

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](#)
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Reports.txt

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

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

Attribute Logical Name	Attribute Physical Name	Mandatory	Data Type (Length)
Adverse Reaction Report (AER) Version Number	VERSION_NO	Yes	NUMBER(3
Latest Received Date	DATRECEIVED	No	DATE
Initial Received Date	DATINTRECEIVED	No	DATE
Market Authorisation Holder (MAH) Adverse Reaction Report (AER) Number	MAH_NO	No	VARCHAR2
Type of Report Code	REPORT_TYPE_CODE	No	VARCHAR2
Type of Report - English	REPORT_TYPE_ENG	No	VARCHAR2
Type of Report - French	REPORT_TYPE_FR	No	VARCHAR2
Gender Code	GENDER_CODE	No	VARCHAR2
Gender - English	GENDER_ENG	No	VARCHAR2
Gender - French	GENDER_FR	No	VARCHAR2
Age	AGE	No	NUMBER(6
Age in Years	AGE_Y	No	NUMBER(6
Age Unit - English	AGE_UNIT_ENG	No	VARCHAR2
Age Unit - French	AGE_UNIT_FR	No	VARCHAR2
Report Outcome Code	OUTCOME_CODE	No	VARCHAR2
Report Outcome - English	OUTCOME_ENG	No	VARCHAR2
Report Outcome - French	OUTCOME_FR	No	VARCHAR2
Weight	WEIGHT	No	NUMBER(7

Attribute Logical Name	Attribute Physical Name	Mandatory	Data Type (Length)
Weight Unit - English	WEIGHT_UNIT_ENG	No	VARCHAR2
Weight Unit - French	WEIGHT_UNIT_FR	No	VARCHAR2
Height	HEIGHT	No	NUMBER(7
Height Unit - English	HEIGHT_UNIT_ENG	No	VARCHAR2
Height Unit - French	HEIGHT_UNIT_FR	No	VARCHAR2
Serious Adverse Reaction Code	SERIOUSNESS_CODE	No	VARCHAR2
Serious Adverse Reaction - English	SERIOUSNESS_ENG	No	VARCHAR2
Serious Adverse Reaction - French	SERIOUSNESS_FR	No	VARCHAR2
Death	DEATH	No	VARCHAR2
Disability	DISABILITY	No	VARCHAR2
Congenital Anomaly	CONGENITAL_ANOMALY	No	VARCHAR2
Life Threatening	LIFE_THREATENING	No	VARCHAR2
Hospitalization Required	HOSP_REQUIRED	No	VARCHAR2
Other Medically Important Condition	OTHER_MEDICALLY_IMP_COND	No	VARCHAR2
Reporter Type - English	REPORTER_TYPE_ENG	No	VARCHAR2
Reporter Type - French	REPORTER_TYPE_FR	No	VARCHAR2
Report Source Code	SOURCE_CODE	No	VARCHAR2
Report Source - English	SOURCE_ENG	No	VARCHAR2
Report Source - French	SOURCE_FR	No	VARCHAR2

Attribute Logical Name	Attribute Physical Name	Mandatory	Data Type (Length)
E2B Safety Report ID Number	E2B_IMP_SAFETYREPORT_ID	No	VARCHAR2
Authority Number	AUTHORITY_NUMB	No	VARCHAR2
Company Number	COMPANY_NUMB	No	VARCHAR2

Drug_Product.txt

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

Attribute Logical Name	Attribute Physical Name	Mandatory	Data 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	Data 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)
Active Ingredient Identifier	ACTIVE_INGREDIENT_ID	No	NUMBER(8)
Active Ingredient Name	ACTIVE_INGREDIENT_NAME	No	VARCHAR2(100)

Reactions.txt

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

Attribute Logical Name	Attribute Physical Name	Mandatory	Data 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)
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	Data 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)

Attribute Logical Name	Attribute Physical Name	Mandatory	Data Type (Length)
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	Data 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	Data 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	Data Type (Length)
Serious Report Identifier	SERIOUSNESS_LX_ID	Yes	NUMBER(7)
Serious Adverse Reaction Code	SERIOUSNESS_CODE	No	VARCHAR2(9)

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

Attribute Logical Name	Attribute Physical Name	Mandatory	Data Type (Length)
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	Data Type (Length)
Report Drug Identifier	REPORT_DRUG_ID	Yes	NUMBER(10)
Adverse Reaction Report (AER) Number (6 digits)	REPORT_ID	No	NUMBER(6)
Drug Product Identifier	DRUG_PRODUCT_ID	No	NUMBER(10)
Brand Name	DRUGNAME	No	VARCHAR(100)
Health Product Role - English	DRUGINVOLV_ENG	No	VARCHAR(100)
Health Product Role - French	DRUGINVOLV_FR	No	VARCHAR(100)
Route of Administration - English	ROUTEADMIN_ENG	No	VARCHAR(100)
Route of Administration - French	ROUTEADMIN_FR	No	VARCHAR(100)
Dose	UNIT_DOSE_QTY	No	NUMBER(10)
Dose Unit - English	DOSE_UNIT_ENG	No	VARCHAR(100)
Dose Unit - French	DOSE_UNIT_FR	No	VARCHAR(100)
Frequency	FREQUENCY	No	NUMBER(10)
Frequency Time	FREQ_TIME	No	NUMBER(10)
Frequency Time - English	FREQUENCY_TIME_ENG	No	VARCHAR(100)

Attribute Logical Name	Attribute Physical Name	Mandatory	Data Type (Length)
Frequency Time - French	FREQUENCY_TIME_FR	No	VARCHAR
Frequency Unit - English	FREQ_TIME_UNIT_ENG	No	VARCHAR
Frequency Unit - French	FREQ_TIME_UNIT_FR	No	VARCHAR
Therapy Duration	THERAPY_DURATION	No	NUMBER
Therapy Duration - English	THERAPY_DURATION_UNIT_ENG	No	VARCHAR
Therapy Duration - French	THERAPY_DURATION_UNIT_FR	No	VARCHAR
Dosage Form - English	DOSAGEFORM_ENG	No	VARCHAR
Dosage Form - French	DOSAGEFORM_FR	No	VARCHAR

Report_Drug_Indication.txt

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

Attribute Logical Name	Attribute Physical Name	Mandatory	Data 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)
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	Data 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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