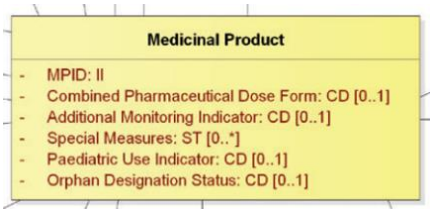
ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk

Entocort Enema, Klistier Lösung + Tabletten

Quelle		
Compendium	ENTOCORT Enema Klistier Lösung + Tabletten	compendium.ch®
SAI	ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk	refdata

Medicinal Product			
MPID	CH-7601001346451-5204201		
Approved Dose Form (EXT)	TABLR	Tabletten und Lösungsmittel zur Herstellung einer Rektalsuspension	

Product Classification	
ATC (Code System)	A07EA06
Heilmittelcode (Value)	S – Synthetika

Medicinal Product Name	
Type (EXT)	Original
Full Name	ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk
Invented Name Part	ENTOCORT Enema
Pharmaceutical Dose Form Part	Klistier Lösung + Tabletten
Container or Pack Part	7 Stk
Delimiter Part	,

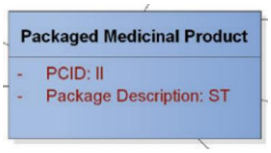
Country / Language			
Language	de	Deutsch	

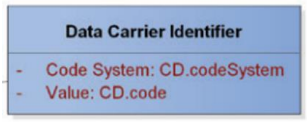
Medicinal Product Name			
Type (EXT)	BAG		
Full Name	ENTOCORT Enema Klistier Lösung + Tabletten		
Invented Name Part	ENTOCORT Enema		
Pharmaceutical Dose Form Part	Klistier Lösung + Tabletten		
Country / Language			
Language	de	Deutsch	

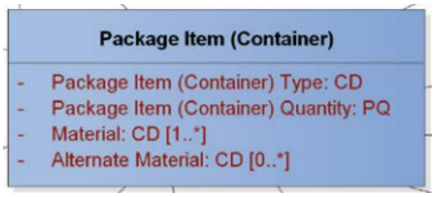
Marketing Authorisation (Medicinal Product)			
Marketing Authorisation Type (EXT)	tbd		
Marketing Authorisation Number	5204201		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	18.06.1993		
Validity Period End	31.12.9999		
Date of First Authorisation	18.06.1993		

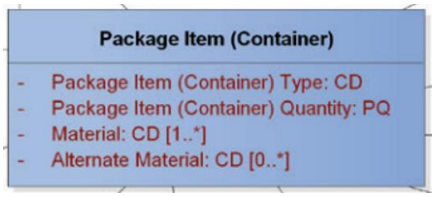
Marketing Authorisation Holder (Organisation)		
Name	Tillotts Pharma AG	
GLN	7601001346451	

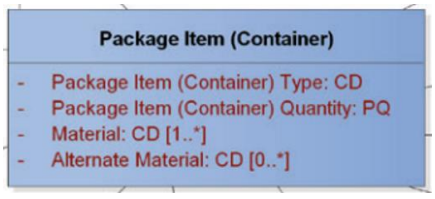
Hinweis: Pack Size, Tablette und Lösungsmittel für Klistier Lösung

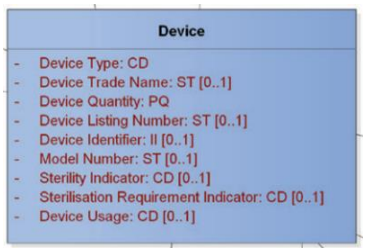
Packaged Medicinal Product		
PCID	CH-7601001346451-5204201-011	
Package Description	ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk	
Pack Size (EXT)	7 Lösung 7 Tablette	

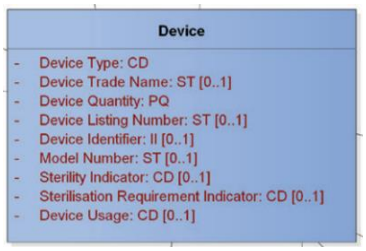
Data Carrier Identifier		
GTIN (Code System)	7680520420118	

Packaged Item (Container)			
Package Item (Container) Type	30009000	Box	
Package Item (Container) Quantity	1		
Material	Karton		

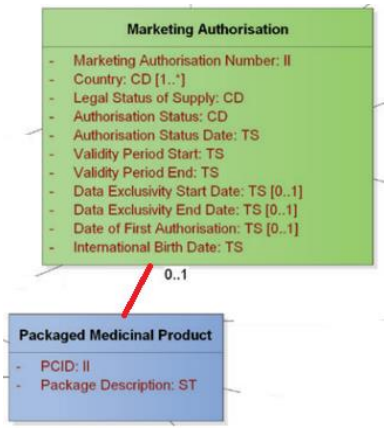
Packaged Item (Container)			
Package Item (Container) Type	30007000	Blister	
Package Item (Container) Quantity	5		
Material	Aluminium, Aluminium		

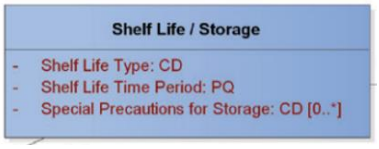
Packaged Item (Container)			
Package Item (Container) Type	30008000	Bottle	
Package Item (Container) Quantity	7		
Material	200000003214	Polyethylen	
Package (Component)			
Component Type	30013000	Cap	
Component Materila	200000003214	Polyethylen	

