HIGHLIGHTS OF PRESCRIBING INFORMATION

**These highlights do not include all the information needed to use PROPRIETARY NAME safely and effectively. See full prescribing information for PROPRIETARY NAME.**

**PROPRIETARY NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol**

**Initial U.S. Approval: YYYY**

|  |
| --- |
| **WARNING: TITLE OF WARNING**  ***See full prescribing information for complete boxed warning.***  **Text (4)**  **Text (5.x)** |

----------------------------RECENT MAJOR CHANGES--------------------------

Section Title, Subsection Title (x.x) M/YYYY

Section Title, Subsection Title (x.x) M/YYYY

-----------------------------INDICATIONS AND USAGE---------------------------

PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for … (1)

Limitations of Use

Text (1)

------------------------DOSAGE AND ADMINISTRATION-----------------------

Text (2.x)

Text (2.x)

---------------------DOSAGE FORMS AND STRENGTHS----------------------

Dosage form(s): strength(s) (3)

-------------------------------CONTRAINDICATIONS-------------------------------

Text (4)

Text (4)

------------------------WARNINGS AND PRECAUTIONS-----------------------

Text (5.x)

Text (5.x)

-------------------------------ADVERSE REACTIONS------------------------------

Most common adverse reactions (incidence > x%) are text (6.x)

**To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or** [**www.fda.gov/medwatch**](http://www.fda.gov/medwatch)**.**

------------------------------DRUG INTERACTIONS--------------------------------

Text (7.x)

Text (7.x)

--------------------------USE IN SPECIFIC POPULATIONS---------------------

Text (8.x)

Text (8.x)

**See 17 for PATIENT COUNSELING INFORMATION and FDA‑approved patient labeling OR and Medication Guide.**

**Revised: M/YYYY**

FULL PRESCRIBING INFORMATION: CONTENTS\*

**WARNING: TITLE OF WARNING**

**1 INDICATIONS AND USAGE**

**2 DOSAGE AND ADMINISTRATION**

2.1 Subsection Title

2.2 Subsection Title

**3 DOSAGE FORMS AND STRENGTHS**

**4 CONTRAINDICATIONS**

**5 WARNINGS AND PRECAUTIONS**

5.1 Subsection Title

5.2 Subsection Title

**6 ADVERSE REACTIONS**

6.1 Clinical Trials Experience

6.2 Postmarketing Experience

**7 DRUG INTERACTIONS**

7.1 Subsection Title

7.2 Subsection Title

**8 USE IN SPECIFIC POPULATIONS**

8.1 Pregnancy

8.2 Lactation

8.3 Females and Males of Reproductive Potential

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Subpopulation X (e.g., Renal Impairment)

**9 DRUG ABUSE AND DEPENDENCE**

9.1 Controlled Substance

9.2 Abuse

9.3 Dependence

**10 OVERDOSAGE**

**11 DESCRIPTION**

**12 CLINICAL PHARMACOLOGY**

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

12.4 Microbiology

12.5 Pharmacogenomics

12.6 Immunogenicity

**13 NONCLINICAL TOXICOLOGY**

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

13.2 Animal Toxicology and/or Pharmacology

**14 CLINICAL STUDIES**

14.1 Subsection Title

14.2 Subsection Title

**15 REFERENCES**

**16 HOW SUPPLIED/STORAGE AND HANDLING**

**17 PATIENT COUNSELING INFORMATION**

\* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

|  |
| --- |
| **WARNING: TITLE OF WARNING**  **Text *[see Contraindications (4)]***  **Text *[see Warnings and Precautions (5.x)]*** |

1 INDICATIONS AND USAGE

PROPRIETARY NAME is indicated for …

Limitations of Use

Text

2 DOSAGE AND ADMINISTRATION

2.1 Subsection Title (e.g., Recommended Dosage and Administration)

2.2 Subsection Title (e.g., Preparation and Administration Instructions)

3 DOSAGE FORMS AND STRENGTHS

Dosage form #1: strength(s), identifying characteristics

Dosage form #2: strength(s), identifying characteristics

4 CONTRAINDICATIONS

*[If no contraindications are known, this section must state “*None*.”]*

5 WARNINGS AND PRECAUTIONS

5.1 Subsection Title (e.g., Clinically Significant Adverse Reaction or Risk #1)

5.2 Subsection Title (e.g., Clinically Significant Adverse Reaction or Risk #2)

**6 ADVERSE REACTIONS**

*[If the source of adverse reactions (AR) cannot be determined (e.g., an older drug) consider eliminating numbered subsections (e.g., remove subsection 6.1 Clinical Trials Experience and 6.2 Postmarketing Experience) and including a list of AR preceded by a modified postmarketing caveat statement. For example, “*The following adverse reactions associated with the use *of [[insert drug name]]* were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.*”]*

The following clinically significant adverse reactions are described elsewhere in the labeling:

* Subsection Title *[see Warnings and Precautions (5.1)]*
* Subsection Title *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

**6.2 Postmarketing Experience**

The following adverse reactions have been identified during postapproval use of DRUG-X. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

