

BAG Beispieldaten für IDMP

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Beispieldaten für IDMP

Thema

Dieses Dokument dient als Grundlage für den IDMP Datenaustausch in der Schweiz. Basierend auf diesen Beispielen wird die FHIR Spezifikation für das IDMP Projekt ePL erstellt. Diese Dokument Version dient dem Review der Beispieldaten.

ı	⊏xan	ipies	∠
	1.1	CUPRIOR Filmtabl 150 mg 72 Stk	17
	1.2	ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk	23
	1.3	ESTALIS Matrixpfl 50/250	31
	1.4	KEYTRUDA Inf Konz 100 mg/4ml Durchstf	41
	1.5	PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk	50
	1.6	TRIOGEN Kaps 250 mg Ds 100 Stk	58
2	Lists.	Error! Bookmark not defi	ned.
	<mark>2.1</mark>	Abkürzungsverzeichnis	66
	2.2	IDMP Model Error! Bookmark not defi	
	2.3	Websites	67
	2.3.1	GSRS	67
	2.3.2	EMA RMS	67
	2.3.3		
	2.4	Gesetze und Vorgaben	69
	2.4.1	Antwort des Bundesrates vom 7.3.2022 betreffend der Einführung von IDMP in der Schweiz	
	2.4.2	Commission Implementing Regulation (EU) No 520/2012	69
3	Versi	onierung	71

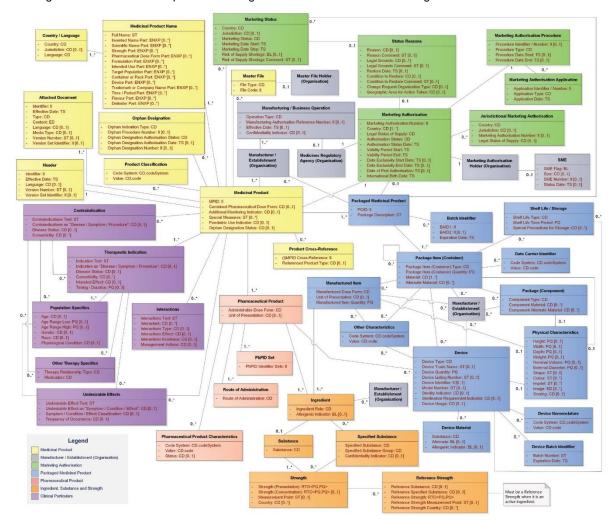


Datenmodel



1.1 Original-Datenmodell der ISO

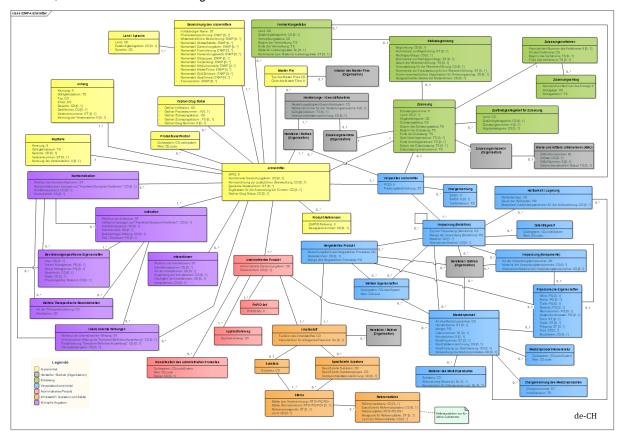
Das folgende Datenmodel entspricht dem Original IDMP Datenmodel der ISO gemäss ISO 11615:2017.





1.2 de-CH lokalisiertes ISO IDMP-Datenmodell

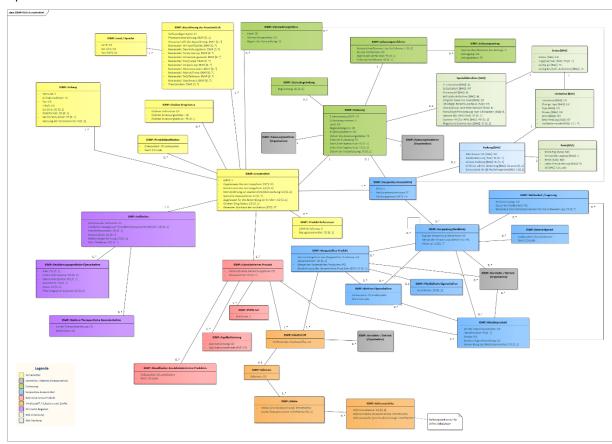
Das folgende Datenmodel illustriert das Original Datenmodel der ISO gemäss ISO 11615:2017 übersetzt nach Deutsch, lokalisiert für die Schweiz gemäss Amendment 1 vom ISO 11615:2017.





1.3 IDMP - BAG-SL-Datenmodell

Das folgende Datenmodel illustriert die für das BAG relevante IDMP Datenmodel erweitert mit den für die Spezialitätenliste relevanten Klassen und Attribute.





1.4 Liste der Klassen und Datenelemente – IDMP – BAG Datenmodell

In der folgenden Tabelle sind die Owner der Wertelisten, sowie die Datentypen und Kardinalitäten zu den einzelnen Elementen aufgeführt.

Data Element	Data Type	List Owner	Cardinality
Medicinal Product	Class	n/a	1*
MPID	Identifier	n/a	11
Authorised Pharmaceutical Form (EXT)	Value List	EDQM	11
Combined Pharmaceutical Dose Form	Value List	EDQM	01
Additional Monitoring Indicator	Value List	Swissmedic	01
Special Measures	Value List	Swissmedic	0*
Paediatric Use Indicator	Boolean	n/a	01
Orphan Designation Status	Boolean	n/a	01
Gesamter Wortlaut der Indikation (EXT)	String	n/a	11
Product Classification	Class	n/a	0*
ATC	Value List	WHO	11
Heilmittelcode	Value List	Swissmedic	11
Orphan Designation	Class	n/a	0*
Orphan Indication Type	Value List	Swissmedic	11
Orphan Designation Authorisation Status	Value List	Swissmedic	11
Orphan Designation Authorisation Date	Date	n/a	01
Product Name	Class	n/a	1*
Name	String	n/a	11
Name Part (Type)	Value List	HL7	0*
Country / Language			1*
Country	Value List	ISO	11
Language	Value List	ISO	11
Product Cross- Reference	Class	n/a	0*



I(MPID) Cross Reference	Identifier	n/a	11
Referenced Product	Value List	Swissmedic	11
Type	Olara	- 1-	
Attached Document	Class	n/a	1*
Identifier	Identifier	n/a	11
Effective Date	Date	n/a	11
Туре	Value List	Swissmedic	11
Content	ED	n/a	11
Language	Value List	ISO	01
Media Type	Value List	EMA	01
Version Number	String	n/a	01
Version Set ID	Identifier	n/a	01
Marketing Authorisation	(Medicinal Product)		11
Regulatory Authorisation Type	Value List	Swissmedic	11
Marketing Authorisation Number	Identifier	n/a	11
Country	Value List	ISO	11
Legal Status of Supply	Value List	Swissmedic	11
Authorisation Status	Value List	Swissmedic	11
Authorisation Status Date	Date	n/a	11
Validity Period End	Date	n/a	11
Data Exclusivity Start Date	Date	n/a	01
Data Exclusivity End Date	Date	n/a	01
Date of First Authorisation	Date	n/a	01
Spezialitätenliste (BAG)	(Medicinal Product)	•	01
IT-Limitation (BAG)	Boolean	n/a	11
Selbstbehalt (BAG)	Integer	n/a	01
(ehem. 20% Selbstbehalt)			
Preismodell (BAG)	Boolean	n/a	01



