

Estándares e Interoperabilidad en Salud

Diccionario Nacional de Medicamentos

A/P Lino Bessonart
Gte Proyecto DINAMED en Salud.uy

Modelo de Datos de DINAMED

- ISO-TC215-N1753
 - The Australian Medicinal Terminology (AMT)
 - NHS dictionary of medicines and devices (DM+D)
 - Singapore Drug Database
 - SNOMED CT
 - Dutch G-Standaard from Z-Index (and Pharmabase from Healthbase) (NEN 7507).
 - TECHNICAL REPORT ISO/TR 22790 Health informatics — Functional characteristics of prescriber support Systems

ISO-TC215-N1753

- En proceso de votación.
- Busca especificar los Requerimientos Funcionales de sistemas de Diccionario de Productos Medicinales para Atención de Salud.
- El documento abarca los siguientes temas:
 - ¿Qué es un Diccionario de Productos Medicinales?
 - ¿Quiénes son los diferentes actores/interesados?
 - ¿Cuáles son los beneficios para los diferentes actores/interesados?
 - ¿Cuáles son las funcionalidades más importantes -centrales- de un Diccionario de Productos Medicinales para la asistencia?

ISO-TC215-N1753

¿Qué es un Diccionario de Productos Medicinales?

Un Diccionario de Medicamentos es una representación consistente de conceptos de medicación en varios niveles de detalle y con significativas relaciones entre los conceptos de forma de que pueda apoyar los diferentes procesos en asistencia de salud en los cuales la medicación juega un rol.

ISO-TC215-N1753

¿Quiénes son los diferentes actores/interesados?

- Prestadores de salud.
- Autoridades reguladores de medicamentos.
- Laboratorios.
- Pacientes.
- Organizaciones de pacientes.
- Financiadores de salud.
- Compradores mayoristas.
- Desarrolladores de software.

ISO-TC215-N1753

¿Cuáles son las funcionalidades más importantes -centrales- de un Diccionario de Productos Medicinales para la asistencia?

- Prescripción.
- Dispensación
- Administración del medicamento (dosis, método, vía, ...)
- Registro histórico de medicación.
- Conciliación de lista de medicamentos.
- Cadena de suministro.
- Estadísticas de medicamentos incluyendo fármaco epidemiología.
- Interoperabilidad: Intercambio electrónico de información de medicamentos entre sistemas de atención de salud y sistemas relacionados.
- Reembolso por medicamentos dispensados.
- Investigación Clínica.
- Seguimiento y localización de pacientes con fines de seguridad pública.
- Aseguramiento de la seguridad del paciente vinculando datos personales con sistemas de toma de decisiones en medicamentos.
- Fármaco vigilancia.

IDMP

Identification of Medicinal Products

Substances

ISO 11238

Data elements and structures for the unique identification and exchange of regulated information on substances

This norm distinguishes Substances (defined based on its main, general characteristics; can have different roles e.g. active ingredient, basis of strength, excipient) and Specified Substances (More granular, specific description of a substance e.g. including manufacturing information, purity, grade; allows for the identification of multiple substances ("Intermediate Products" e.g. AS03 - adjuvant composed of squalene (10.69 milligrams), DL- α -tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams))

Substancias

Dose forms, etc.

ISO 11239

Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

Identifies, for example injection solution, injection emulsion, infusion solution (or a less granular regional term linked to these)

Dosis, Forma terapéutica, Vías

MPID

ISO 11615

Data elements and structures for the unique identification and exchange of regulated Medicinal Product information

Defines, characterizes and identifies regulated medicinal products that can use during their entire lifecycle (Development, authorization, marketing and renewal or withdrawal from the market) and provides definitions and concepts; Describes data elements and their structural relationships required for the detailed description and unique identification of medicinal products

Productos Comerciales

Units of measurement

ISO 11240

Data elements and structures for the unique identification and exchange of units of measurement

Specify rules for the usage of units of measurement for IDMP; Define requirements for traceability to metrological standards; Establish reference code system for units; Provide standards and rules for mapping between different unit vocabularies and language translations, linking to existing systems, dictionaries and repositories

Unidades de Medida

PhPID

ISO 11616

Data elements and structures for the unique identification and exchange of regulated Medicinal Product information

Pharmaceutical Product Identification (PhPID) based on the following subset of elements that describe a pharmaceutical product:

- Substance(s)/Specified Substance(s)
- Strength(s) - Strength units (units of measurement and/or unit of presentation)
- Reference Strengths
- Administrable Dose Form

