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Canada Vigilance Adverse Reaction Online Database - Data Structure

Although the Canada Vigilance Adverse Reaction Online Database is a relational database, there is a requirement to provide the data to users in a common format; therefore the data has been extracted into a flat file format. All files are dollar (\$) sign delimited enclosed in "quotes".

The data extract is comprised of 11 files that contain raw data extracted from the [Canada Vigilance Adverse Reaction Online Database](#). It does not include the scripts (programming) used to produce the online version of the Database.

The technical information below is provided for users who are familiar with working with databases or spreadsheets in ASCII format;

- [Reports.txt](#)
- [Drug_Product.txt](#)
- [Drug_Product Ingredients.txt](#)
- [Reactions.txt](#)
- [Outcome LX.txt](#)
- [Gender LX.txt](#)
- [Report Type LX.txt](#)
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- [Report Drug.txt](#)
- [Report Drug Indication.txt](#)
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Reports.txt

Purpose: This table provides the information about reports and patients.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Adverse Reaction Report (AER) Number (6 digits)	REPORT_ID	Yes	NUMBER
Adverse Reaction Report (AER) Number (9 digits)	REPORT_NO	Yes	VARCHAR2(9)
Adverse Reaction Report (AER) Version Number	VERSION_NO	Yes	NUMBER(3)
Latest Received Date	DATRECEIVED	No	DATE
Initial Received Date	DATINTRECEIVED	No	DATE

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Market Authorisation Holder (MAH) Adverse Reaction Report (AER) Number	MAH_NO	No	VARCHAR2(20)
Type of Report Code	REPORT_TYPE_CODE	No	VARCHAR2(9)
Type of Report - English	REPORT_TYPE_ENG	No	VARCHAR2(6)
Type of Report - French	REPORT_TYPE_FR	No	VARCHAR2(6)
Gender Code	GENDER_CODE	No	VARCHAR2(9)
Gender - English	GENDER_ENG	No	VARCHAR2(6)
Gender - French	GENDER_FR	No	VARCHAR2(6)
Age	AGE	No	NUMBER(6,3)
Age in Years	AGE_Y	No	NUMBER(6,3)
Age Unit - English	AGE_UNIT_ENG	No	VARCHAR2(6)
Age Unit - French	AGE_UNIT_FR	No	VARCHAR2(6)

Attribute	Attribute Physical Name	Mandatory	Date Type (Length)
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Report Outcome Code	OUTCOME_CODE	No	VARCHAR2(9)
Report Outcome - English	OUTCOME_ENG	No	VARCHAR2(60)
Report Outcome - French	OUTCOME_FR	No	VARCHAR2(60)
Weight	WEIGHT	No	NUMBER(7,3)
Weight Unit - English	WEIGHT_UNIT_ENG	No	VARCHAR2(60)
Weight Unit - French	WEIGHT_UNIT_FR	No	VARCHAR2(60)
Height	HEIGHT	No	NUMBER(7,3)
Height Unit - English	HEIGHT_UNIT_ENG	No	VARCHAR2(60)
Height Unit - French	HEIGHT_UNIT_FR	No	VARCHAR2(60)
Serious Adverse Reaction Code	SERIOUSNESS_CODE	No	VARCHAR2(9)

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
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Serious Adverse Reaction - English	SERIOUSNESS_ENG	No	VARCHAR2(6)
Serious Adverse Reaction - French	SERIOUSNESS_FR	No	VARCHAR2(6)
Death	DEATH	No	VARCHAR2(9)
Disability	DISABILITY	No	VARCHAR2(9)
Congenital Anomaly	CONGENITAL_ANOMALY	No	VARCHAR2(9)
Life Threatening	LIFE_THREATENING	No	VARCHAR2(9)
Hospitalization Required	HOSP_REQUIRED	No	VARCHAR2(9)
Other Medically Important Condition	OTHER_MEDICALLY_IMP_COND	No	VARCHAR2(9)
Reporter Type - English	REPORTER_TYPE_ENG	No	VARCHAR2(6)
Reporter Type	REPORTER_TYPE_FR	No	VARCHAR2(6)

- French Attribute			Date Type
Logical Name	Attribute Physical Name	Mandatory	(Length)