Befristete Aufnahme (BAG)	Boolean	n/a	11
Original Generika Code (BAG)	Value List	BAG	11
LOA-Regel Berechnung Ppub (BAG)	Value List	BAG	11
Überprüfung nach Patientenlauf (BAG)	Boolean	n/a	11
Freiwillige Preissenkung nach 18 Monaten (BAG)	Boolean	n/a	11
Gamme (für APV) (BAG)	ST	n/a	01
Gammen-FR (für APV) (BAG)	INT	n/a	01
Allgemeinde Kommentare (BAG)	ST	n/a	01
Status (BAG) (Medicinal	Product)		11
Status (BAG)	Value list	BAG	11
Integriert am (BAG)	Date	n/a	01
Gültig ab (BAG)	Date	n/a	11
Gültig bis (befr. Aufnahme) (BAG)	Date	n/a	11
Status Reason (Marketin	ng Authorisation)		01
Reason	Value List	Swissmedic	01
Marketing Authorisation	Procedure (Medicinal P	roduct)	11
Procedure Type	Value List	Swissmedic	11
Procedure Identifier/Number	Identifier	n/a	01
Procedure Date Start	Date	n/a	01
Procedure Date End	Date	n/a	01
Marketing Authorisation	I Application (Medicinal F	Product)	0*
Application Identifier/Number	Identifier	n/a	11



Application Type	Value List	Swissmedic	11
Application Date	Date	n/a	11
Application Date	Date	1,,4	11
Marketing Authorisation	Holder		11
Name	Address	n/a	11
GLN	Identifier	n/a	11
Medicines Regulatory A	l gency		11
Name	Address	n/a	11
GLN	Identifier	n/a	11
Packaged Medicinal Pro	duct		1*
PCID	Identifier	n/a	11
Package Description	String	n/a	11
Pack Size (EXT)	Physical Quantity	EDQM	01
(2/11)	[number, unit]	[Unit]	
Data Carrier Identifier	, ,	,	0*
ID Code System	Value List	GS1	11
GTIN	Identifier	n/a	11
Packaged Item			1*
Package Item (Container)	Value List	EDQM	11
Туре			
Package Item	Physical Quantity	n/a	11
(Container) Quantity	[number]		
Material	Value List	EMA	1*
Manufactured Item	Physical Quantity	UCUM	11
Quantity	[number, unit]	[Unit]	
Other Characteristics (P	ackage Item)		0*
Code System/Value	Value List	Swissmedic	11
Marketing Authorisation	(Packaged Medicinal P	roduct)	
Marketing Authorisation Number	Identifier	n/a	11
Legal Status of Supply	Value List	Swissmedic	11
Authorisation Status	Value Liste	Swissmedic	11
		1	



Authorisation Status Date	Date	n/a	11
Validity Period End	Date	n/a	11
Marketing Status (Packaged Medicinal Product)			0*
Marketing Status	Value List	Swissmedic	11
Marketing Date Start	Date	n/a	11
Packung (BAG) (Packag	ged Medicinal Product)		01
BAG Dossier-Nr. (BAG)	Integer	n/a	11
Modal Packung (BAG)	Boolean	n/a	01
Grosse Packung (BAG)	Boolean	n/a	01
GTIN vor admin. Änderung (BAG)	Value List	BAG	01
Swissmedic Nr. (8) Parallelimporten (BAG)	Identifier	n/a	01
Limitation (BAG) (Packa	ged Medicinal Product)	1	11
Limitation (BAG)	Value List	BAG	11
Change Type (BAG)	Value List	BAG	11
Type (BAG)	Value List	BAG	11
Niveau (BAG)	Value List	BAG	11
Wert (BAG)	Integer	n/a	11
Beschreibung (BAG)	String	n/a	11
Indikationscode (BAG)	Identifier	n/a	1*
Status (BAG) (Medicinal	Product)	•	11
Status (BAG)	Value List	BAG	11
Integriert am (BAG)	Date	n/a	01
Gültig ab (BAG)	Date	n/a	11
Gültig bis (befr. Aufnahme) (BAG)	Date	n/a	11



Preis (BAG) (Packaged Medicinal Product)			11
Preis-Typ (BAG)	Value List	n/a	11
Preisänderungstyp (BAG)	Value List	BAG	11
Preis (BAG)	Money	n/a	11
Letzte Preisänderung (BAG)	Date	n/a	01
Shelf Life / Storage			0*
Shelf Life Type	Value List	EMA	11
Shelf Life Time Period	Physical Quantity	UCUM [Unit]	11
Special Precautions of Storage	Value List	Swissmedic	0*
Physical Characteristics			0*
Scoring	Value List	Swissmedic	01
Manufactured Item			0*
Manufactured Dose Form	Value List	EDQM	11
Unit of Presentation	Value List	EDQM	01
Description	String	n/a	01
Ingredient (Manufactured	d Item)		1*
Ingredient Role	Value List	Swissmedic	11
Substance			11
Substance	Value List	GSRS (UNII) [WHO ab 2025]	11
Strength			11
Quantity Operator	Value List	EMA	11
Strength (presentation)	Physical Quantity	EDQM UCUM	11
Strength (concentration)	Physical Quantity	UCUM	01
Reference Strength			0*
Reference Substance	Value List	GSRS (UNII) [WHO ab 2025]	11
	Value List	EMA	11
Quantity Operator	value List	LIVIA	11



		UCUM	
Pharmaceutical Product			1*
Administrable Dose Form	Value List	EDQM	11
Unit of Presentation	Value List	EDQM	01
Route of Administration			1*
Route of Administration	Value List	EDQM	11
Methode of Administration	Value List	EMA	01
Ingredient (Pharmaceutic	cal Product)		
Ingredient Role	Value List	Swissmedic	11
Substance			11
Substance	Value List	GSRS (UNII)	11
		[WHO ab 2025]	
Manufacturer (Substance))		0*
Name	Address	n/a	11
GLN	Identifier	n/a	11
Confidentiality Indicator	Value List	EMA	11
Strength			11
Quantity Operator	Value List	EMA	11
Strength (presentation)	Physical Quantity	EDQM	11
		UCUM	
Strength (concentration)	Physical Quantity	UCUM	01
Reference Strength			0*
Reference Substance	Value List	GSRS (UNII) [WHO ab 2025]	11
Quantity Operator	Value List	EMA	11
Reference Strength	Physical Quantity	EDQM	11
_		UCUM	
Therapeutic Indication			1*
Indication as	Value List	MSSO	11
Comorbidity	Value List	MSSO	11
Intended Effect		EMA	11
Intoriada Endot	Value List	LIVIA	11
Population Specifics	Value List	EIVIA	1*



Age Range Low	Physical Quantity	UCUM	01
Age Range High	Physical Quantity	UCUM	01
Gender	Value List	EMA	01
Race	Value List	EMA	01
Physiological Condition	Value List	EMA	01
Other Therapy Specifics			0*
Therapy Relationship Type	Value List	EMA	11
Medication	Value List	EMA	11

