Assessm Dermatitis.

[Footnotes] [PM 25A]
* IGA and EASI-75 responder proportion corrected for placebo are 22.5% ar respectively.
† Similar results are found in the IMOLCET 110 mg dose group.
‡ IGA responders were patients with IGA score of clear (0) or almost clear (scale) and a reduction from baseline of ≥2 points.
§ EASI-75 responders were patients with ≥75% improvement in EASI, from
# Defined as an improvement of ≥4 points in the severity of PP-NRS.

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SPOT-ON. ENGAGING CONTENT

[PAGE 5 – SAFETY]

[Eyebrow/Tab]
Safety Profile

[Headline]
IMOLCET demonstrated a well-tolerated safety profile[1]

[Table title]
Adverse Events (AE) in ≥1% of patients up to 16 weeks by decreasing seriousness (results pooled from 4 placebo-controlled studies)[1] [PM 13A]

[Table] [PM 13B]

	Placebo N = 342	IMOLCET 110 mg N = 608	IMOLCET 220 mg N = 590
Nausea	2.0%	6.1%	14.6%
Vomiting	0.9%	1.5%	3.2%
Abdominal pain upper	0.0%	0.7%	1.9%
Herpes simplex*	1.8%	3.3%	4.2%
Headache	3.5%	5.9%	7.8%
Dizziness	0.9%	1.8%	2.9%
Acne	0.0%	1.6%	4.7%
Blood CPK increased	1.5%	2.3%	2.9%

[Copy]
- Most frequent serious AEs were infections [PM 12A]
- Serious infections have been reported in 2 patients (2.31 per 100 patient-years) treated with placebo, 6 patients (3.80 per 100 patient- years) with IMOLCET 110 mg, and 2 patients (1.28 per 100 patient-years) with IMOLCET 220 mg [PM 13C]
- The most common serious infections were herpes simplex, herpes zoster, and pneumonia [PM 13D]
- In the All Exposure Pool†, adolescents were more likely to have any AE relative to the 18 to <65-year-old age group [PM 15A]

[Abbreviations]
AE, adverse events.

[Footnotes]
* Herpes simplex includes oral herpes, ophthalmic herpes simplex, genital herpes, and herpes dermatitis. [PM 13E]
† The All Exposure Pool included subjects from 5 clinical studies and a long-term extension study. [PM 15A]

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COPY DEVELOPMENT

[PAGE 6 – PSP] [PSP by pharma co]

[Eyebrow/Tab]
Patient Support Program

[Headline]
Pharma Co. Cares™ patient support program offers support to both patients a
[Approval #XXX] [PSP by pharma co, A]

[Icon/Copy]

<Insert icon>	<Insert icon>	<Ins
Reimbursement assistance	**Dose reminder**	**Nurse**
Specialists help patients to correctly fill out paperwork for reimbursement [PSP by pharma co, B]	Pharma Co. Cares™ app reminds patients of their daily dose and prescription refills [PSP by pharma co, C]	Nurses ad about IMO 55 [PSP by

[CTA] [PSP by pharma co, E]
Enrol your patients today
Visit www.imolcet.com

[PAGE 7 – Balance]

[Eyebrow/Tab]
Important Safety Information

Indications and clinical use:

- IMOLCET is indicated for the treatment of patients ≥12 years with refra severe atopic dermatitis, who have had an inadequate response to oth (e.g., steroid or biologic), or for whom these treatments are not advisa IMOLCET can be used with or without medicated topical therapies for [PM 4A]
- Use of IMOLCET in combination with other JAK inhibitors, biologic imr or potent immunosuppressants such as methotrexate and cyclosporin studied and is not recommended. [PM 4B]
- Geriatrics ≥65 years of age: Clinical study results indicated that elderly increased risk for specific serious adverse events. There are limited da years of age and older. [PM 4C]

Most serious warnings and precautions:
Serious infections: Patients treated with IMOLCET may be at increased risk serious bacterial, fungal, viral and opportunistic infections that may lead to ho death. More frequently reported serious infections were predominately viral. [

Malignancies [PM 5B] **and thrombosis** [PM 5C]**:** Lymphoma and other malig venous thrombosis, pulmonary embolism, and arterial thrombosis have occur inflammatory conditions when treated with JAK inhibitors. Many of the thromb events were serious and some resulted in death.

Major Adverse Cardiovascular Events (MACE): MACE including non-fatal infarction were observed more frequently in rheumatoid arthritis patients ≥50 trial with a different Janus kinase inhibitor compared to tumor necrosis factor i

Other relevant warnings and precautions: [PM 8]

- Driving and operating machinery [PM 9A]
- Dose-dependent dyslipidemia [PM 9B]
- Hematologic abnormalities [PM 9C]
- Vaccinations [PM 9D]
- Do not use in patients with active tuberculosis [PM 10A]
- Viral reactivation [PM 10B]
- Do not use in patients with viral hepatitis [PM 10C]
- Fertility [PM 11A], reproductive potential [PM 11B], pregnancy [PM 11 breastfeeding [PM 11D]

For more information: [PM 36A]
Please consult the product monograph at http://hc-sc.gc.ca/index-eng.php for information relating to adverse reactions, drug interactions, and dosing inform not been discussed in this piece.
The product monograph is also available by calling us at 1-800-463-6001.

