[Product Monograph Template – Notice of Compliance with Conditions]

[Title Page]

PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

<Scheduling Symbol> <**BRAND NAME**>

<Proper name>

<Dosage Form(s), Strength(s) and Route(s) of Administration>

<Pharmaceutical Standard (if applicable)>

<Therapeutic Classification>

"*<Brand name>, indicated for:*
- < >
has been issued marketing authorization with conditions, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization. For further information for <Brand name> please refer to Health Canada's Notice of Compliance with conditions - drug products web site."
"

[For market authorizations without conditions]
"<Brand name> indicated for:
- < >
has been issued marketing authorization without conditions."

<Sponsor Name>
<Sponsor Address>

Date of Initial Approval:
<MON DD,YYYY>

Date of Revision:
<MON DD,YYYY>

Submission Control No: <control number>

This product has been authorized under the Notice of Compliance with Conditions (NOC/c) for one or all of its indicated uses.

What is a Notice of Compliance with Conditions (NOC/c)?

An NOC/c is a form of market approval granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada.

Products authorized under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

What will be different about this Product Monograph?

The following Product Monograph will contain boxed text at the beginning of each major section clearly stating the nature of the market authorization. Sections for which NOC/c status holds particular significance will be identified in the left margin by the symbol NOC/c. These sections may include, but are not limited to, the following:

- Indications;
- Action and Clinical Pharmacology;
- Warnings and Precautions;
- Adverse Reactions;
- Dosage and Administration; and
- Clinical Trials.

Adverse Drug Reaction Reporting and Re-Issuance of the Product Monograph

Health care providers are encouraged to report Adverse Drug Reactions associated with normal use of these and all drug products to Health Canada's Canada Vigilance Program at 1-866-234-2345. The Product Monograph will be re-issued in the event of serious safety concerns previously unidentified or at such time as the sponsor provides the additional data in support of the product's clinical benefit. Once the latter has occurred, and in accordance with the NOC/c policy, the conditions associated with market authorization will be removed.

RECENT MAJOR LABEL CHANGES

<Section Heading>, <Subsection heading> <(Section or Subsection number)> <MON, YYYY>
<Section Heading>, <Subsection heading> <(Section or Subsection number)> <MON, YYYY>

TABLE OF CONTENTS

[To update, right-click anywhere in the Table of Contents and select “Update Field”, “Update entire table”, click OK.]

"<Brand name>, indicated for:
- < >
has been issued marketing authorization with conditions, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization. For further information for <Brand name> please refer to Health Canada's Notice of Compliance with conditions - drug products web site:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/index-eng.php"

[For market authorizations without conditions]
"<Brand name> indicated for:
- < >
has been issued marketing authorization without conditions."

PART I: HEALTH PROFESSIONAL INFORMATION

NOC/c

1 INDICATIONS

<Brand name (proper name)> is indicated for:
- <text>
- <text>

[Include a brief discussion of any promising clinical information.]
<text>

1.1 Pediatrics

[One of the following or similar statements should be used:]

Pediatrics <(age range)>: Based on the data submitted and reviewed by Health Canada, the safety and efficacy of <Brand name> in pediatric patients has been established; therefore, Health Canada has authorized an indication for pediatric use. <(cross-reference to relevant sections)>

[or]

Pediatrics <(age range)>: No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

[or]

Pediatrics <(age range)>: Based on the data submitted and reviewed by Health Canada, the safety and efficacy of <Brand name> in pediatric patients has not been established; therefore, Health Canada has not authorized an indication for pediatric use. <(cross-reference to relevant sections)>

1.2 Geriatrics

[One of the following or similar statements may be used:]

Geriatrics <(> *x* years of age)>:No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

[or]

Geriatrics <(> *x* years of age)>:Evidence from clinical studies and experience suggests that use in the geriatric population is associated with differences in safety or effectiveness.

NOC/c 2 CONTRAINDICATIONS

<Proper name> is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see Dosage Forms, Strengths, Composition and Packaging.

- <text>
- <text>

NOC/c 3 SERIOUS WARNINGS AND PRECAUTIONS BOX

[Delete this section if there is no Serious Warnings and Precautions box.]

Serious Warnings and Precautions

[Clinically significant or serious (e.g., life-threatening) safety hazards should be placed in this box, with a cross reference to the relevant section(s) for more detailed information. Generally not to exceed 20 lines]

- <text>
- <text>

NOC/c 4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

[Briefly list all situations that may affect dosing of the drug:]

- <text>
- <text>

4.2 Recommended Dose and Dosage Adjustment

[Include dosages for each indication, route of administration and/or dosage form:]
<text>

[In the absence of a Health Canada authorized pediatric indication, the following or similar statement should be used:]

Health Canada has not authorized an indication for pediatric use. <(cross-reference to relevant sections, if applicable)>

4.3 Administration

<text and/or table>

4.4 Reconstitution

Oral Solutions: <text and/or table>
Parenteral Products: <table and text>

Vial Size	Volume of Diluent to be Added to Vial	Approximate Available Volume	Nominal Concentration per mL

[Include any specific precautions, storage periods and incompatibilities.]