Report Source Code	SOURCE_CODE	No	VARCHAR2(9)
Report Source - English	SOURCE_ENG	No	VARCHAR2(6)
Report Source - French	SOURCE_FR	No	VARCHAR2(6)
E2B Safety Report ID Number	E2B_IMP_SAFETYREPORT_ID	No	VARCHAR2(10)
Authority Number	AUTHORITY_NUMB	No	VARCHAR2(10)
Company Number	COMPANY_NUMB	No	VARCHAR2(10)



Drug_Product.txt

Purpose: This table provides the information about all drug names and their codes.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
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Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Drug Product Identifier	DRUG_PRODUCT_ID	Yes	NUMBER(8)
Brand Name	DRUGNAME	No	VARCHAR2(100)

Drug_Product_Ingredients.txt

Purpose: This table provides the information about the active ingredients associated with all drugs.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Drug Product - Active Ingredient Identifier	DRUG_PRODUCT_INGREDIENT_ID	Yes	NUMBER(15)
Drug Product Identifier	DRUG_PRODUCT_ID	No	NUMBER(8)
Brand Name	DRUGNAME	No	VARCHAR2(100)

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Active Ingredient Identifier	ACTIVE_INGREDIENT_ID	No	NUMBER(8)
Active Ingredient Name	ACTIVE_INGREDIENT_NAME	No	VARCHAR2(12)



Reactions.txt

Purpose: This table provides the information about the reaction terms associated with report.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Reaction Identifier	REACTION_ID	Yes	NUMBER
Adverse Reaction Report (AER) Number (9 digits)	REPORT_ID	No	NUMBER
Reaction Duration	DURATION	No	NUMBER(9,3)
Reaction Duration Unit - English	DURATION_UNIT_ENG	No	VARCHAR2(60)
Reaction Duration Unit - French	DURATION_UNIT_FR	No	VARCHAR2(60)
Adverse Reaction Term - English	PT_NAME_ENG	No	VARCHAR2(250)

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Adverse Reaction Term - French	PT_NAME_FR	No	VARCHAR2(250)
System Organ Class - English	SOC_NAME_ENG	No	VARCHAR2(250)
System Organ Class - French	SOC_NAME_FR	No	VARCHAR2(250)
MedDRA Version	MEDDRA_VERSION	No	VARCHAR2(9)

Outcome_LX.txt

Purpose: This table provides the information about the outcome presentation text associated with the outcome code.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Outcome Identifier	OUTCOME_LX_ID	Yes	NUMBER(4)
Report Outcome Code	OUTCOME_CODE	No	VARCHAR2(3)
Report Outcome - English	OUTCOME_EN	No	VARCHAR2(60)
Report Outcome - French	OUTCOME_FR	No	VARCHAR2(60)

Gender_LX.txt

Purpose: This table provides the information about the gender presentation text associated with the gender code.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Gender Identifier	GENDER_LX_ID	Yes	NUMBER(7)
Gender Code	GENDER_CODE	No	VARCHAR2(9)
Gender - English	GENDER_EN	No	VARCHAR2(60)
Gender - French	GENDER_FR	No	VARCHAR2(60)

Report_Type_LX.txt

Purpose: This table provides the information about the report type presentation text associated with the report type code.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Report Type Identifier	REPORT_TYPE_LX_ID	Yes	NUMBER(7)
Report Type Code	REPORT_TYPE_CODE	No	VARCHAR2(9)
Report Type - English	REPORT_TYPE_EN	No	VARCHAR2(60)
Report Type - French	REPORT_TYPE_FR	No	VARCHAR2(60)

Seriousness_LX.txt

Purpose: This table provides the information about the report seriousness presentation text associated with the report seriousness code.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Serious Report Identifier	SERIOUSNESS_LX_ID	Yes	NUMBER(7)
Serious Adverse Reaction Code	SERIOUSNESS_CODE	No	VARCHAR2(9)
Serious Adverse Reaction - English	SERIOUSNESS_EN	No	VARCHAR2(60)
Serious Adverse Reaction - French	SERIOUSNESS_FR	No	VARCHAR2(60)