IDMP Element	Example Code	List Owner	
Medicinal Product			
MPID	CH-7601007957330-5603801	Swissmedic	
Domain	HAM	Swissmedic	
Authorised Pharmaceutical Form	VAGI	Swissmedic	
Product Classification	on		
ATC	G02BB01	WHO	
Heilmittelcode	Synthetica Human	Swissmedic	
Country / Language			
Language	fr	ISO	
Marketing Authorisa	tion (Medicinal Product)		
Marketing Authorisation Number	5603802	Swissmedic	
Legal Status of Supply	В	Swissmedic	
Authorisation Status	Z	Swissmedic	
Marketing Authorisation Holder			
GLN	7601007957330	GS1	
Packaged Medicina	l Product		
PCID	CH-7601007957330-5603801-002	Swissmedic	
Data Carrier Identifier			



GTIN	7680560380021	GS1
Packaged Item		
Package Item (Container) Quantity	1 Box	Unit: EDQM
Packaged Item		
Manufactured	1 System / box	Numerator Unit: EDQM
Item Quantity	1 System / sachet	Denominator Unit: EDQM
Marketing Authorisa	ation (Packaged Medicinal Product)	
Legal Status of Supply	В	Swissmedic
Authorisation Number	29550001	Swissmedic
Authorisation Status	Z	Swissmedic
Shelf Life / Storage		
Shelf Life Type	100000073403	EMA
Shelf Life Time Period	40 mt	Unit: UCUM
Special Precautions of Storage	100000073414	EMA
Device Nomenclatu	re	
Value	IIb	EMA
Manufactured Item		
Manufactured Dose Form	10915000	EDQM
Unit of Presentation	15053000	EDQM
Ingredient (Manufac	ctured Item)	
Ingredient Role	Active	Swissmedic
Substance	304GTH6RNH	UNII
Strength (presentation)	11.7 mg / System	Numerator Unit: UCUM
	11.7 mg / Ring	Denominator Unit: EDQM
Strength (concentration)	0.005 mg / h	Numerator Unit: UCUM
(concentration)	0.12 mg / 24 h	Denominator Unit: UCUM
Pharmaceutical Pro		
Administrable Dose Form	10915000	EDQM
Unit of Presentation	15053000	EDQM



Route of Administration	20072000	EDQM
Methode of Administration	20000002039	EMA
Ingredient (Pharma	ceutical Product)	
Ingredient Role	Active	Swissmedic
Substance	304GTH6RNH	UNII
Strength	11.7 mg / System	Numerator Unit: UCUM
(presentation)	11.7 mg / Ring	Denominator Unit: EDQM
Strength	0.005 mg / h	Numerator Unit: UCUM
(concentration)	0.12 mg / 24 h	Denominator Unit: UCUM
Therapeutic Indicati	ion	
Indication as	10073728	MSSO
Comorbidity	10027308	MSSO
Intended Effect	20000003194	EMA



Datenbeispiele 2

In diesem Kapitel sind diverse Beispielprodukte basierend auf dem IDMP-BAG-SL-Datenmodel aufgebaut. Das Kapitel enthält die folgenden Beispielprodukte:

Beispielprodukt	Produktmerkmale	Verpackungsmerkmale
Cuprior		
Entocort Enema	Klistier Lösung	
Estalis	Pflaster	
Keytruda		
Paxlovid		2 Wirkstoffe separat in einer Packung
Triogen	Gleiche aktive Substanz, anderes Salz (siehe Cuprior)	. dokung



2.1 CUPRIOR Filmtabl 150 mg 72 Stk



Quelle		
Compendium	CUPRIOR Filmtabl 150 mg	compendium.ch®
SAI	CUPRIOR Filmtabl 150 mg 72 Stk	

Medicinal Product				
MPID	CH-7640	109110007-6771901	-	Medicinal Product
Approved Dose Form (EXT)	FILM	Filmtabletten	1 1 1 1	MPID: II Combined Pharmaceutical Dose Form: CD [01] Additional Monitoring Indicator: CD [01] Special Measures: ST [0*] Paediatric Use Indicator: CD [01] Orphan Designation Status: CD [01]

Product Classification			
ATC	A16AX12	Product Classification	
Heilmittelcode	S – Synthetika	- Code System: CD.codeSystem - Value: CD.code	

Medicinal Produ	uct Name	
Type (EXT)	Original	Medicinal Product Name
Full Name	Cuprior 150 mg, Filmtabletten	- Full Name: ST - Invented Name Part: ENXP [0*]
Invented Name Part	Cuprior	Scientific Name Part: ENXP [0*] Strength Part: ENXP [0*] Pharmaceutical Dose Form Part: ENXP [0*] Formulation Part: ENXP [0*] Intended Use Part: ENXP [0*]
Pharmaceutical Dose Form Part	Filmtabletten	- Target Population Part: ENXP [0*] - Container or Pack Part: ENXP [0*] - Device Part: ENXP [0*] - Trademark or Company Name Part: ENXP [0*] - Time / Period Part: ENXP [0*] - Flavour Part: ENXP [0*]
Strength Part	150 mg	- Playou Part, ENXP [0*]
Delimiter	,	
Country / Langu	ıage	



Language	de	Deutsch	Country / Language
			- Country: CD - Jurisdiction: CD [01] - Language: CD

Medicinal Produ	uct Name		
Type (EXT)	BAG		Medicinal Product Name
Full Name	CUPRIO	R Filmtabl 150 mg	- Full Name: ST - Invented Name Part: ENXP [0*]
Invented Name Part	CUPRIO	R	Scientific Name Part: ENXP [0*] Strength Part: ENXP [0*] Pharmaceutical Dose Form Part: ENXP [0*] Formulation Part: ENXP [0*] Intended Use Part: ENXP [0*]
Pharmaceutical Dose Form Part	Filmtabl		Target Population Part: ENXP [0*] Container or Pack Part: ENXP [0*] Device Part: ENXP [0*] Trademark or Company Name Part: ENXP [0*] Time / Period Part: ENXP [0*] Flavour Part: ENXP [0*]
Strength Part	150 mg		- Delimiter Part: ENXP [0*]
Country / Langu	ıage		
Language	de	Deutsch	Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD

Marketing Auth	orisation	(Medicinal Product)	
Marketing Authorisation Type (EXT)	tbd		Marketing Authorisation
Marketing Authorisation Number	6771901		Marketing Authorisation Number: II Country: CD [1*] Legal Status of Supply: CD Authorisation Status: CD Authorisation Status Date: TS Validity Period Stat. TS Validity Period Stat. TS
Legal Status of Supply	В	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	- Validity Period End: TS - Data Exclusivity Start Date: TS [01] - Data Exclusivity End Date: TS [01] - Date of First Authorisation: TS [01]
Authorisation Status	Z	Zugelassen	- International Birth Date: TS Medicinal Product
Authorisation Status Date	21.01.20	021	- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01]
Validity Period End	20.01.20	026	Special Measures: ST [0*] Paediatric Use Indicator: CD [01] Orphan Designation Status: CD [01]
Date of First Authorisation	21.01.20	021	
Spezialitätenlis	te (BAG)	(Medicinal Product)	
Selbstbehalt (BAG)	-		
Preismodell (BAG)	-		