7 DRUG INTERACTIONS

7.1 Subsection Title (e.g., Effects of Other Drugs on DRUG-X)

7.2 Subsection Title (e.g., Effects of DRUG-X on Other Drugs)

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry (omit if not applicable)

Risk Summary (required heading)

Clinical Considerations (omit if none of the subheadings below are applicable)

*Disease-Associated Maternal and/or Embryo/Fetal Risk* (omit if not applicable)

*Dose Adjustments During Pregnancy and the Postpartum Period* (omit if not applicable)

*Maternal Adverse Reactions* (omit if not applicable)

*Fetal/Neonatal Adverse Reactions* (omit if not applicable)

*Labor or Delivery* (omit if not applicable)

Data (omit if none of the subheadings below are applicable)

*Human Data* (omit if not applicable)

*Animal Data* (omit if not applicable)

**8.2 Lactation**

Risk Summary (required heading)

Clinical Considerations (omit if not applicable)

Data (omit if not applicable)

8.3 Females and Males of Reproductive Potential

Pregnancy Testing (omit if not applicable)

Contraception (omit if not applicable)

*Females* (may include if applicable)

*Males* (may include if applicable)

Infertility (omit if not applicable)

*Females* (may include if applicable)

*Males* (may include if applicable)

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Subpopulation X (e.g., Renal Impairment)

**9 DRUG ABUSE AND DEPENDENCE**

**9.1 Controlled Substance**

**9.2 Abuse**

**9.3 Dependence**

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

Cardiac Electrophysiology

12.3 Pharmacokinetics

Absorption

*Effect of Food*

Distribution

Elimination

*Metabolism*

*Excretion*

Specific Populations

*Geriatric Patients*

##### *Pediatric Patients*

#### *Male and Female Patients*

#### *Racial or Ethnic Groups*

#### *Patients with Renal Impairment*

#### *Patients with Hepatic Impairment*

#### *Pregnant Women*

Drug Interaction Studies

*Drug A*

*Drug B*

12.4 Microbiology

12.5 Pharmacogenomics

**12.6 Immunogenicity**

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Mutagenesis

Impairment of Fertility

13.2 Animal Toxicology and/or Pharmacology

14 CLINICAL STUDIES

14.1 Subsection Title

14.2 Subsection Title

15 REFERENCES

*[The format for cross-referencing to another section of the Full Prescribing Information (FPI) differs from citing a reference in Section 15. Unlike the cross-referencing format [see Clinical Studies (14.1)], reference citations in the text of the FPI use a numerical superscript (e.g., 1) to cite the reference. List the references in numerical order.]*

**16 HOW SUPPLIED/STORAGE AND HANDLING**

17 PATIENT COUNSELING INFORMATION

*[This section must reference any FDA-approved patient labeling. The reference should appear at the beginning of Section 17 and include the type(s) of FDA-approved patient labeling. Recommended options for the reference statement include the following:]*

* Advise the patient to read the FDA-approved patient labeling (Patient Information).
* Advise the patient to read the FDA-approved patient labeling (Instructions for Use).
* Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).
* Advise the patient to read the FDA-approved patient labeling (Medication Guide).
* Advise the patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

Clinically Significant Adverse Reaction or Risk #1 *(this is a placeholder; not a heading)*

Clinically Significant Adverse Reaction or Risk #2 *(this is a placeholder; not a heading)*

*[Include additional headings for additional patient counseling information topics (e.g., “*Important Administration Instructions;*” “*Unique Storage and Handling Instructions;*” and, “*Pregnancy Exposure Registry*”).]*

*For NDAs must include at least one of the following: the manufacturer’s name (e.g., Firm-M) and their place of business; distributor’s name (e.g., Firm-D) and their place of business, or packer’s name (e.g., Firm-P) and their place of business:*

* *The manufacturer’s, distributor’s, and/or packer’s name may be the name of a parent, subsidiary, or affiliate company where the related companies are under common ownership and control.*
* *The place of business must include the street address, city, state, and zip code; however, may omit the street address if the address is shown in a current city or telephone directory. For a foreign manufacturer must also include the country and any applicable mailing code.*
* *If the manufacturer information is included and there are joint manufacturers must state: “Jointly Manufactured By [insert name of all of the manufacturers]”*
* *If the distributor is included, must use one of the following phrases: “Manufactured for Firm-D”, “Distributed by Firm-D”, “Manufactured by Firm-M for Firm-D”, “Manufactured for Firm-D by Firm-M”, “Distributor: Firm-D”, “Marketed by Firm-D”.*
* *If the packer is included, must use one of the following phrases: “Packed by Firm-P” or “Packaged by Firm-P”*

*For BLAs must include the license manufacturer’s name (i.e., the applicant on Form 356h) along with the license manufacturer’s address and U.S. license number.*

* *The distributor’s name and address may also be included.*
* *If the distributor is included must include one of the following phrases: “Manufactured for Firm-D”, “Distributed by Firm-D”, “Manufactured by Firm-M for Firm-D”, “Manufactured for Firm-D by Firm-M”, “Distributor: Firm-D”, or “Marketed by Firm-D”.*