




# Product information

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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:	2015-04-10
Original market date: <sup>1</sup>	2015-04-10
Product name:	AURO-VALGANCICLOVIR
Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the <a href="#">alternate format help section</a> .	
DIN:	02435179
Product Monograph/Veterinary Labelling:	<b>Date:</b> 2018-03-14  <a href="#">Product monograph/Veterinary Labelling (PDF version ~ 175</a>
Company:	<a href="#">AURO PHARMA INC</a> 3700 Steeles Avenue West, Suite 402 Woodbridge Ontario Canada L4L 8K8
Class:	Human
Dosage form(s):	Tablet
Route(s) of administration:	Oral
Number of active ingredient(s):	1
Schedule(s):	Prescription
American Hospital Formulary Service (AHFS): <sup>3</sup>	08:18.32

Anatomical Therapeutic Chemical (ATC):<sup>4</sup>J05AB14 VALGANCICLOVIR

Active ingredient group (AIG) number:<sup>5</sup>0147203001

List of active ingredient(s)

Active ingredient(s) <sup>8</sup>	Strength
VALGANCICLOVIR (VALGANCICLOVIR HYDROCHLORIDE)	450 MG

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[Same active ingredient group number](#)

Footnotes

- 1The earliest marketed date recorded in the Drug Product Database.
- 3The American Hospital Formulary Service permits an easy review of information on a group of drugs with similar activities and uses and allows the reader to determine quickly the similarities and differences among drugs within a group. *AHFS® Pharmacologic/Therapeutic Classification*© used with permission. © 2022, the American Society of Health-System Pharmacists, Inc. (ASHP). The Data is a part of the AHFS Drug Information ASHP is not responsible for the accuracy of transpositions from the original context.
- 4The 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.
- 5The 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 ingredients(s),
  - the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.
- 8An asterisk \* preceding an active ingredient indicates that the name of the active ingredient has been shortened to fit inside the database's field and that the active ingredient's full name is available on the product's Product Monograph/Veterinary Labelling available above and/or in the NOTES section of the QRYM\_ACTIVE\_INGREDIENTS extract available in the Drug product database (DPD) data extracts. The followir link provides an explanation of the ordering of the data values contained in the DPD data extracts [Read me fi](#)

# Drug & health product inspections

## Licensing information

**Establishment name:** Auro Pharma Inc

**Building name:** Not available

**Address:** 3700 Steeles Avenue West, 402  
Woodbridge, Ontario  
Canada  
L4L 8K8

**Reference number:** 501813

**Site:** A

**Licence number:** 101305

**Currently licensed:** Yes

**Activities(categories):**

- Distribute (Biological)
- Import (Pharmaceutical)
- Distribute (Pharmaceutical)

**Terms and conditions:** Yes

## Inspection information

Inspection:	Inspection start date	Rating	Type of inspection
	2023-09-27	<u>Compliant</u>	GMP Domestic-Initial Inspection
	2022-10-24	<u>Compliant</u>	GMP Domestic-Regular Inspection
	2018-09-18	<u>Compliant</u>	GMP Domestic-Regular Inspection
	2016-07-20	<u>Compliant</u>	GMP Domestic-Initial Inspection

Date modified: 2016-11-08