4.5 Missed Dose

<text>

5 OVERDOSAGE

<text>

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
<oral>	<tablet 5 mg, 10 mg>	[List all non-medicinal ingredients in alphabetical order.]

<text>

NOC/c

7 WARNINGS AND PRECAUTIONS

[If applicable, include the following statement:]

Please see the Serious Warnings and Precautions Box at the beginning of Part I: Health Professional Information.

[Subheadings to be included as applicable, in alphabetical order:]

General
<text>

Carcinogenesis and Mutagenesis
<text>

Cardiovascular
<text>

Dependence/Tolerance
<text>

Driving and Operating Machinery
[This subheading should include the following or similar statement:]

Due caution should be exercised when driving or operating a vehicle or potentially dangerous machinery.

Ear/Nose/Throat
<text>

Endocrine and Metabolism
<text>

Gastrointestinal
<text>

Genitourinary
<text>

Hematologic
<text>

Hepatic/Biliary/Pancreatic
<text>

Immune
<text>

Monitoring and Laboratory Tests
<text>

Neurologic
<text>

Ophthalmologic
<text>

Peri-Operative Considerations
<text>

Psychiatric
<text>

Renal
<text>

Respiratory
<text>

Sensitivity/Resistance
<text>

Sexual Health
Reproduction
<text>

Function
<text>

Fertility
<text>

Skin
<text>

7.1 Special Populations

7.1.1 Pregnant Women

<text>
[The extent of exposure in pregnancy during clinical trials should be included:

Wide:	> 1,000 pregnancies
Limited:	< 1,000 pregnancies
Very Limited:	individual cases only
No experience]	

7.1.2 Breast-feeding

<text>
[In the absence of human data, pertinent animal data should be included along with the following or similar statement:]
It is unknown if the drug is excreted in human milk. Because many drugs are excreted in human milk precaution should be exercised.

7.1.3 Pediatrics

[In the absence of a Health Canada authorized pediatric indication, one of the following or similar statements should be used:]

Pediatrics <(age range)>: No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

[or]

Pediatrics <**(age range)**>: Based on the data submitted and reviewed by Health Canada, the safety and efficacy of <Brand name> in pediatric patients has not been established; therefore, Health Canada has not authorized an indication for pediatric use. <(cross-reference to relevant sections)>

<text>

7.1.4 Geriatrics

<text>

NOC/c

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

<text>

8.2 Clinical Trial Adverse Reactions

Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

[Include a brief description of data sources.]
<text>

Table <#> <Title of Table>

	<drug name> n = <#> (%)	**<placebo> n = <#> (%)**
[use MedDRA terms for headings, as applicable] **Cardiovascular** <text>		

[A brief narrative should follow the table to explain or supplement the information provided in the table:]
<text>

8.3 Less Common Clinical Trial Adverse Reactions

[Present as a list, categorized by System Organ Class, alphabetically:]
Cardiovascular: <text>
Gastrointestinal: <text>

8.4 Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data

<table>

8.5 Clinical Trial Adverse Reactions (Pediatrics)

<text>

8.6 Post-Market Adverse Reactions

<text and/or table>

9 DRUG INTERACTIONS

9.1 Serious Drug Interactions Box

[Delete this section if there is no Serious Drug Interactions box.]

Serious Drug Interactions

[Serious (e.g., life-threatening) drug interactions should be highlighted in this box. Not to exceed 20 lines.]

- <text>
- <text>

9.2 Overview

<text>

9.3 Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

[or]

Interactions with other drugs have not been established.

Table <#> - Established or Potential Drug-Drug Interactions

<Proper/Common name>	Source of Evidence	Effect	Clinical comment
<drug A>	<level of evidence, see legend>	<drug A> conc	<Caution is warranted and therapeutic concentration monitoring is recommended>

Legend: C = Case Study; CT = Clinical Trial; T = Theoretical

9.4 Drug-Food Interactions

<text>

9.5 Drug-Herb Interactions

<text>

9.6 Drug-Laboratory Test Interactions

<text>

9.7 Drug-Lifestyle Interactions

<text>

NOC/c

10 ACTION AND CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

<text>

10.2 Pharmacodynamics

<text>

10.3 Pharmacokinetics

Table <#> - Summary of <proper name> Pharmacokinetic Parameters in <specific patient population>

	C_{max}	T_{max}	$t_{½}$ (h)	$AUC_{0-\infty}$	CL	Vd
Single dose mean						

Absorption: <text>

Distribution: <text>

Metabolism: <text>

Elimination: <text>

Special Populations and Conditions

Pediatrics: <text>

Geriatrics: <text>

Sex: <text>

Pregnancy and Breast-feeding: <text>

Genetic Polymorphism: <text>

Ethnic origin: <text>

Hepatic Insufficiency: <text>

Renal Insufficiency: <text>

Obesity: <text>

11 STORAGE, STABILITY AND DISPOSAL

<text>

12 SPECIAL HANDLING INSTRUCTIONS

<text>

PART II: SCIENTIFIC INFORMATION

"<Brand name>, indicated for:
- < >
has been issued marketing authorization with conditions, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization. For further information for <Brand name> please refer to Health Canada's Notice of Compliance with conditions - drug products web site:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/index-eng.php"

[For market authorizations without conditions]
"<Brand name> indicated for:
- < >
has been issued marketing authorization without conditions."