Original Generika Cod (BAG)	e -	Spezialitätenliste [BAG] - IT-Limitation [BAG]: BL - Selbstbehalt [BAG]: INT	
BAG Dossier- Nr. (BAG)	21208	- Seinstenati (BAG): BL - Preismodel [BAG]: BL - Befristete Aufnahme [BAG]: BL - Original Generica Code [BAG]: CD - LOA-Regel Berechnung Ppub [BAG]: CD - Überprüfung nach Patentablauf [BAG]: BL - Freiwillige Preisserkung nach 18 Monaten [BAG]: BL - Gamme (für APV) [BAG]: ST [01] - Gammen-FR (für APV) [BAG]: INT [01] - Allgemeine Kommentare [BAG]: ST [01]	
Status (BAG)	(Medicinal Product)		
Integriert am (BAG)	01.08.2021		
gültig ab (BAG)	01.08.2021	Status [BAG] - Status [BAG]: CD - Ingegriert am [BAG]: TS [01]	
gültig bis (bef Aufnahme) (BAG)	r. 31.12.9999	- Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS	
Marketing Au	uthorisation Holder (Organisation)		
Name	Curatis AG	Marketing Authorisation Holder (Organisation)	
GLN	7640109110007	Tiolder (Organisation)	
Hinweis: Pac	k Size, 72 Filmtabletten		
Packaged Me	edicinal Product		
PCID	CH-7640109110007-6771901-001	Packaged Medicinal Product	
Package Description	CUPRIOR Filmtabl 150 mg 72 Stk	- PCID: II - Package Description: ST	
Pack Size (EXT)	72 Tablette(n)		
Data Carrier	Identifier		
GTIN (Code System)	7680677190018	Data Carrier Identifier - Code System: CD.codeSystem - Value: CD.code	



Material	Karton		
Packaged Item	(Container)		
Package Item (Container) Type	30007000 Blister Unknown		Package Item (Container) - Package Item (Container) Type: CD
Package Item (Container) Quantity			- Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]
Material	Aluminium, A	Aluminium	
Packaged Item	(Manufactur	ed Item)	
Manufactured Item Quantity	72	Tabletten (per box)	Manufactured Item - Manufactured Dose Form: CD - Unit of Presentation: CD [01] - Manufactured Item Quantity: PQ
Marketing Auth	orisation (Pa	ackaged Medicinal Product)	
Marketing Authorisation Type	tbd		Marketing Authorisation - Marketing Authorisation Number: II - Country: CD [1]
Marketing Authorisation Number	67719001		- Legal Status of Supply: CD - Authorisation Status: CD - Authorisation Status: Date: TS - Validity Period Start: TS - Validity Period End: TS - Validity Period End: TS
Legal Status of Supply	В	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	Data Exclusivity Start Date: TS [01] Data Exclusivity End Date: TS [01] Date of First Authorisation: TS [01] International Birth Date: TS 01
Authorisation Status	Z	Zugelassen	Packaged Medicinal Product
Authorisation Status Date	21.01.2021		- PCID: II - Package Description: ST
Validity Period End	20.01.2026		
Preis (BAG) (Pa	ackaged Med	licinal Product)	
FAP (BAG)	CHF 3022.2	28	Preis [BAG] - Preis-Typ [BAG]: MO
PP (BAG)	CHF 3343.8	85	Preisänderungstyp [BAG]: II Preis [BAG]: MO Letzte Preisänderung [BAG]: TS SB [BAG]: CD.code
Preis- änderungstyp (BAG)	Preisänder Überprüfun	ung nach 3-jährlicher g der Aufnahmebedingungen	



Limitation (BA	G) (Packaged Medicinal Product)	
Limitation (BAG)	L	Limitation [BAG] - Limitation [BAG]: CD
Beschreibung (BAG)	xxx	- Change Type [BAG]: CD - Type [BAG]: CD - Niveau [BAG]: CD - Wert [BAG]: INT - Beschreibung [BAG]: ST - Indikationscode [BAG]: II [1*]
Status (BAG) (I	Packaged Medicinal Product)	
Gültig ab (BAG)	01.08.2021	Status [BAG]
Gültig bis (BAG)	31.12.9999	- Status [BAG]: CD - Ingegriert am [BAG]: TS [01] - Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS

Shelf Life / Storage	ge		
Shelf Life Type	100000073403	Closed Package	0. 41 % 10
Shelf Life Time Period	24 mo		Shelf Life / Storage - Shelf Life Type: CD
Special Precautions of Storage	NO30	Nicht über 30°C lagern	Shelf Life Time Period: PQ Special Precautions for Storage: CD [0*]

Manufactured I	tem		
Manufactured Dose Form	10221000	Filmtablette	Manufactured Item - Manufactured Dose Form: CD - Unit of Presentation: CD [01] - Manufactured Item Quantity: PQ
Unit of Presentation	15054000	Tablette	

Ingredient (Mar	Ingredient (Manufactured Item) / Substance / Strength / Reference Strength					
Ingredient Role	WIRKS	Wirkstoff		Ingredient Ingredient Role: CD Allergenic Indicator: BL [0.1]		
Substance	SJ76Y07H5F	Trientinum		Substance	Specified Substance	
Strength 150 mg (presentation) (per LIOP)				- Substance: CD - Spe	collect Substance Goup: CD collect Substance Group: CD filderstallry indicator: CD [0.1]	
(Free construction)	(per UoP)			Strength Strength (Presentation): RTO-PIQ-PID- Strength (Concentration): RTO-PIQ-PID- Measurement Point: ST [0.1] Country: CD [0.7]	Reference Sterength Reference Specified Substance: CD [0,1] Reference Specified Substance: CD [0,1] Reference Sterength RTO-PD_PD- Reference Sterength Resummer Point ST [0,1] Reference Sterength Country, CD [0,7]	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength					
Ingredient Role	WIRKS	Wirkstoff			



Substance	Trientini tetr	ahydrochloridum	- Substance - Specil - Specil	Specified Substance filed Substance: CD filed Substance: CD filed Substance: Group: CD dentably Indicator: CD [0,1]
			Strength rength (Presentation): RTO <pq,pq> rength (Concentration): RTO<pq,pq> [0,1]</pq,pq></pq,pq>	Reference Strength - Reference Substance: CD [01] - Reference Specified Substance: CD [01]
		- Mes	easurement Point: ST [0_1] ountry: CD [0*]	Reference Strength: RTO <pq.pq> Reference Strength Measurement Point: ST [01] Reference Strength Country: CD [01]</pq.pq>

Ingredient (Ma	anufactured Item) /	Substance / Strength / Referen	ce Strength	
Ingredient Role	HNIDK	Hilfsstoff	Ingredient Ingredient Roke: CD Altergenic Indicator: BL [01]	ł
Substance	30WL53L36A	Mannitolum	Substance	Specified Substance cified Substance: CD
	ETJ7Z6XBU4	Silica colloidalis anhydrica	- Substance: CD - Spec	offied Substance Group: CD fidentiality indicator: CD [0, 1]
	R8WTH25YS2	Glyceroli dibehenas	Strength - Strength (Presentation): RTO <pq,pq></pq,pq>	Reference Strength - Reference Substance: CD [0.1]
	532B59J990	Poly (alcohol vinylicus)	Strength (Concentration): RTO <pq:pq> [01] Measurement Point: ST [01] Country: CD [01]</pq:pq>	Reference Specified Substance: CD [0.1] Reference Strength: RTO <pq.po> Reference Strength Measurement Point: ST [0.1] Reference Strength Country: CD [0.1]</pq.po>
	7SEV7J4R1U	Talc Talcum		
	15FIX9V2JP	TITANII DIOXIDUM CL 77891 E 171		
	HYE7O27HAO	Glyceroli monocaprylocapras		
	EX438O2MRT	E 172 (flavum) YELLOW LAKE CLF 3076 (E104 AND E172)		
	368GB5141J	Natrii laurilsulfas		
	9NEZ333N27	0.057 mg Natrium		

