[Product Monograph Template - Standard]

[Title Page]

PRODUCT MONOGRAPH

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

<Proper name>

< Dosage Form(s) and Strength(s)>

<Pharmaceutical standard (if applicable)>

<Therapeutic Classification>

<Sponsor Name>
<Sponsor Address>

Date of Preparation:
<MON DD, YYYY>
or
Date of Revision:
<MON DD, YYYY>

Submission Control No: <control number> [optional]

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<PROPRIETARY OR BRAND NAME>

< proper name >

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
< oral>	<tablet 5 mg , 10 mg>	<ethanol, gluten, etc> *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

<Brand Name (proper name)> is indicated for:
- treatment of <text>
- prevention of <text>
- diagnosis of <text>

[Brief discussion of any relevant clinical information - if applicable]

[Distribution restrictions - if applicable]

[When the product is not recommended - if applicable]

Geriatrics (> *x* years of age):
<text>

Pediatrics (*x* - *y* years of age) or (< years of age):
<text>

CONTRAINDICATIONS

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the product monograph. [if applicable]
- <text>
- <text>

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

[Clinically significant or serious life-threatening warnings should be placed in the warning box. Generally not to exceed 20 lines]

- <text>
- <text>

[headings to be included as applicable]

General

<text>

Carcinogenesis and Mutagenesis

<text>

Cardiovascular

<text>

Dependence/Tolerance

<text>

Ear/Nose/Throat

<text>

Endocrine and Metabolism

<text>

Gastrointestinal

<text>

Genitourinary

<text>

Hematologic

<text>

Hepatic/Biliary/Pancreatic

<text>

Immune

<text>

Neurologic
<text>

Ophthalmologic
<text>

Peri-Operative Considerations
<text>

Psychiatric
<text>

Renal
<text>

Respiratory
<text>

Sensitivity/Resistance
<text>

Sexual Function/Reproduction
<text>

Skin
<text>

Special Populations

Pregnant Women: <text>
[The extent of exposure in pregnancy during clinical trials should be included:
Wide: > 1000 pregnancies
Limited: < 1000 pregnancies
Very Limited: individual cases only
No experience]

Nursing Women: <text>

Pediatrics (*x* - *y* years of age): or (< years of age): <text>

Geriatrics (> *x* years of age): <text>

Monitoring and Laboratory Tests
<text>

ADVERSE REACTIONS

Adverse Drug Reaction Overview

[An overview of the ADR information that may affect prescribing decisions. It should contain: serious and important ADRs; the most frequent ADRs; and ADRs that most commonly result in clinical intervention.]

Clinical Trial Adverse Drug 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 drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.*

[Include description of data sources]

Table <#> - <Title of Table>

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

[Narrative to follow table to explain or supplement the information provided in the table]

Less Common Clinical Trial Adverse Drug Reactions (<1%)

[Presented as a list and categorized by body system]
Cardiovascular: <text>
Digestive: <text>
Gastrointestinal: <text>

Abnormal Hematologic and Clinical Chemistry Findings

<table>

Post-Market Adverse Drug Reactions

<narrative>

DRUG INTERACTIONS

Serious Drug Interactions

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

- <text>
- <text>

Overview

<narrative>

[should include the following information: interactions suspected based on the pharmacokinetic or pharmacologic profile of the drug (e.g., cytochrome P450 interactions); drug class statements if the interaction has not yet been documented, but would be clinically significant; potential interaction with alcohol].

Drug-Drug Interactions

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

<Proper name>	Ref	Effect	Clinical comment
< drug A>	<level of evidence, see legend>	9 <drug A> conc	<Caution is warranted and therapeutic concentration monitoring is recommended>

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

Drug-Food Interactions

<narrative>

Drug-Herb Interactions

<narrative>

Drug-Laboratory Interactions

<narrative>

Drug-Lifestyle Interactions

<narrative>

DOSAGE AND ADMINISTRATION

Dosing Considerations

[include all situations that may affect dosing of the drug]

- <text>
- <text>

Recommended Dose and Dosage Adjustment
[Include for each indication, route of administration or dosage form]
<narrative>

Missed Dose
<narrative>

Administration
<narrative>

Reconstitution:

Oral Solutions: <text>

Parenteral Products:

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

<any specific precautions, storage periods and incompatibilities>

OVERDOSAGE
<narrative>

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action
<narrative>
[For anti-infective products: a brief description of action against micro-organisms]

Pharmacodynamics
<narrative>

Pharmacokinetics

Table <#> Summary of <proper name>'s Pharmacokinetic Parameters in a <specific patient population>

