

CADTH REIMBURSEMENT REVIEW

# Clinical Review Report

GENERIC DRUG NAME (BRAND NAME)

(Sponsor)

Indication:

Service Line:

Version:

Publication Date:

Report Length:

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**About CADTH:** CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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## Abbreviations

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## Executive Summary

**Table 1: Submitted for Review**

Item	Description
Drug product	
Indication	
Reimbursement request	
Health Canada Approval Status	
Health Canada Review Pathway	
NOC date	
Sponsor	

### Introduction

#### Stakeholder Perspectives

Patient Input

Clinician input

Drug program input

#### Clinical Evidence

Pivotal Studies and Protocol Selected Studies

*Description of studies*

*Efficacy Results*

*Harms Results*

*Critical Appraisal*

Indirect Comparisons

*Description of studies*

*Efficacy Results*

*Harms Results*

*Critical Appraisal*

Other Relevant Evidence

*Description of studies*

*Efficacy Results*

*Harms Results*

*Critical Appraisal*

**Conclusions**

## Introduction

### Disease Background

### Standards of Therapy

### Drug

**Table 2: Key characteristics**

<b>Mechanism of Action</b>		
<b>Indication<sup>a</sup></b>		
<b>Route of Administration</b>		
<b>Recommended Dose</b>		
<b>Serious Adverse Effects or Safety Issues</b>		
<b>Other</b>		



## Stakeholder Perspectives

### Patient Group Input

### Clinician Input

Clinician group input

Input from clinical experts consulted by CADTH

**Unmet Needs**

**Place in therapy**

**Patient population**

**Assessing response to treatment**

**Discontinuing treatment**

**Prescribing conditions**

**Additional considerations**

### Drug Program Input

## Clinical Evidence

### Systematic Review (Pivotal and Protocol Selected Studies)

Objectives

Methods

**Table 3: Inclusion criteria for the systematic review**

Patient Population	
Intervention	
Comparators	
Outcomes	
Study Design	

### Findings from the Literature

**Figure 1: Flow Diagram for Inclusion and Exclusion of Studies**

**Table 4: Details of Included Studies**

		Study Name	Study Name
<b>DESIGNS &amp; POPULATIONS</b>	<b>Study Design</b>		
	<b>Locations</b>		
	<b>Patient Enrolment Dates</b>		
	<b>Randomized (N)</b>		
	<b>Inclusion Criteria</b>		
	<b>Exclusion Criteria</b>		
<b>DRUGS</b>	<b>Intervention</b>		
	<b>Comparator(s)</b>		
<b>DURATION</b>	<b>Phase</b>		
	Run-in		
	Double-blind		
	Follow-up		
<b>OUTCOMES</b>	<b>Primary End Point</b>		
	<b>Secondary and Exploratory End Points</b>		
<b>NOTES</b>	<b>Publications</b>		

## Description of studies

### Populations

*Inclusion and exclusion criteria*

*Baseline characteristics*

**Table 5: Summary of Baseline Characteristics**

Characteristic	Study	Study

### Interventions

### Outcomes

**Table 6: Summary of Outcomes of Interest Identified in the CADTH Review Protocol**

Outcome Measure	Study	Study

### Statistical analysis

#### Primary Outcome(s) of the Studies

#### Secondary Outcomes of the Studies

## Results

Patient Disposition

Exposure to study treatments

Efficacy

*Efficacy outcome 1*

*Efficacy outcome 2*

Harms

*Adverse events*

*Serious adverse events*

*Withdrawals due to adverse events*

*Mortality*

*Notable harms*

Critical Appraisal

*Internal validity*

*External validity*

## Indirect Evidence

Objectives and Methods for the Summary of Indirect Evidence

Description of Indirect Comparison(s)

Methods

*Objectives*

*Study Selection Methods*

*ITC analysis methods*

Results

*Summary of included studies*

*Results*

Critical Appraisal

Summary

## Other Relevant Evidence

This section includes submitted long-term extension studies and additional relevant studies included in the sponsor's submission to CADTH that were considered to address important gaps in the evidence included in the systematic review.

### Long-term extension studies

*Methods*

*Populations*

*Interventions*

*Outcomes*

*Statistical analysis*

*Patient Disposition*

*Exposure to study treatments*

*Efficacy*

*Harms*

*Critical Appraisal*

## Discussion

### Summary of Available Evidence

### Interpretation of Results

Efficacy

Harms

Other Considerations

### Conclusions



## Appendix 1: Literature Search Strategy

Sample Template

## Appendix 2: Excluded Studies

**Table 7: Excluded Studies**

Reference	Reason for Exclusion

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**Appendix 3: Detailed Outcome Data**

Sample Template

## Appendix 4: Description and Appraisal of Outcome Measures

### Aim

To describe the following outcome measures and review their measurement properties (validity, reliability, responsiveness to change, and minimal important difference):

### Findings

Sample Template

## Appendix 5: Companion Diagnostic Testing

Sample Template

## References

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