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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: [1]	2007-08-13
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 alternate format help section .

DIN:	02290979
Product Monograph/Veterinary Labelling:	**Date:** 2017-12-21 Product monograph/Veterinary Labelling (PDF version ~ 175K)
Company:	

SAOL THERAPEUTICS RESEARCH LIMITED
Peter Street, Unit G04, Adelaide Chambers
Dublin 8
--
Ireland

Class:	Human
Dosage form(s):	Solution
Route(s) of administration:	Intravenous, Intramuscular
Number of active ingredient(s):	1
Schedule(s):	Schedule D
Biosimilar Biologic Drug:	No
American Hospital Formulary Service (AHFS): [3]	80:04.00 SERUMS

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

New search

Same active ingredient group number

Footnotes

1 The earliest marketed date recorded in the Drug Product Database.

3 The 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.

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 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

Drug product database terminology

Drug product database data extracts

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Date modified: 2021-08-03

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