Drug Product Database (DPD)

Terminology

Active Ingredient

An Active Ingredient is any component that has medicinal properties, and supplies pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or any function of the body of a human or an animal.

The name and strength of each active ingredient contained in the product is listed. Information enclosed within brackets represents the salt and identifies how the ingredient is supplied. This information is only included for some ingredients. The number in the strength field refers to the active portion of the drug. For example, for calcium (calcium carbonate) 200 milligram (mg) - 200 mg is the strength of elemental calcium, not calcium carbonate.

Health Canada has a reference text hierarchy for ingredient nomenclature. The International Non Proprietary Names (INN) is used as Health Canada's standard to assign the preferred name to ingredients. There are other standards such as the United States Adopted Names (USAN), Martindale,

Merck Index, etc., that are used to code ingredients if they are not listed in the INN. They are also used to maintain a synonym's list in our internal database.

For example, if an ingredient is not found in the INN reference text but is listed in the USAN, then Health Canada would use the USAN as the preferred name until INN lists the ingredient in their reference text. If the ingredient is not found in either the INN or the USAN then Health Canada hierarchy would be followed and the Martindale reference text would be used. The process would continue until all resources are exhausted and, in that case, internet reference and/or articles would be used until it is listed in any of the previous reference text.

Please note that before 2005, USAN was considered Health Canada's nomenclature standard. Therefore, there are some exceptions listed on the DPD Online where the ingredients are coded using that standard. For more information on INN, please visit the following link on the World Health Organization website.

Active Ingredient Group (AIG) Number

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%.

The Active Ingredient Group structure is illustrated in the examples provided below:

Active Ingredient Group	Number of Ingredients	Ingredient Group	Strength Group	Products
0302037001	03	02037 acetaminophen caffeine citrate codeine phosphate	001 325mg 30 mg 15 mg	Atasol 15 Exdol 15
0302037002	03	02037 acetaminophen caffeine citrate codeine phosphate	002 325 mg 30 mg 30 mg	Atasol 30 Exdol30
0106827001	01	06827 dimethicone	001 40 mg	Ovol drops 40mg/ml (milligrams per millilitre) Ovol tablets 40 mg
0106827002	01	06827 dimethicone	002 80 mg	Ovol 80 mg

American Hospital Formulary Service (AHFS)

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.

The classification of a substance in the AHFS system is not a recommendation for use, nor does it imply any judgments about efficacy of drugs and groups of drugs. The names of the drugs are the *United States Adopted Names* (USAN) and other names described in the *USP Dictionary of USAN and International Drug Names*.

More than one AHFS code can be assigned to a product to reflect different indications, as per the AHFS classification system's guiding principles.

Anatomical Therapeutical Chemical (ATC) Classification System

The purpose of the ATC classification system is to be used as a tool for drug utilization research in order to improve quality of drug use. One component of this is the presentation and comparison of drug consumption statistics at international and other levels.

The classification of a substance in the ATC classification system is not a recommendation for use, nor does it imply any judgments about efficacy of drugs and groups of drugs. In the ATC classification system, the drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutical properties. The drugs are classified in groups at five different levels, as described in the example below:

- **A**: Alimentary tract and metabolism (1st level, anatomical main group)
- A**10**: Drugs used in diabetes (2nd level, therapeutic subgroup)
- A10**B**: Blood glucose lowering drugs, excluding insulins (3rd pharmacological subgroup)
- A10B**A**: Biguanides (4th level, chemical subgroup)
- A10BA**02**: Metformin (5th level, chemical substance)

Brand Name

This is the brand name approved by Health Canada, under which the drug product may be marketed.

Class of Drug Product

The class identifies whether the drug is for human use, veterinary use or used as a radiopharmaceutical or a disinfectant.

Description

The description field displays important product information that might differentiate between two identical products (i.e. same product formulations with or without preservative) or to indicate specific characteristic of a product (i.e. single use syringe).

Drug

According to the *Food and Drug Act*, a drug includes any substance or mixture of substances manufactured, sold or represented for use in:

a. the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof in man or animal
b. restoring, correcting or modifying organic functions in man or animal, or
c. disinfection in premises in which food is manufactured, prepared or kept

Drug Identification Number (DIN)

A Drug Identification Number (DIN) is a computer-generated eight digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada.

A DIN uniquely identifies the following product characteristics:

- manufacturer;
- product name;
- active ingredient(s);
- strength(s) of active ingredient(s);
- pharmaceutical form; and
- route of administration.

Drug Statuses

The statuses listed below are a direct representation of the status available in DPD Online Query and the description of each status is summarized below. For more information on how to search using these new statuses, please refer to the Search Tips page.

- **Approved**: refers to an active DIN for a product that has been reviewed and authorized for sale in Canada but has not yet been marketed in Canada.
- **Authorized by Interim Order**: refers to an active DIN for a product that has been reviewed and authorized for sale in Canada, pursuant to an Interim Order issued by the Minister of Health, where the corresponding drug product has not yet been marketed in Canada.
- **Authorization by Interim Order Revoked**: refers to DIN for which the product authorization has been revoked as per section 19(2) and (3) of

the Regulations Amending the Food and Drug Regulations (Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19).