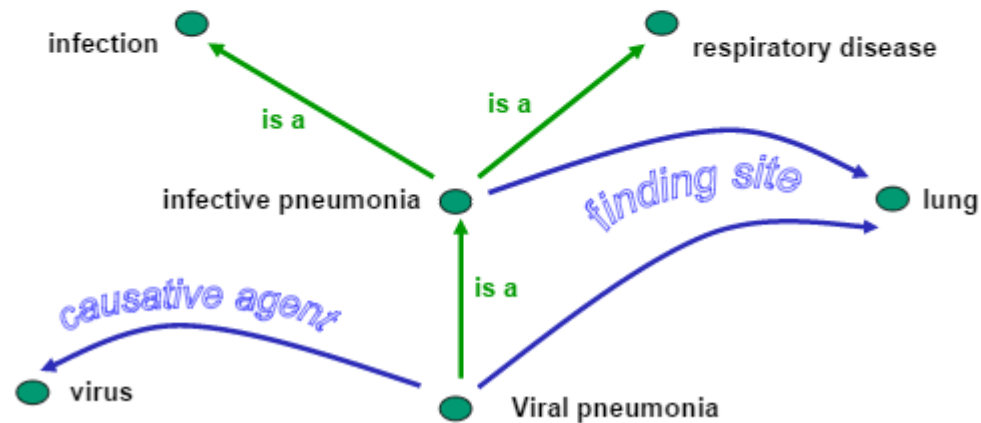
Genérico

TS 16791
Provides guidance for the identification of medicinal products by using international supply chain standards, securing traceability, safe supply chain and other market requirements.



SNOMED CT adds meaning

- Every coded concept is linked to related concepts
 - Multi-axial subtype hierarchy ('is a' relationships)
 - Logical definitions (attribute relationships)