Pharmaceutica	Product / Route	of Administration	
Administrable Dose Form	10221000	Filmtablette	Pharmaceutical Product
Unit of Presentation	15054000	Tablet	- Administrable Dose Form: CD - Unit of Presentation: CD [01]
Route of Administration	20053000	Oral use	
Methode of Administration (Swissmedic)	200000002052	Swallowing	- Route of Administration: CD

Therapeutic Ind	Therapeutic Indication						
Indication as	10061091	Copper metabolism disorder (Morbus Wilson)	Therapeutic Indication - Indication Text: ST				
Intended Effect	20000003194	Therapie	- Indication as "Disease / Symptom / Procedure": CD [01] - Disease Status: CD [01] - Comorbidity: CD [01] - Intended Effect: CD [01] - Timing / Duration: PQ [01]				



ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk



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

Medicinal Produ	ıct			
MPID	CH-7601	001346451-5204201	Medicinal Product	
Approved Dose Form (EXT)	TABLR	Tabletten und Lösungsmittel zur Herstellung einer Rektalsuspension	- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01] - Special Measures: ST [0*] - Paediatric Use Indicator: CD [01] - Orphan Designation Status: CD [01]	

Product Classification				
ATC	A07EA06			
(Code System)		Product Classification		
Heilmittelcode	S – Synthetika	- Code System: CD.codeSystem - Value: CD.code		
(Value)		Valide. Obloods		



Country / Language

Country: CD Jurisdiction: CD [0..1] Language: CD

Medicinal Produ	ıct Name		
Type (EXT)	Original		
Full Name	ENTOC Tablette	ORT Enema Klistier Lösung + en 7 Stk	Medicinal Product Name - Full Name: ST - Invented Name Part: ENXP [0*]
Invented Name Part	ENTOC	ORT Enema	Scientific Name Part: ENXP [0*] Strength Part: ENXP [0*] Pharmaceutical Dose Form Part: ENXP [0*] Formulation Part: ENXP [0*]
Pharmaceutical Dose Form Part	Klistier L	Lösung + Tabletten	Intended Use Part. ENXP [0*] Target Population Part. ENXP [0*] Container or Pack Part. ENXP [0*] Device Part. ENXP [0*] Trademark or Company Name Part: ENXP [0*] Time / Period Part. ENXP [0*]
Container or Pack Part	7 Stk		- Flavour Part: ENXP [0*] - Delimiter Part: ENXP [0*]
Delimiter Part	,		
Country / Langu	ıage		
Language	de	Deutsch	Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD
Medicinal Produ	ıct Name		
Type (EXT)	BAG		Medicinal Product Name - Full Name: ST
Full Name	ENTOCORT Enema Klistier Lösung + Tabletten		- Invented Name Part: ENXP [0.*] - Scientific Name Part: ENXP [0.*] - Strength Part: ENXP [0.*] - Pharmaceutical Dose Forn Part: ENXP [0.*]
Invented Name Part	ENTOC	ORT Enema	Formulation Part: ENXP [0,-*] Intended Use Part: ENXP [0,-*] Target Population Part: ENXP [0,-*] Container or Pack Part: ENXP [0,-*] Device Part: ENXP [0,-*]
Pharmaceutical Dose Form	Klistier L	_ösung + Tabletten	- Trademark or Company Name Part: ENXP [0*] - Time / Period Part: ENXP [0*] - Flavour Part: ENXP [0*] - Delimiter Part: ENXP [0*]

Part

Language

Country / Language

de

Deutsch



Marketing Auth	orisation	(Medicinal Product)	
Marketing Authorisation Type (EXT)	tbd		Marketing Authorisation - Marketing Authorisation Number: II - Country: CD [1*] - Legal Status of Supply: CD - Authorisation Status CD - Authorisation Status Date: TS
Marketing Authorisation Number	520420	1	- Validity Period Start: TS - Validity Period End: TS - Validity Period End: TS - Data Exclusivity Start Date: TS [0,.1] - Data Exclusivity End Date: TS [0,.1] - Date of First Authorisation: TS [0,.1] - Intermational Birth Date: TS
Legal Status of Supply	В	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	Medicinal Product
Authorisation Status	Z	Zugelassen	- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01] - Special Measures: ST [01]
Authorisation Status Date	18.06.1	993	Paediatric Use Indicator: CD [01] Orphan Designation Status: CD [01]
Validity Period End	31.12.9	999	
Date of First Authorisation	18.06.1	993	
Spezialitätenlis	te (BAG)	(Medicinal Product)	
Selbstbehalt (BAG)	-		Spezialitătenliste [BAG]
Preismodell (BAG)	-		- IT-Limitation [BAG]: BL - Selbstbehalt [BAG]: INT - Preismodel [BAG]: BL - Befristete Aufnahme [BAG]: BL
Original Generika Code (BAG)			Original Generica Code [BAG]: CD LOA-Regel Berechnung Ppub [BAG]: CD Überprüfung nach Patentablauf [BAG]: BL Freiwillige Preisserkung nach 18 Monaten [BAG]: BL Gamme (für APV) [BAG]: ST [01]
BAG Dossier- Nr. (BAG)	17973		- Gammen-FR (für APV) [BAG]: INT [01] - Allgemeine Kommentare [BAG]: ST [01]
Status (BAG) (N	/ledicinal	Product)	1
Integriert am (BAG)	01.02.20	004	
gültig ab (BAG)	01.02.2004		Status [BAG] - Status [BAG]: CD - Ingegriert am [BAG]: TS [01]
gültig bis (befr. Aufnahme) (BAG)	31.12.9	999	- Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS



Marketing Authorisation Holder (Organisation)				
Name	Tillotts Pharma AG	Marketing Authorisation Holder (Organisation)		
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	- PCID: II - Package Description: ST				
Pack Size (EXT)	7 Lösung 7 Tablette					

Data Carrier Identifier				
GTIN (Code System)	7680520420118	Data Carrier Identifier - Code System: CD.codeSystem - Value: CD.code		

Packaged Item	(Container)		
Package Item (Container) Type	30009000	Вох	Package Item (Container)
Package Item (Container) Quantity	1		 Package Item (Container) Type: CD Package Item (Container) Quantity: PQ Material: CD [1*] Alternate Material: CD [0*]
Material	Karton		

Packaged Item (Container)				
Package Item (Container) Type	30007000	Blister	Package Item (Container)	
Package Item (Container) Quantity	5		- Package Item (Container) Type: CD - Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]	
Material	Aluminium, A	luminium		ı

Packaged Item (Container)			
Package Item (Container) Type	30008000	Bottle	Package Item (Container)
Package Item (Container) Quantity	7		- Package Item (Container) Type: CD - Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]
Material	200000003214	Polyethylen	



Package (Component)				
Component Type	30013000	Сар	Package (Component)	
Component Materila	20000003214	Polyethylen	- Component Type: CD - Component Material: CD [0*] - Component Alternate Material: CD [0*]	

Device				
Device Type	30012000	Rektalkanüle (Applikator Enema)	Device - Device Type: CD	
Device Quantity	7		Device Trade Name: ST [01] Device Quantity: PQ Device Listing Number: ST [01] Device Identifier: II [01] Model Number: ST [01] Sterility Indicator: CD [01] Sterilisation Requirement Indicator: CD [01] Device Usage: CD [01]	

