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Government of Canada

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> Drug Product Database online query

Product information

From Health Canada

New search

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: 2019-02-11

Original market date: 2007-08-13

<u>1</u>

Product name: HEPAGAM B

Description: HEPAT. B IMMUNE GLOBULIN (HUMAN). ACTIVE

INGREDIENT STRENGTH > 312 IU/ML

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

DIN: 02290979

Product Date: 2017-12-21

Labelling: $(PDF \text{ version } \sim 175K)$

Company: SAOL THERAPEUTICS RESEARCH LIMITED

Peter Street, Unit G04, Adelaide Chambers

Dublin 8

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Ireland

Class: Human

Dosage form(s): Solution

Route(s) of Intramuscular, Intravenous

administration:

Number of active

ingredient(s):

Schedule(s): Schedule D

Anatomical J06BB04 HEPATITIS B IMMUNOGLOBULIN

Therapeutic Chemical

(ATC): $\frac{4}{}$

Active ingredient 0114080004

group (AIG) number: ⁵

List of active ingredient(s)

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

New search

Same active ingredient group number

Footnotes

- <u>1</u> The earliest marketed date recorded in the Drug Product Database.
- 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.

- <u>5</u> 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

Search tips

<u>Drug product database terminology</u>

<u>Drug product database data extracts</u>

Related information

MedEffect Canada

Adverse drug reaction - veterinary drugs

Notice of compliance database

Licensed natural health products database

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<u>Technical support</u>

Version 3.9.2

Date modified: 2022-03-10

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