Government of Canada Gouvernement du Canada

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:

1992-12-31

Original market date: [1]

1992-12-31

Product name:

BOTOX

Description:

50U/50ALLERGAN U VIAL, 100U/100ALLERGAN U VIAL, 200U/200ALLERGAN U VIAL

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:

01981501

Product Monograph/Veterinary Labelling:

Date: 2018-10-16

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

ALLERGAN INC
SUITE 500 85 Enterprise Blvd
Markham
Ontario
Canada L6G 0B5

Class:

Human

Dosage form(s):

Powder For Solution

Route(s) of administration:

Intramuscular

Number of active ingredient(s):

1

Schedule(s):

Schedule D, Prescription

American Hospital Formulary Service (AHFS): [3]

92:92.00 OTHER MISCELLANEOUS THERAPEUTIC AGENTS

Anatomical Therapeutic Chemical (ATC): [4]

M03AX01 BOTULINUM TOXIN

Active ingredient group (AIG) number: [5]

0151557001

List of active ingredient(s)

Active ingredient(s)	Strength
ONABOTULINUMTOXINA	100 UNIT / VIAL

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

Related information

MedEffect Canada

Adverse drug reaction - veterinary drugs

Notice of compliance database

Licensed natural health products database

Contact us

Content support

Technical support

Version 3.7.1

Date modified: 2019-03-19