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: <text>

Chemical name: <text>

Molecular formula and molecular mass: <text>

Structural formula: <image>

Physicochemical properties: <text>

NOC/c

14 CLINICAL TRIALS

14.1 Trial Design and Study Demographics

Table <#> - Summary of patient demographics for clinical trials in <specific indication>

Study #	Trial design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex

[Provide a brief narrative describing the demographic characteristics of the study population:]
<text>

14.2 Study Results

Table <#> - Results of study <#> in <specific indication>

Primary Endpoints	Associated value and statistical significance for Drug at specific dosages	Associated value and statistical significance for Placebo or active control

[Include Comparative Bioavailability Studies (if required). See format in Standard Template.]

15 MICROBIOLOGY

<text>
<table>

16 NON-CLINICAL TOXICOLOGY

[Narrative where possible. Include a table only where presentation is made more concise.]
<text>

17 SUPPORTING PRODUCT MONOGRAPHS

[Where there are no supporting product monographs, this section should be omitted.]

[numbered list:]
<Brand name> <(dosage form, strength)>, submission control <number>, Product Monograph, <sponsor>. <(MON, DD, YYYY)>

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

<BRAND NAME>
<Proper Name in final dosage form>

Read this carefully before you start taking **<Brand name>** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **<Brand name>**.

What is <Brand name> used for?
[Briefly summarize the indication(s) and refer to the reader to the NOC/c summary box below for additional detail.]

"For the following indication(s) <Brand name> has been approved *with conditions* (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional."

[Provide a bullet listing of the indications from Part I.]

- <text>

[If the Indications section includes lifestyle recommendations as part of the therapy, they should be included here.]

"For the following indication(s) <Brand name> has been approved *without conditions*. This means it has passed Health Canada's review and can be bought and sold in Canada."

[Provide a bullet listing of the indications from Part I.]

- <text>

[If the Indications section includes lifestyle recommendations as part of the therapy, they should be included here.]

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively

monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

Serious Warnings and Precautions

- **<**text**>**
- **<**text**>**

How does <Brand name> work?
[At the grade 6-8 reading level, explain the mechanism of action, in one or two sentences. Indicate how long it takes to work and how to know if it is working.]
<text>

What are the ingredients in <Brand name>?
Medicinal ingredients: [List all medicinal ingredients from Part I.]
Non-medicinal ingredients: [List all non-medicinal ingredients in alphabetical order from Part I.]

<Brand name> comes in the following dosage forms:
[To maintain brevity, this is the only information required in this section.]
<dosage form(s) and strength(s**)>**

Do not use <Brand name> if:
[Enter one point for each contraindication from Part I.]

- **<**text**>**
- **<**text**>**

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take <Brand name>. Talk about any health conditions or problems you may have, including if you:
[Enter one point for each warning and precaution from Part I.]

- **<**text**>**
- **<**text**>**

Other warnings you should know about:
[Enter general information that would not appear in the serious warnings and precautions box or other existing headings. Otherwise this heading is not required.]
<text**>**

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with <Brand name>:

- **<**list**>**

How to take <Brand name>:
<text**>**

Usual dose:
<text**>**

Overdose:
<text**>**

If you think you have taken too much <Brand name>, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

[The boxed message may be modified to provide the most appropriate advice according to current standards of care for this drug product.]

Missed Dose:
<text**>**

What are possible side effects from using <Brand name>?

These are not all the possible side effects you may feel when taking <Brand name>. If you experience any side effects not listed here, contact your healthcare professional.

<text**>**
[Self-limiting side effects should be described in the text section only. Serious side effects must be listed in the serious side effects table. Each side effect should appear only once, in text or in the table, as duplication generally is not wanted in Part III.]

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON < Condition: symptom / effect>			
< Condition: symptom / effect>			
COMMON < Condition: symptom / effect>			
< Condition: symptom / effect>			
RARE < Condition: symptom / effect>			
< Condition: symptom / effect>			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
<text**>**

Keep out of reach and sight of children.

If you want more information about <Brand name>:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website <website>, or by calling 1-800-<phone number>.

This leaflet was prepared by <Sponsor Name>

Last Revised <MON-DD-YYYY>