- **Cancelled Post-Market**: refers to a DIN that is cancelled further to the discontinuation of the sale of the product by the manufacturer pursuant to Section C.01.014.6 (1) (a) of the Regulations.
- **Cancelled Pre-Market**: refers to a DIN that is cancelled before the product was ever marketed in Canada.
- **Cancelled (Safety Issue):** refers to a DIN that is cancelled under
    - Section C.01.014.6 (2) (b) of the Regulations due to failure to provide evidence regarding the safety and effectiveness of a drug, under Section C.01.013 of the Regulations.
    - Section C.01.014.6 (2) (b) of the Regulations following the suspension of and Notice of Compliance under section C.08.006
    - Section C.01.014. 6 (3) (a) of the Regulations following the failure to comply with the order issued under section 21.31 of the Act to conduct an assessment and provide the results
    - Section C.01.014.6 (3) (b) of the Regulations following the examination of the results of an assessment provided in response to an order issued under section 21.31 of the Act
- **Cancelled (Unreturned Annual)**: refers to a DIN that is cancelled due to failure to provide the Annual Notification pursuant to Section C.01.014.6 (2) (a) of the Regulations.
- **Dormant**: refers to an active DIN for a product that was previously marketed in Canada but for which there have been no sales for period of at least 12 consecutive months.
- **Marketed**: refers to an active DIN for a product that is currently being sold in Canada.

- **Restricted Access**: refers to an active DIN where the sale of the corresponding drug product is restricted to federal, provincial and territorial, and municipal government(s), pursuant to C.08.002.02 of the Regulations.

Nomenclature Naming

Refer to the Active Ingredient text for a detailed explanation

Number of Active Ingredient(s)

This represents the total number of active (medicinal) ingredient(s) contained in a product.

Pharmaceutical Form

The pharmaceutical form is the form of presentation in which the product is supplied, for example, tablet, capsule, powder, etc.

A product can have more than one dosage form when it is a kit (e.g. tablet, capsule).

Prescribing Information (PI)

Drugs regulated solely under Division 1 of the Food and Drug Regulations are not required to have a product monograph (PM). Rather, many Division 1 drugs have PI, which includes important information such as the mode of action, indications, contraindications of use, and dosage instructions. This information is helpful for the optimal, safe and effective use of a drug product, and informs health care professionals and the general public of the authorized conditions of use of a drug. Often, PI is similar to the package insert included in drug products.

Product Monograph (PM)

A PM is a factual, scientific document on the drug product that, devoid of promotional material, describes the properties, claims, indications, and conditions of use for the drug, and that contains any other information that may be required for optimal, safe, and effective use of the drug. A PM should include appropriate information respecting the name of the drug, its therapeutic or pharmacologic classification, its actions and/or clinical pharmacology, and its indications and clinical uses.

The PM should also include contraindications, warnings, precautions, adverse reactions, drug interactions and effects on laboratory tests, symptoms and treatment of over dosage, dosage and administration, storage and stability, pharmaceutical information, dosage forms, pharmacology, toxicology, microbiology, special handling instructions, information on clinical trials, information for the consumer, references, and the dates of the initial printing and current revision.

Route of Administration

Indicates the part of the body on which, through which or into which the product is to be introduced (e.g. oral, topical, intramuscular, rectal).

A product can have more than one route of administration (e.g. intravenous, intramuscular, intra articular).

Schedule

Each drug is assigned one or more of the following schedules, according to the *Food and Drug Regulations*, and the *Controlled Drugs and Substances Act*.

- Prescription (prescription drugs included in the Prescription Drug List)
- Prescription Recommended (drugs that are recommended to be listed on the Prescription Drug List)
- Schedule G (control drugs)

- Schedule G (*Controlled Drugs and Substances Act* [CDSA] III)
- Schedule G (CDSA IV)
- Schedule C (drugs listed in Schedule C of the *Food and Drugs Act,* for example, radiopharmaceutical drugs)
- Schedule D (drugs listed in Schedule D of the *Food and Drugs Act,* ie. biological products)
- Narcotic (*Narcotic Control Act*)
- Narcotic (CDSA I)
- Narcotic (CDSA II)
- Targeted (CDSA IV)
- CDSA Recommended- Undergoing Regulatory Amendment to add this new substance to Controlled Drugs Substances Act
- OTC (over the counter drugs that do not appear on a schedule or are not recommended to appear on any schedule)
- Ethical: a drug that, in accordance with Federal Legislation, does not require a prescription, but that is generally prescribed by a medical practitioner. Ethical products are unscheduled non-prescription professional use products (e.g. MRI contrast agents, hemodialysis solutions) and a few emergency use products (e.g. nitroglycerine)

Status Date

The current status date represents the date of the current status of a product (i.e. when a product was approved, marketed or cancelled in Canada).

The original market date represents the earliest marketed date recorded in the Drug Product Database. This is the date when the product first entered the Canadian market.

It is important to note that the date for older products may be listed as a generic date. For example, if the marketed date is listed as 1972.12.31, it represents the year the products was marketed in Canada and not necessarily the actual date of December 31, 1972. This strictly happens for older products that were marketed prior to September 1996. This is due to the migration of data from an old system to the DPD. The format of the status date was converted from 'YYYY' to 'YYYY.MM.DD' format. Therefore, in order to accommodate the DPD date format, a default date of December 31 was picked therefore any products marketed within that year will show December 31, 19XX.

Strength

This refers to the strength of the active ingredient. If the strength is reported per a dosage unit (e.g.: 5 millilitre [mL] or 15 mL), this information will immediately follow the strength (e.g., 10 mg/5 mL).

Veterinary Labelling

The veterinary labelling may consist of an outer label, an inner label, and/or a package insert to be used in connection with a veterinary drug. The labels for a veterinary drug must specify adequate directions for use, including withdrawal periods for drugs intended for use in food-producing animals.

A veterinary labelling should include appropriate information respecting the name of the drug, its therapeutic or pharmacologic classification, its actions and/or clinical pharmacology, its indications, its clinical uses and its animal's species for which it is approved. The veterinary labelling could also include contraindications, warnings, cautions, adverse reactions, dosage forms, dosage and administration, microbiology, special handling instructions, and storage and stability.

Veterinary Species

This field displays the type of species for a certain veterinary product (e.g. sheep, dog, cattle, and poultry).

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