Device				
Device Type	tbd	Plastikhandschutz	Device	
Device Quantity	7		Device Type: CD Device Trade Name: ST [01] Device Quantity: PQ Device Listing Number: ST [01] Device Identifier: II [01] Model Number: ST [01] Sterility Indicator: CD [01] Sterilisation Requirement Indicator: CD [01] Device Usage: CD [01]	

Packaged Item (Manufactured Item)			
Manufactured Item Quantity	7	Tabletten (per blister)	Manufactured Item
Manufactured Item Quantity	7	Lösungsmittel (per box)	Manufactured Dose Form: CD Unit of Presentation: CD [01] Manufactured Item Quantity: PQ

Marketing	Marketing 52042011			
Authorisation Number	32042011		Marketing Authorisation Marketing Authorisation Number: II Country: CD [1*]	
Legal Status of Supply	В	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	Legal Status of Supply: CD Authorisation Status: CD Authorisation Status Date: TS Validity Period Start: TS	
Authorisation Status	Z	Zugelassen	Validity Period End: TS Data Exclusivity Start Date: TS [01] Data Exclusivity End Date: TS [01] Date of First Authorisation: TS [01] International Birth Date: TS	
Authorisation Status Date	18.06.199	3	Packaged Medicinal Product - PCID: II - Package Description: ST	



Preis (BAG) (Pa	ckaged Medicinal P	roduct)	
FAP (BAG)	CHF 40.89		Preis [BAG] - Preis-Typ [BAG]: MO
PP (BAG)	CHF 63.35		- Preisänderungstyp [BAG]: II - Preis [BAG]: MO - Letzte Preisänderung [BAG]: TS - SB [BAG]: CD.code
Preis- änderungstyp (BAG)	Preisänderung na Überprüfung der A	ch 3-jährlicher Aufnahmebedingungen	
Limitation (BAG) (Packaged Medici	nal Product)	
Limitation (BAG)	L		Limitation [BAG] - Limitation [BAG]: CD
Beschreibung (BAG)	xxx		- Change Type [BAG]: CD - Type [BAG]: CD - Niveau [BAG]: CD - Wert [BAG]: INT - Beschreibung [BAG]: ST - Indikationscode [BAG]: II [1*]
Status (BAG) (P	ackaged Medicinal	Product)	
Gültig ab (BAG)	01.01.2007		Status [BAG]
Gültig bis (BAG)	31.12.9999		- Status [BAG]: CD - Ingegriert am [BAG]: TS [01] - Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS
Shelf Life / Stora	age		
Shelf Life Type	100000073403	Closed Package	
Shelf Life Time Period	60 mo	_1	Shelf Life / Storage - Shelf Life Type: CD - Shelf Life Time Period: PQ
Special Precautions of Storage	NO30	Nicht über 30°C lagern	- Special Precautions for Storage: CD [0*]

Manufactured Item				
Manufactured Dose Form	11012000	Tablet for rectal suspension	Manufactured Item - Manufactured Dose Form: CD	
Unit of Presentation	15054000	Tablette	- Unit of Presentation: CD [01] - Manufactured Item Quantity: PQ	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength				
Ingredient Role	WIRKS	Wirkstoff	Ingredient - log-edient Roke CD - Allergenie bedrater: BL (0.1)	
Substance	Q3OKS62Q6X	Budesonidum	Substance Specified Substance	
Strength (presentation)	2.3 mg (per UoP)		Specified Statistance: CD Specified Statistance: CD Specified Statistance: Group: CD Confidentially Indicator: CD [01]	
			Strength Presentation; RTCHPD.PD: - Strength (Concentration), RTCHPD.PD: - Brength (RTCHPD.PD: - Reference Strength Measurement P Reference Strength Country CD [0.1]	0 [01] Point: ST [01]



Ingredient (M	Ingredient (Manufactured Item) / Substance / Strength / Reference Strength					
Ingredient Role	HNIDK	Hilfsstoff	Ingredient - Ingredient Role: CD - Allergenic Indicator: BL [01]	-		
Substance	3SY5LH9PMK	Lactosum	Substance Species Su			
	957E53WV42 Riboflavini natrii phosphas		- Substance: CD - Spec	ecified Substance Group: CD infidentiality Indicator: CD [0, 1]		
	2S7830E561	Crospovidonum	Strength (Presentation): RTO <pq.pq> Strength (Concentration): RTO<pq.pq> [0.1] - Measurement Point: ST [0.1] - Country: CD [0.1] - Reference Strength: RTO<pq.pq> Reference Strength: RTO<pq.pq> Reference Strength: RTO<pq.pq></pq.pq></pq.pq></pq.pq></pq.pq></pq.pq>	Reference Strength - Reference Substance: CD I0.11		
	ETJ7Z6XBU4	Silica colloidalis anhydrica		Reference Specified Substance: CD [0.1] Reference Strength: RTO-PQ-PQ> Reference Strength Measurement Point: ST [0.1] Reference Strength Country: CD [0.1]		
	70097M6I30	Magnesii stearas				

Manufactured Item				
Manufactured Dose Form	13035000	Lösungsmittel	Manufactured Item - Manufactured Dose Form: CD	
Unit of Presentation	15009000	Bottle	- Unit of Presentation: CD [01] - Manufactured Item Quantity: PQ	

Ingredient (M	Ingredient (Manufactured Item) / Substance / Strength / Reference Strength					
Ingredient Role	HNIDK	Hilfsstoff	Ingredient - Ingredient Role: CD - Allergenic Indicator: BL [0.1]			
Substance	A2I8C7HI9T	METHYLPARABEN E 218	Substance Specified Substance - Specified Substance CD			
	Z8IX2SC1OH	Propylis parahydroxybenzoas	- Substance: CD - Specified Substance Corp.: CD - Specified Substance Group: CD - Confidentially Indicator: CD (0, 1) Strength Reference	e Strength		
	451W47IQ8X	Natrii chloridum	- Strength (Presentation); RTO <pq.pq> - Strength (Concentration); RTO<pq.pq> [0,1] - Reference Specified Sultranse: Concentration); RTO<pq.pq> [0,1] - Reference Strength; RTI - Reference Strength; RTI</pq.pq></pq.pq></pq.pq>	D [01] betance: CD [01] D <pq.pq></pq.pq>		
	059QF0KO0R	Aqua purificata	- Country; CD [0.*] - Reference Strength Mea	surement Point: ST [01] http://CD [01]		

Pharmaceutica	I Product / Route	of Administration	
Administrable Dose Form	11006000	Rectal suspension	Pharmaceutical Product
Unit of Presentation	15009000	Bottle	- Administrable Dose Form: CD - Unit of Presentation: CD [01]
Route of Administration	20061000	Rectal use	
Methode of Administration (Swissmedic)	200000002039	Application	Route of Administration - Route of Administration: CD

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength				
Ingredient Role	WIRKS	Wirkstoff		
Substance	Q3OKS62Q6X	Budesonidum		





Ingredient (Mai	Ingredient (Manufactured Item) / Substance / Strength / Reference Strength				
Ingredient Role	HNIDK	Hilfsstoff	Ingredient - Ingredient Role; CD - Allergenic Indicator: BL [I	9.1]	
Substance	3SY5LH9PMK	Lactosum	Substance	Specified Substance Specified Substance: CD	
	957E53WV42	Riboflavini natrii phosphas	- Substance: CD	Specified Substance Group: CD Confidentiality Indicator: CD [01]	
	2S7830E561	Crospovidonum	Strength - Strength (Presentation); RTO <pq,pq></pq,pq>	Reference Strength - Reference Substance: CD [0.1]	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	- Strength (Concentration): RTO <pq.pq>[01] - Measurement Point: ST [01] - Country: CD [01]</pq.pq>	Reference Specified Substance; CD [01] Reference Strength: RTO <pq_pq> Reference Strength Measurement Point: ST [01] Reference Strength Country: CD [01]</pq_pq>	
	70097M6I30	Magnesii stearas			
	A2I8C7HI9T	METHYLPARABEN E 218			
	Z8IX2SC1OH	Propylis parahydroxybenzoas			
	451W47IQ8X	Natrii chloridum			
	059QF0KO0R	Aqua purificata			