Source_LX.txt

Purpose: This table provides the information about the report source presentation text associated with the report source code.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Report Source Identifier	SOURCE_LX_ID	Yes	NUMBER(7)
Report Source Code	SOURCE_CODE	No	VARCHAR2(9)

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Report Source - English	SOURCE_EN	No	VARCHAR2(60)
Report Source - French	SOURCE_FR	No	VARCHAR2(60)

Report_Links_LX.txt

Purpose: This table provides the information about the linked/duplicate reports presentation text associated with the code.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Report Link Identifier	REPORT_LINK_ID	Yes	NUMBER
Adverse Reaction Report (AER) Number (6 digits)	REPORT_ID	Yes	NUMBER
Record Type - English	RECORD_TYPE_ENG	No	VARCHAR2(9)
Record Type - French	RECORD_TYPE_FR	No	VARCHAR2(7)
Duplicate or Linked Adverse Reaction Report (AER) Number	REPORT_LINK_NO	No	VARCHAR2(18)

Report_Drug.txt

Purpose: This table provides the information about drugs associated with specific reports.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Report Drug Identifier	REPORT_DRUG_ID	Yes	NUMBER(1)

Adverse Reaction Report (AER) Number (6 digits)	REPORT_ID	No	NUMBER(1)
Drug Product Identifier	DRUG_PRODUCT_ID	No	NUMBER(8)
Brand Name	DRUGNAME	No	VARCHAR2
Health Product Role - English	DRUGINVOLV_ENG	No	VARCHAR2
Health Product Role - French	DRUGINVOLV_FR	No	VARCHAR2
Route of Administration - English	ROUTEADMIN_ENG	No	VARCHAR2
Route of Administration	ROUTEADMIN_FR	No	VARCHAR2

Administration			
Attribute	Attribute		Date Type
Logical Name	Physical Name	Mandatory	(Length)
Dose	UNIT_DOSE_QTY	No	NUMBER(2)
Dose Unit - English	DOSE_UNIT_ENG	No	VARCHAR2
Dose Unit - French	DOSE_UNIT_FR	No	VARCHAR2

Frequency	FREQUENCY	No	NUMBER(3)
Frequency Time	FREQ_TIME	No	NUMBER(1)
Frequency Time - English	FREQUENCY_TIME_ENG	No	VARCHAR2
Frequency Time - French	FREQUENCY_TIME_FR	No	VARCHAR2
Frequency Unit - English	FREQ_TIME_UNIT_ENG	No	VARCHAR2
Frequency Unit - French	FREQ_TIME_UNIT_FR	No	VARCHAR2
Therapy Duration	THERAPY_DURATION	No	NUMBER(1)
Therapy Duration - English	THERAPY_DURATION_UNIT_ENG	No	VARCHAR2
Therapy Duration - French	THERAPY_DURATION_UNIT_FR	No	VARCHAR2

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Duration - French			
Dosage Form - English	DOSAGEFORM_ENG	No	VARCHAR2
Dosage Form - French	DOSAGEFORM_FR	No	VARCHAR2



Report_Drug_Indication.txt

Purpose: This table provides the information about indications associated with specific reports.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Report Drug Identifier	REPORT_DRUG_ID	Yes	NUMBER(15)
Adverse Reaction Report (AER) Number (6 digits)	REPORT_ID	No	NUMBER(15)
Drug Product Identifier	DRUG_PRODUCT_ID	No	NUMBER(8)
Brand Name	DRUGNAME	No	VARCHAR2(100)
Indication - English	INDICATION_NAME_ENG	No	VARCHAR2(250)

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Indication - French	INDICATION_NAME_FR	No	VARCHAR2(250)

Literature_Reference.txt

Purpose: This table provides the information about literature references.

Attribute Logical Name	Attribute Physical Name	Mandatory	Date Type (Length)
Adverse Reaction Report (AER) Number (6 digits)	REPORT_ID	Yes	NUMBER
Adverse Reaction Report (AER) Number (9 digits)	REPORT_NO	Yes	VARCHAR2(9)
Adverse Reaction Report (AER) Version Number	VERSION_NO	Yes	NUMBER(3)

Literature Reference Sequence	SEQ_LITERATURE	No	NUMBER(4)
Literature reference	LITERATURE_REFERENCE	No	VARCHAR2(1000)

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