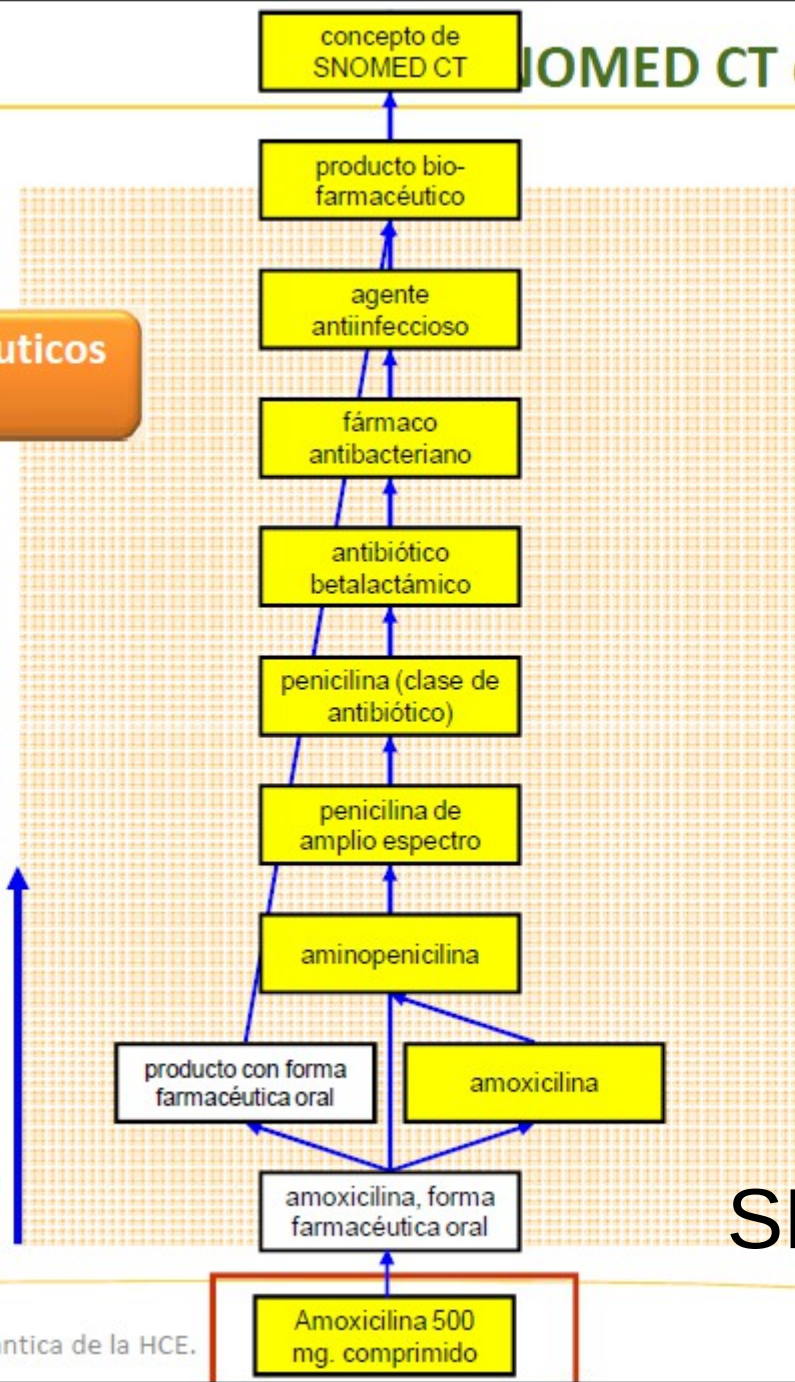




Productos Farmacéuticos y Biológicos

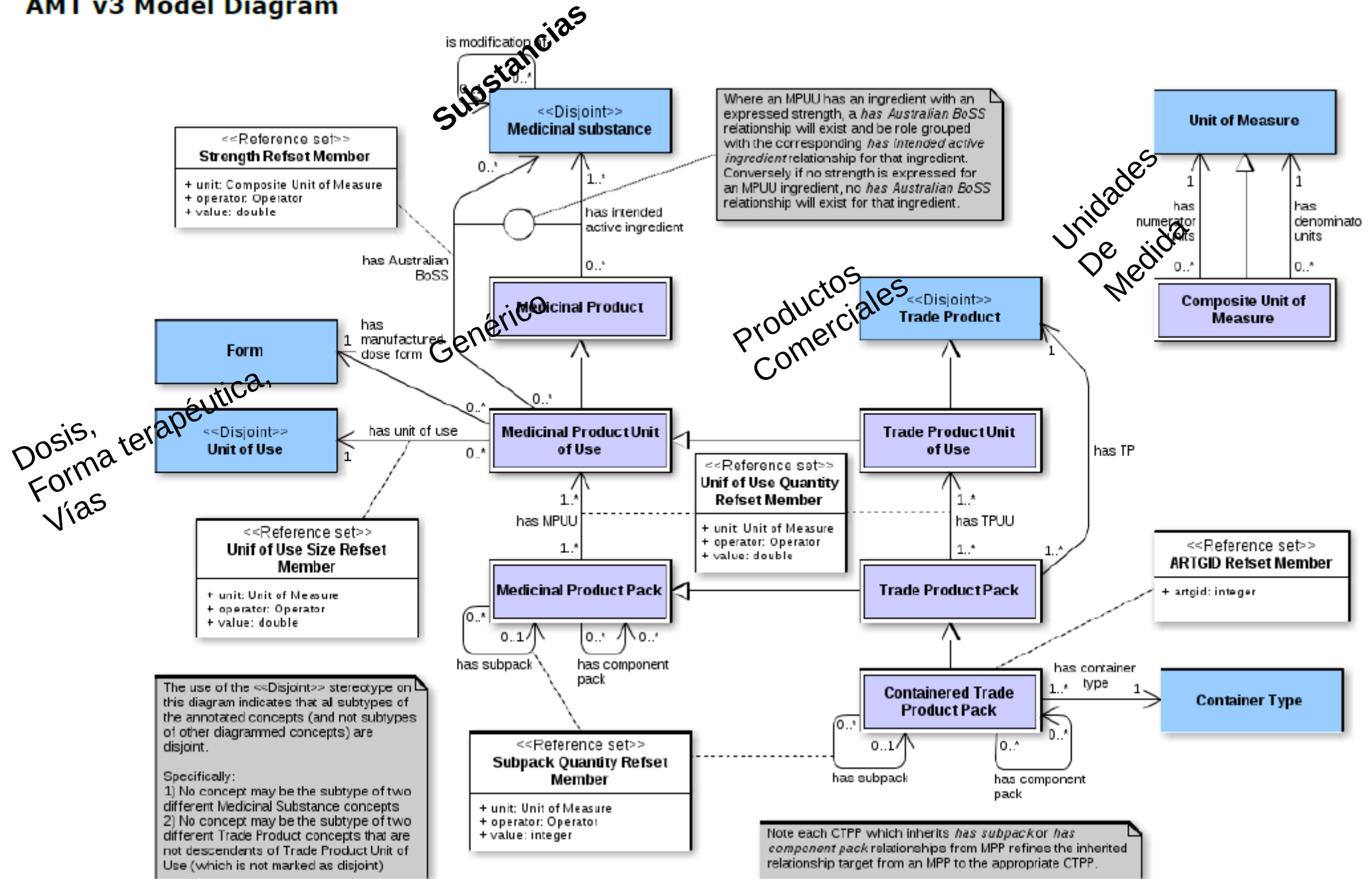


Es un/una



Porque SNOMED CT

AMT v3 Model Diagram



dm+d data model

Key use cases:

Dose based prescribing (i.e. most commonly used prescribing model in secondary care).