Therapeutic Ind	lication		
Indication Text		chwere Colitis ulcerosa des es Colon sigmoideum	Therapeutic Indication
Indication as	10009900	Colitis ulcerative	Indication as "Disease / Symptom / Procedure": CD [01] Disease Status: CD [01]
Intended Effect	200000003194	Therapie	 Comorbidity: CD [0*] Intended Effect: CD [01] Timing / Duration: PQ [01]



2.3 ESTALIS Matrixpfl 50/250



Quelle				
Compendium	ESTALIS Matrixpfl 50/250	compendium.ch®		
SAI	ESTALIS Matrixpfl 50/250 8 Stk ESTALIS Matrixpfl 50/250 24 Stk	rof lata.		

Medicinal Product						
MPID	CH-7601	1001029439-5470402	Medicinal Product			
Approved Dose Form (EXT)	TRAP	Transdermales Pflaster	- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01] - Special Measures: ST [0*] - Paediatric Use Indicator: CD [01] - Orphan Designation Status: CD [01]			

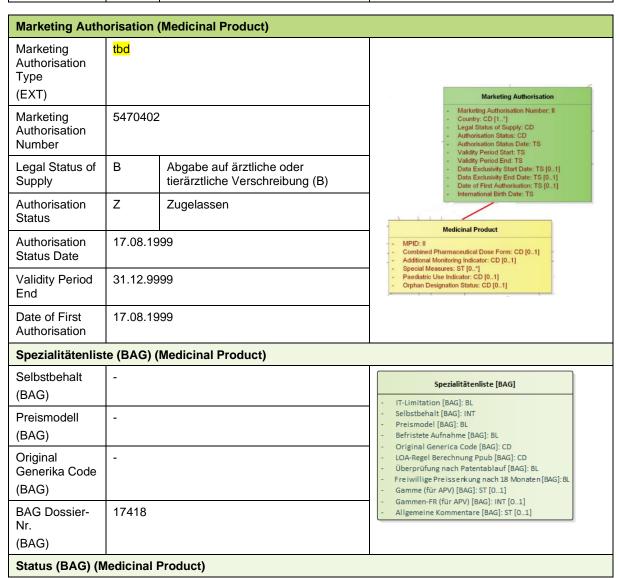
Product Classification				
ATC (Code System)	G03FA01	Product Classification		
Heilmittelcode (Value)	S – Synthetika	- Code System: CD.codeSystem - Value: CD.code		



Medicinal Produ	uct Name		
TYPE (EXT)	Original		
Full Name	ESTALIS	S Matrixpfl 50/250 8 Stk	Medicinal Product Name
Invented Name Part	ESTALIS		- Full Name: ST - Invented Name Part: ENXP [0*] - Scientific Name Part: ENXP [0*] - Strength Part: ENXP [0*] - Pharmaceutical Dose Form Part: ENXP [0*]
Strength Part	50/250		- Formulation Part: ENXP [0*] Intended Use Part: ENXP [0*] Target Population Part: ENXP [0*]
Pharmaceutical Dose Form Part	Matrixpfl		- Container or Pack Part: ENXP [0*] - Device Part: ENXP [0*] - Trademark or Company Name Part: ENXP [0*] - Time / Period Part: ENXP [0*] - Flavour Part: ENXP [0*] - Palvour Part: ENXP [0*]
Container or Pack Part	8 Stk		
Country / Langu	ıage		
Language	de	Deutsch	Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD
Medicinal Produ	ıct Name		
TYPE (EXT)	Original		
Full Name	ESTALIS Matrixpfl 50/250 24 Stk		Medicinal Product Name - Full Name: ST
Invented Name Part	ESTALIS 50/250		- Invented Name Part: ENXP [0*] - Scientific Name Part: ENXP [0*] - Strength Part: ENXP [0*] - Pharmaceutical Dose Form Part: ENXP [0*] - Formulation Part: ENXP [0*]
Strength Part			- Intended Use Part: ENXP [0*] - Target Population Part: ENXP [0*]
Pharmaceutical Dose Form Part	Matrixpfl		- Container or Pack Part: ENXP [0*] - Device Part: ENXP [0*] - Trademark or Company Name Part: ENXP [0*] - Time / Period Part: ENXP [0*] - Flavour Part: ENXP [0*] - Delimiter Part: ENXP [0*]
Container or Pack Part	24 Stk		
Country / Langu	ıage		
Language	de Deutsch		Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD
Medicinal Produ	uct Name		
Type (EXT)	BAG		
Full Name	ESTALIS Matrixpfl 50/250		
Invented Name Part	ESTALIS ESTALIS		
Strength Part	50/250		



Pharmaceutical Dose Form Part	Matrixpfl		Medicinal Product Name Full Name: ST Invented Name Part: ENXP [0*] Scientific Name Part: ENXP [0*] Strength Part: ENXP [0*] Pharmaceutical Dose Form Part: ENXP [0*] Formulation Part: ENXP [0*] Intended Use Part: ENXP [0*] Container or Pack Part: ENXP [0*] Container or Pack Part: ENXP [0*] Trademark or Company Name Part: ENXP [0*] Time / Period Part: ENXP [0*] Flavour Part: ENXP [0*] Delimiter Part: ENXP [0*]
Country / Langu	ıage		
Language	de	Deutsch	- Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD





Integriert a (BAG)	m 15.04.2000	
gültig ab (BAG)	15.04.2000	Status [BAG] - Status [BAG]: CD - Ingegriert am [BAG]: TS [01]
gültig bis (t Aufnahme) (BAG)		- Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS
Marketing	Authorisation Holder (Organisation)	
Name	Sandoz Pharmaceuticals AG	Marketing Authorisation Holder (Organisation)
GLN	7601001029439	

Hinweis: Pack Size, 8 Pflaster. Mehrere Packungsgrössen werden wie folgt separat erfasst				
Packaged Mo	edicinal Product			
PCID	CH-7601001029439-5470402-089			
Package Description	ESTALIS Matrixpfl 50/250 8 Stk	- PCID: II - Package Description: ST		
Pack Size (EXT)	8 Pflaster			

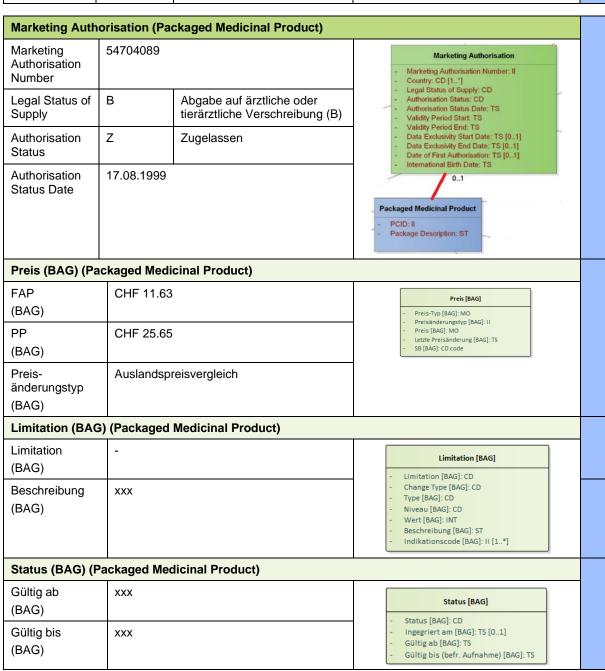
Data Carrier Identifier			
GTIN (Code System)	7680547040894	Data Carrier Identifier - Code System: CD.codeSystem - Value: CD.code	

