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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

Company:	<u>SAOL THERAPEUTICS RESEARCH LIMITED</u> Peter Street, Unit G04, Adelaide Chambers Dublin 8 -- Ireland
Class:	Human
Dosage form(s):	Solution
Route(s) of administration:	Intramuscular, Intravenous
Number of active ingredient(s):	1
Schedule(s):	Schedule D
Anatomical Therapeutic Chemical (ATC): ⁴	J06BB04 HEPATITIS B IMMUNOGLOBULIN
Active ingredient group (AIG) number: ⁵	0114080004

List of active ingredient(s)

Active ingredient(s)	Strength
HEPATITIS B IMMUNOGLOBULIN (HUMAN)	312 UNIT / ML

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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.

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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 ingredients(s),
 - the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.
-

Application information

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