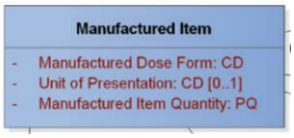
Device			
Device Type	30012000	Rektalkanüle (Applikator Enema)	
Device Quantity	7		

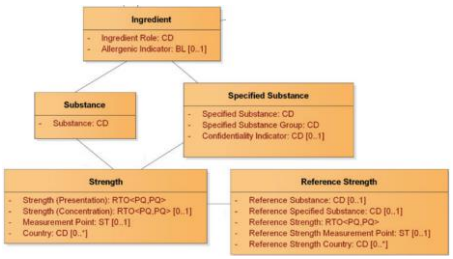
Device			
Device Type	tbd	Plastikhandschutz	
Device Quantity	7		

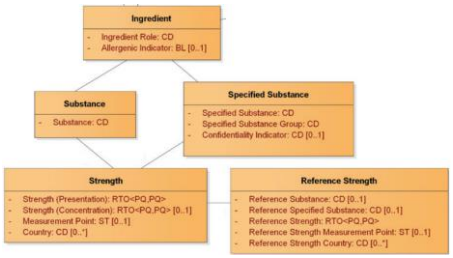
Packaged Item (Manufactured Item)			
Manufactured Item Quantity	7	Tabletten (per blister)	
Manufactured Item Quantity	7	Lösungsmittel (per box)	

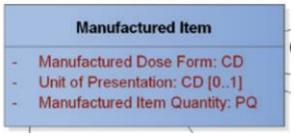
Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Number	52042011		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	18.06.1993		

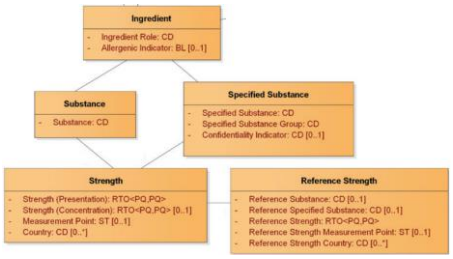
Shelf Life / Storage			
Shelf Life Type	100000073403	Closed Package	
Shelf Life Time Period	60 mo		
Special Precautions of Storage	NO30	Nicht über 30°C lagern	

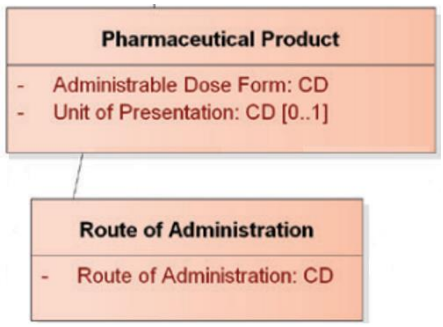
Manufactured Item			
Manufactured Dose Form	11012000	Tablet for rectal suspension	
Unit of Presentation	15054000	Tablette	

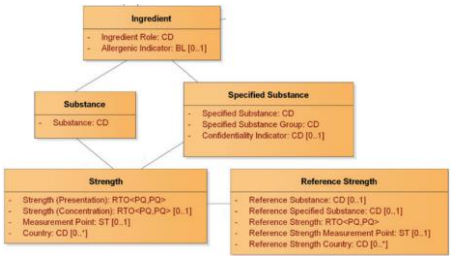
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	Q3OKS62Q6X	Budesonidum	
Strength (presentation)	2.3 mg (per UoP)		

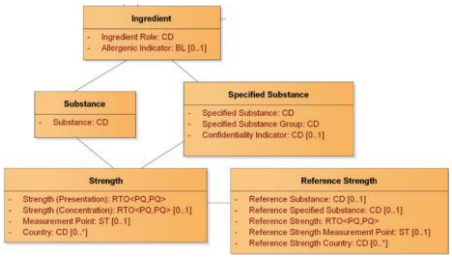
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	3SY5LH9PMK	Lactosum	
	957E53WV42	Riboflavini natrii phosphas	
	2S7830E561	Crospovidonum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	70097M6I30	Magnesii stearas	

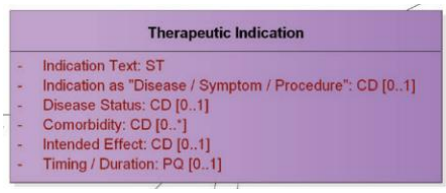
Manufactured Item			
Manufactured Dose Form	13035000	Lösungsmittel	
Unit of Presentation	15009000	Bottle	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	A2I8C7HI9T	METHYLPARABEN E 218	
	Z8IX2SC1OH	Propylis parahydroxybenzoas	
	451W47IQ8X	Natrii chloridum	
	059QF0KO0R	Aqua purificata	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	11006000	Rectal suspension	
Unit of Presentation	15009000	Bottle	
Route of Administration	20061000	Rectal use	
Methode of Administration (Swissmedic)	200000002039	Application	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	Q3OKS62Q6X	Budesonidum	
Strength (presentation)	2.0 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	3SY5LH9PMK	Lactosum	
	957E53WV42	Riboflavini natrii phosphas	
	2S7830E561	Crospovidonum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	70097M6I30	Magnesii stearas	
	A2I8C7HI9T	METHYLPARABEN E 218	
	Z8IX2SC1OH	Propylis parahydroxybenzoas	
	451W47IQ8X	Natrii chloridum	
	059QF0KO0R	Aqua purificata	

Therapeutic Indication			
Indication Text	Leichte bis mittelschwere Colitis ulcerosa des Rectums sowie des Colon sigmoideum		
Indication as	10009900	Colitis ulcerative	
Intended Effect	200000003194	Therapie	