[PAGE 8 – BACK COVER]

[Headline]
IMOLCET is designed for fast* [PM 25B] and lasting† [PM 22B, 27A] effects on patients with moderate-to-severe atopic dermatitis[1]

[Icon/Copy]

<Icon>	<Icon>	<Icon>
IMOLCET has demonstrated efficacy in patients with refractory AD	IMOLCET is indicated for both adults and adolescents	IMOLCET has demonstrated a well-tolerated safety profile

[CTA]
Consider IMOLCET for patients ≥12 years with refractory atopic dermatitis

[Abbreviations]
AD, atopic dermatitis; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; JAK1, Janus kinase 1; PP-NRS, Peak Pruritus Numerical Rating Scale; STAT, signal transducers and activators of transcription.

[Footnotes]
* The proportions of patients achieving PP-NRS4 with IMOLCET 110 mg and 220 mg once daily were significantly higher than placebo by Day 9 and Day 4, respectively, and remained significantly higher than placebo with both IMOLCET doses at Week 2. [PM 25B]
† The majority of patients who achieved a response at Week 12 of a qualifying study and entered EXTEND did not show evidence of a loss of the treatment response at Week 48 [60% and 70% for IGA (0 or 1) response, 79% and 87% for EASI-75, and 62% and 83% for PP-NRS4 with 110 mg once daily and 220 mg once daily, respectively]. [PM 27A]

[References]
Reference: 1. IMOLCET (imocitinib) Product Monograph. Pharma Co. Canada, Inc. July 15, 2022.

[Legal]

[Code]
PHA001

[Logos]
<PrIMOLCET® Imocitinib tablets>

[Disclaimer]
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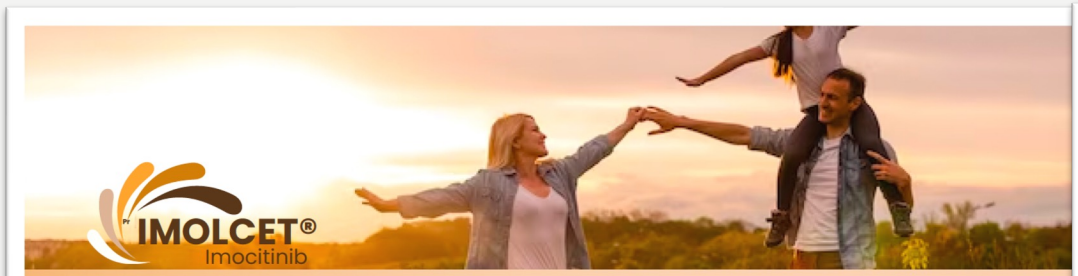
THE FINISHED PRODUCT

The First Two Pages



DEMONSTRATED EFFICACY IN TREATING REFRACTORY ATOPIC DERMATITIS IN ADULTS AND ADOLESCENTS[1]

With 62.7% EASI-75 responders compared to 11.8% in the placebo group ($p<0.0001$)[1]*

IMOLCET is indicated for the treatment of patients ≥12 years with refractory moderate to severe atopic dermatitis, including the relief of pruritus, who have had an inadequate response to other systemic drugs (e.g., steroid or biologic), or for whom these treatments are not advisable.
IMOLCET can be used with or without medicated topical therapies for atopic dermatitis.

EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; PSAAD, Pruritus and Symptoms Assessment for Atopic Dermatitis.

* A double-blind, placebo-controlled Phase 3 trial, Monotherapy-1, evaluated the efficacy and safety of IMOLCET in patients ≥12 years of age with moderate-to-severe atopic dermatitis. 387 patients complying with the inclusion criteria were randomized 2:2:1 to receive IMOLCET 110 mg (n=146), 220 mg (n=154), or placebo (n=71) once daily for 12 weeks. The co-primary endpoints were IGA 0/1 and EASI-75 responses at week 12 and the key secondary endpoints were PP-NRS4 and PSAAD change at week 12 from the baseline. IGA 0/1 responders were patients with IGA scores of clear (0) or almost clear (1) (on a 5-point scale) and a reduction from baseline of ≥2 points. EASI-75 responders were patients with ≥75% improvement in EASI, from baseline at week 12. PP-NRS4 responders were patients with ≥4-point improvement in PP-NRS from baseline.

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Dosing

SIMPLE ONCE DAILY DOSE[1]

For adolescents and adults

- The recommended dose is 110 mg or 220 mg based on individual therapy goals and potential risk for adverse reactions
- For patients using the 220 mg dosage, after symptom control is achieved by week 12, consider a dose reduction to 110 mg

IMOLCET can be used with or without other medicated topical therapies for atopic dermatitis

Once daily, same time each day

With or without food

Mechanism

IMOLCET is a highly selective JAK1/STAT signaling pathway inhibitor[1]

JAK inhibitors are used to treat inflammatory conditions

- JAKs transmit cytokine signals from cell membrane to influence immune cell function
- IMOLCET reversibly and selectively binds the ATP binding site on JAK1 enzyme to inhibit it

ATP, adenosine triphosphate; JAK1, Janus kinase 1; STAT, signal transducers and activators of transcription.

IMOLCET® Imocitinib

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Tania Sultana, PhD

ANNOTATED LAYOUT FOR US BRANDS

For Editorial Review and Fact-Checking

Tania Sultana, PhD

CONTACT INFO

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