

**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**





## **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**

Mechanism of Action		
Indicationa		
Route of Administration		
Recommended Dose	·	
Serious Adverse Effects or Safety Issues		
Other		



## **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
Š	Study Design		
ᅙ	Locations		
DESIGNS & POPULATIONS	Patient Enrolment Dates		
<u>ය</u>	Randomized (N)		
SN	Inclusion Criteria		
DESIG	Exclusion Criteria		
Drugs	Intervention		
٥	Comparator(s)		
z	Phase		
O E	Run-in		
DURATION	Double-blind		
	Follow-up		
ES	Primary End Point		
OUTCOMES	Secondary and Exploratory End Points		
Notes	Publications		



**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.

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

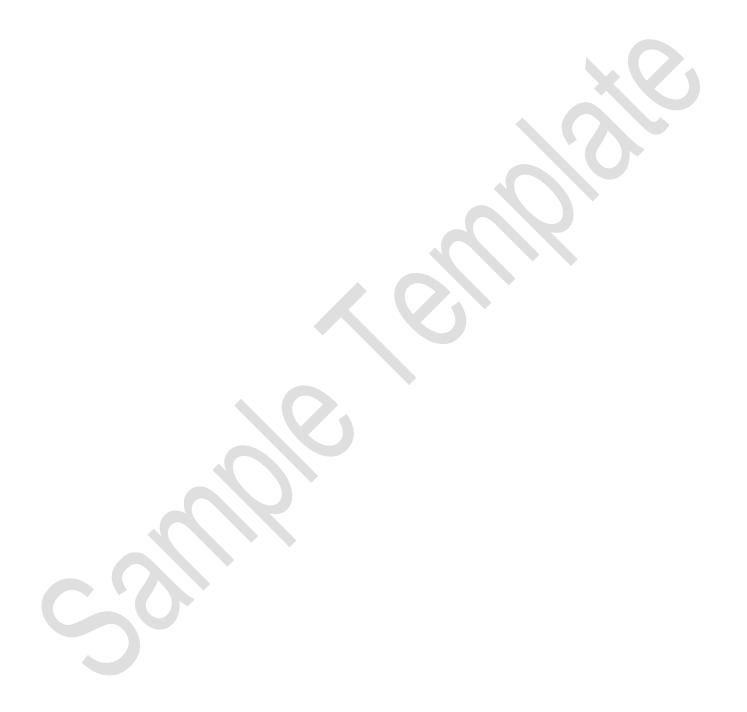
Harms

Other Considerations

**Conclusions** 



## **Appendix 1: Literature Search Strategy**





## **Appendix 2: Excluded Studies**

**Table 7: Excluded Studies** 

Reference	Reason for Exclusion



## **Appendix 3: Detailed Outcome Data**





## **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**



## **Appendix 5: Companion Diagnostic Testing**





#### References