Recording of partial medication information.

Key use cases:

Product (generic) based prescribing (i.e. most commonly used prescribing model in primary care).

Product identification and selection for dispensing/administration.

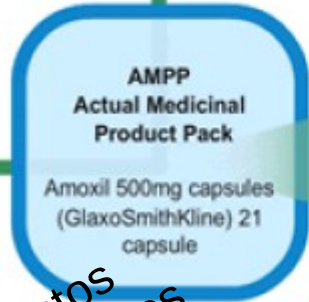
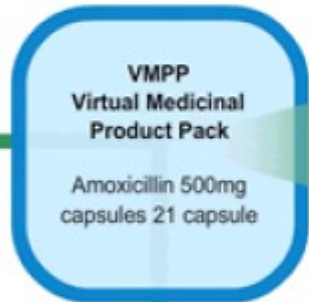
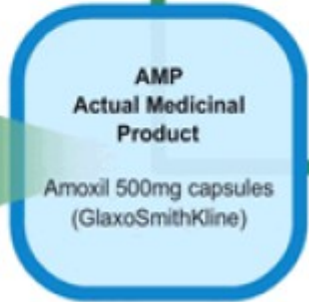
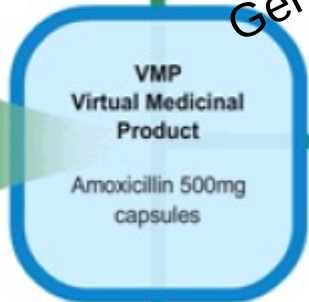
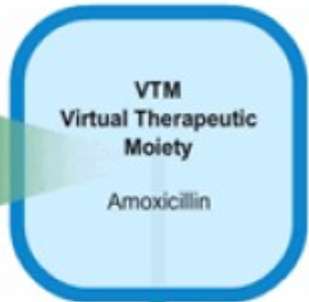
Recording of information within patient records.

Key use cases:

Product (brand/manufacture) based prescribing.

Product identification and selection for dispensing/administration.

Recording of information within patient records.



Key use cases:

Identification/selection of pack size for dispensing.

To record dispensed items including pack size.

Provides information for electronic reimbursement.

Key use cases:

Identification of pack size + availability.

To record dispensed items including pack size and manufacturer/brand.

Pricing.

Links to supply chain (e.g. GTIN (barcode) mapping).

Provides information for electronic reimbursement.

Genérico

Productos Comerciales

Unidades De Medida
Dosis,
Forma terapéutica,
Vías
Substancias

Panadol Extra soluble tablets (GlaxoSmithKline Consumer Healthcare)

Panadol Extra soluble tablets (GlaxoSmithKline Consumer Healthcare)

Attributes

Attribute Name	Attribute Value	Description
Manufacturer	4012401000001102	GlaxoSmithKline Consumer Healthcare
Licensed Route	26643006	Oral
Availability Restriction Code	0001	None
Licensing Authority	0001	Medicines - MHRA/EMA

Actual Product Interesting Excipients

Name Strength UOM

None in SPC

Appliance Product Information

Attribute Name Attribute Value Description

No Product Availability information exists

SNOMED Information

SNOMED Code 4928511000001103

Paracetamol 500mg / Caffeine 65mg effervescent tablets sugar free

Paracetamol 500mg / Caffeine 65mg efferv tab sugar free

Names

	Value	Description
Basis of Preferred Name	0007	Other
Date of Name Applicability	11/05/2004	
Previous Name	Paracetamol 500mg / Caffeine 65mg effervescent tablets	
Basis of Previous Name	0007	Other
Reason for Name Change	0004	Other

Attributes

Attribute Name	Attribute Value	Description
Prescribing Status	0001	Valid as a prescribable product
Sugar Free Ind	0001	Sugar-free

Unit Dose & Form Information

Attribute Name	Attribute Value	Description
DF Indicator	1	Discrete
UDFS Indicator 1	1	
UDFS UOM	428673006	tablet
Unit Dose UOM	428673006	tablet

Drug Form & Route Information

Attribute Name	Attribute Value	Description
Form	385058004	Effervescent tablet
Route	26643006	Oral
Ont Form/Route	0005	solution.oral

Virtual Product Ingredients

Name	Basis of Strength	Description	BOSS	Strength	UOM
Paracetamol	0001	Based on Ingredient Substance	500	mg	
Caffeine	0001	Based on Ingredient Substance	65	mg	

Attribute Name	Attribute Value	Description
CD Category	0000	No Controlled Drug Status

SNOMED Information

SNOMED Code 358501001

Paracetamol 500 mg cafeína 65 mg.

