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Product information

From [Health Canada](#)

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The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Marketed

Current status date:

2021-03-10

Original market date: ¹

2021-03-10

Product name:

CELGENE 2006
ADOTEX v. CELGENE

ONUREG

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the [alternate format help section](#).

DIN:

02510197

Product Monograph/Veterinary Labelling:

Date: 2021-01-04

 [Product monograph/Veterinary Labelling \(PDF version ~ 175K\)](#)

Company:

CELGENE INC

300 2344 Alfred-Nobel Boulevard

Saint-Laurent

Quebec

Canada H4S 0A4

Class:

Human

Dosage form(s):

Tablet

Route(s) of administration:

Oral

Number of active ingredient(s):

1

Prescription

Anatomical Therapeutic Chemical (ATC): ⁴

L01BC07 AZACITIDINE

Active ingredient group (AIG) number: ⁵

0152665002

List of active ingredient(s)

Active ingredient(s)	Strength
AZACITIDINE	200 MG

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[Same active ingredient group number](#)

Footnotes

- 1 The earliest marketed date recorded in the Drug Product Database.
- 4 The purpose of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system is to be used as a tool for drug utilization research in order to improve quality of drug use. Drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutical properties.

5 The AIG number is a 10 digit number that identifies products that have the same active ingredient(s) and ingredient strength(s). The AIG is comprised of three portions:

- the first portion (2 digits) identifies the number of active ingredients,
 - the second portion (5 digits) identifies the unique groups of active ingredient(s),
 - the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.
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Application information

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