	C_{max}	$t_{½}$ (h)	AUC_{0-4}	Clearance	Volume of distribution
Single dose mean					

Absorption: <text>

Distribution: <text>

Metabolism: <text>

Excretion: <text>

Special Populations and Conditions

Pediatrics: <text>

Geriatrics: <text>

Gender: <text>

Race: <text>

Hepatic Insufficiency: <text>

Renal Insufficiency: <text>

Genetic Polymorphism: <text>

STORAGE AND STABILITY
<narrative>

SPECIAL HANDLING INSTRUCTIONS
<narrative>

DOSAGE FORMS, COMPOSITION AND PACKAGING
<narrative>

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: <text>

Chemical name: <text>

Molecular formula and molecular mass: <text>

Structural formula: <image>

Physicochemical properties: <text>

CLINICAL TRIALS

Study demographics and trial design

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

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

[Provide a brief narrative describing the demographic characteristics of the study population].

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

Comparative Bioavailability Studies

[narrative outlining the design of the bioequivalence study. The values in the table should be based on the measured data from the study; no potency correction should be applied.]

[Table for single dose studies:]

Analyte Name **(__ x __ mg)** **From measured data** **Geometric Mean** **Arithmetic Mean (CV %)**

Parameter	**Test***	**Reference†**	**% Ratio of Geometric Means**	**Confidence Interval #**
AUC_T‡ (units)				
AUC_I (units)				
C_{MAX} (units)				
T_{MAX}§ (h)				
$T_{½}$2 (h)				

* Identity of the test product.

† Identity of the reference product, including the manufacturer, and origin (country of purchase).

‡ For drugs with a half-life greater than 24 hours AUC_T should be replaced with AUC_{0-72}.

§ Expressed as either the arithmetic mean (CV%) or the median (range) only.

2 Expressed as the arithmetic mean (CV%) only.

\# Indicate % Confidence Interval (i.e., 90% or 95%) in the column heading and list for the AUC_T, AUC_I and C_{MAX} (if required).

[Table for multiple dose studies:]

Analyte Name **(__ x __ mg)** **From measured data** **Geometric Mean** **Arithmetic Mean (CV %)**

Parameter	**Test***	**Reference†**	**% Ratio of Geometric Means**	**Confidence Interval #**
AUC_{tau} (units)				
C_{MAX} (units)				
C_{MIN} (units)				
T_{MAX}‡ (h)				

* Identity of the test product.

† Identity of the reference product, including the manufacturer, and origin (country of purchase), where applicable.

‡ For drugs with a half-life greater than 24 hours AUC_T should be replaced with AUC_{0-72}.

\# Indicate % Confidence Interval (i.e., 90% or 95%) in the column heading and list for the AUC_T, AUC_I and C_{MAX} (if required).

DETAILED PHARMACOLOGY
<narrative>

MICROBIOLOGY
<narrative>

TOXICOLOGY
[table format wherever possible]

REFERENCES
[numbered list]

PART III: CONSUMER INFORMATION

<Brand name>
<Proper Name>

This leaflet is part III of a three-part "Product Monograph" published when <brand name> was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about <brand name>. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
<narrative> and/or
- **<text>**
- **<text>**

What it does:
<text>

When it should not be used:
<text>

What the medicinal ingredient is:
<proper name>

What the important nonmedicinal ingredients are:
<alphabetical listing>
For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:
<dosage form(s) and strength(s)>

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
- **<text>**
- **<text>**

BEFORE you use <brand name> talk to your doctor or pharmacist if:
- **<Activities (Warnings and Precautions, e,g, under Occupational Hazards) >**
- **<Current conditions (Contraindications, Warnings and Precautions)>**
- **<Past diseases (Contraindications, Warnings and Precautions)>**
- **<Reproductive issues (Contraindications, Warnings and Precautions)>**
- **<Anticipated medical procedures (Warnings and Precautions)>**
- **<Any allergies to this drug or its ingredients or components of the container (Contraindications)>**

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with <brand name> include: <text>.

PROPER USE OF THIS MEDICATION

Usual dose:
<text>

Overdose:
<text>

In case of drug overdose, contact a health care practitioner, 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>

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

<text>

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	<symptom / effect> <symptom / effect>	T	T	
Uncommon	<symptom / effect> <symptom / effect>		T	T

This is not a complete list of side effects. For any unexpected effects while taking <Brand Name>, contact your doctor or pharmacist.

HOW TO STORE IT

<text>

REPORTING SUSPECTED SIDE EFFECTS

NOTE: Should you require information related to the management of side effects, contact your health professional. gnxdigital does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.gnxdigital.com/productmonograph
or by contacting the sponsor, <Sponsor Name>, at:
91-022-XXX-XXX

This leaflet was prepared by <Sponsor Name>

Last revised: <MON DD, YYYY>.