NHS dm+d

<VTMID>350309002</VTMID>
<NM>Paracetamol + Caffeine</NM>

Genérico

<DFORM>
<VPID>358501001</VPID>
<FORMCD>385058004</FORMCD>
</DFORM>

<VMP>
<VPID>358501001</VPID>
<VTMID>350309002</VTMID>
<NM>Paracetamol 500mg / Caffeine 65mg effervescent tablets sugar free</NM>
<ABBREVM>Paracetamol 500mg / Caffeine 65mg efferv tab sugar free</ABBREVM>
<BASISCD>0007</BASISCD><NMMDT>2004-05-11</NMMDT>
<NMPREV>Paracetamol 500mg / Caffeine 65mg effervescent tablets</NMPREV>
<BASIS_PREVCD>0007</BASIS_PREVCD>
<NMCHANGECD>0004</NMCHANGECD>
<PRES_STATCD>0001</PRES_STATCD>
<SUG_F>0001</SUG_F>
<DF_INDCD>1</DF_INDCD>
<UDFS>1</UDFS>
<UDFS_UOMCD>428673006</UDFS_UOMCD>
<UNIT_DOSE_UOMCD>428673006</UNIT_DOSE_UOMCD>
</VMP>

SNOMED Int.

<INFO>U. De Medida
<CD>258684004</CD>
<DESC>mg</DESC>
</INFO>

Ingrediente (sustancia)

<ING>
<ISID>387517004</ISID>
<ISIDDT>2005-08-02</ISIDDT>
<ISIDPREV>3573011000001105</ISIDPREV>
<NM>Paracetamol</NM></ING>

<ING>
<ISID>255641001</ISID>
<NM>Caffeine</NM>
</ING>

<VPI>
<VPID>358501001</VPID>
<ISID>387517004</ISID>
<BASIS_STRNTCD>0001</BASIS_STRNTCD>
<STRNT_NMRTR_VAL>500</STRNT_NMRTR_VAL>
<STRNT_NMRTR_UOMCD>258684004</STRNT_NMRTR_UOMCD>
</VPI>
<VPI>
<VPID>358501001</VPID>
<ISID>255641001</ISID>
<BASIS_STRNTCD>0001</BASIS_STRNTCD>
<STRNT_NMRTR_VAL>65</STRNT_NMRTR_VAL>
<STRNT_NMRTR_UOMCD>258684004</STRNT_NMRTR_UOMCD>
</VPI>

Panadol Extra soluble tablets

Paracetamol 500 mg cafeína 65 mg.

Genérico

```
<VMP>
<VPID>358501001</VPID>
<VTMID>350309002</VTMID>
<NM>Paracetamol 500mg / Caffeine 65mg effervescent tablets sugar free</NM>
<ABBREVM>Paracetamol 500mg / Caffeine 65mg efferv tab sugar free</ABBREVM>
<BASISCD>0007</BASISCD><NMDT>2004-05-11</NMDT>
<NMPREV>Paracetamol 500mg / Caffeine 65mg effervescent tablets</NMPREV>
<BASIS_PREVCD>0007</BASIS_PREVCD>
<NMCHANGECD>0004</NMCHANGECD>
<PRES_STATCD>0001</PRES_STATCD>
<SUG_F>0001</SUG_F>
<DF_INDCD>1</DF_INDCD>
<UDFS>1</UDFS>
<UDFS_UOMCD>428673006</UDFS_UOMCD>
<UNIT_DOSE_UOMCD>428673006</UNIT_DOSE_UOMCD>
</VMP>
```

SNOMED Int.

SNOMED
UK Edition

Comercial

```
<AMP>
<APID>4928511000001103</APID>
<VPID>358501001</VPID><NM>Panadol Extra soluble tablets</NM>
<DESC>Panadol Extra soluble tablets (GlaxoSmithKline Consumer Healthcare)</DESC>
<SUPPCD>4012401000001102</SUPPCD>
<LIC_AUTHCD>0001</LIC_AUTHCD>
<AVAIL_RESTRICTCD>0001</AVAIL_RESTRICTCD>
</AMP>
```

Proyecto DINAMED

- Guía de publicación.
- Modelo de datos.
- Obtención datos del MSP.
- Carga de tablas de referencia.
- Carga de vtm, vmp.
- Carga de amp, ampp, vmpp
- Alimentos.
- Cosméticos.
- Dispositivos.