Packaged Item (Container)			
Package Item (Container) Type	30009000	Вох	Package Item (Container) - Package Item (Container) Type: CD
Package Item (Container) Quantity	1		- Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]
Material	Karton		

Packaged Item	(Container)		
Package Item (Container) Type	30054000	Sachet	Package Item (Container) - Package Item (Container) Type: CD
Package Item (Container) Quantity	8		- Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]
Material	Unknown		



Packaged Item (Manufactured Item)				
Manufactured Item Quantity	1	Patches (per Sachet)	Manufactured Item Manufactured Dose Form: CD Unit of Presentation: CD [01] Manufactured Item Quantity: PQ	





Hinweis: Pack	Size, 24 Pflas	ter. Mehrere Packungsgröss	en werden wie folgt separat erfasst.
Packaged Med	icinal Produc	t	
PCID	CH-7601001029439-5470402-097		Packaged Medicinal Product
Package Description	ESTALIS M	atrixpfl 50/250 24 Stk	- PCID: II - Package Description: ST
Pack Size (EXT)	24 Pflaster		
Data Carrier Id	entifier		
GTIN (Code System)	7680547040	0979	Data Carrier Identifier - Code System: CD.codeSystem - Value: CD.code
Packaged Item	(Container)		
Package Item (Container) Type	30009000	Вох	Package Item (Container) - Package Item (Container) Type: CD
Package Item (Container) Quantity	1		- Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]
Material	Karton		
Packaged Item	(Container)		
Package Item (Container) Type	30054000	Sachet	Package Item (Container) - Package Item (Container) Type: CD
Package Item (Container) Quantity	24		- Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]
Material	Unknown		
Packaged Item	(Manufacture	ed Item)	<u> </u>
Manufactured Item Quantity	1	Patch (per Sachet)	Manufactured Item - Manufactured Dose Form: CD - Unit of Presentation: CD [01] - Manufactured Item Quantity: PQ
Marketing Autl	horisation (Pa	ckaged Medicinal Product)	
Marketing Authorisation Number	54704097		



Legal Status of Supply	В	B Abgabe auf ärztliche oder tierärztliche Verschreibung (B)			Marketing Authorisation - Marketing Authorisation Number: II
Authorisation Status	Z	Zugelassen			- Country: CD {1*} - Legal Status of Supply: CD - Authorisation Status: CD - Authorisation Status TS
Authorisation Status Date	17.08	17.08.1999			Validity Period Start: TS Validity Period End: TS Data Exclusivity Start Date: TS [01] Data Exclusivity End Date: TS [01] Date of First Authorisation: TS [01] International Birth Date: TS 01
					PCID: II Package Description: ST
Preis (BAG) (Pa	ckage	d Medicinal I	Product)		
FAP (BAG)	СН	F 32.44			Preis [BAG] - Preis-Typ [BAG]: MO - Preisänderungstyp [BAG]: II
PP (BAG)	СН	F 53.65			Preis [BAG]: MO - Letzte Preisänderung [BAG]: TS - SB [BAG]: CD.code
Preis- änderungstyp (BAG)	Aus	slandspreisver	gleich		
Limitation (BAC	3) (Pac	kaged Medic	inal Product)		
Limitation (BAG)	-				Limitation [BAG] - Limitation [BAG]: CD
Beschreibung (BAG)	xxx				- Change Type [BAG]: CD - Type [BAG]: CD - Niveau [BAG]: CD - Wert [BAG]: INT - Beschreibung [BAG]: ST - Indikationscode [BAG]: II [1*]
Status (BAG) (F	Packag	ed Medicinal	Product)		
Gültig ab (BAG)	xxx				Status [BAG]
Gültig bis (BAG)	xxx	xxx			- Status [BAG]: CD - Ingegriert am [BAG]: TS [01] - Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS
Shelf Life / Stor	age			<u> </u>	
Shelf Life Type	10	0000073403	Closed Package		
Shelf Life Time Period	6 r	no	ı		Shelf Life / Storage - Shelf Life Type: CD
Special Precautions of Storage	NO	D25	Nicht über 25°C		- Shelf Life Time Period: PQ - Special Precautions for Storage: CD [0*]
- Storage	L		vor Licht Schützen		



2	Im Kühlschrank (2°C - 8°C)	



Manufactured Item				
Manufactured Dose Form	10519000	Transdermal patch	Manufactured Item - Manufactured Dose Form: CD	
Unit of Presentation	15036000	Patch	- Unit of Presentation: CD [0.1] - Manufactured Item Quantity: PQ - The Company of the Company	

Ingredient (Mar	Ingredient (Manufactured Item) / Substance / Strength / Reference Strength					
Ingredient Role	WIRKS	Wirkstoff	Ingredient			
Substance	CXY7B3Q98Z	Estradiolum hemihydricum	- Ingredient Role; CD - Allergenic Indicator: BL [01]			
Strength (presentation)	0.512 mg (per UoP)		Substance - Specifi - Substance: CD - Specifi	Specified Substance led Substance: CD ed Substance Group: CD entiality Indicator: CD [0.1]		
Reference Substance	ENB39R14VF	Estradiol	Strength Strength (Presentation): RTO-PQ.PQ> Strength (Concentration): RTO-PQ.PQ> [0.1] Measurement Points 37 [0.1]	Reference Strength Reference Substance: CD [0.1] Reference Specified Substance: CD [0.1] Reference Specified Substance: CD [0.1]		
Reference Strength	0.496 mg (per UoP)		Country CD [0]	Reference Steegth Measurement Point: ST [01] Reference Steegth Country: CD [01] Reference Steegth Country: CD [01]		

Ingredient (Mar	nufactured Item)	/ Substance / Strength / Re	eference Strength
Ingredient Role	WIRKS	Wirkstoff	Ingredient
Substance	9S44LIC7OJ	Norethisteroni acetas	Ingredient Role: CD Allergerie Indicator: BL [0.1]
Strength (presentation)	4.8 mg (per UoP)		Substance Specified Substance Specified Substance Specified Substance: CD Specified Substance: CD Conferentially includer: CD [0, 1]
Reference Substance	T18F433X4S Norethisteronum		Strength - Strength (Presentation): RTO-PQ-PQ Strength (Concentration): RTO-PQ-PQ- [0.1] - Reference Special Solutionsc. CD [0.1]
Reference Strength	4.2073 mg (per UoP)		Measurement Point ST [0.1] Country: CD [0.1] Reference Steength: RTG-PD, POP Reference Steength Country: CD [0.1] Reference Steength Country: CD [0.1]

Ingredient (Ma	Ingredient (Manufactured Item) / Substance / Strength / Reference Strength					
Ingredient Role	HNIDK	Hilfsstoff	Ingredient - Ingredient Roke CD - Allergenie Indicator: (EL [0.1])			
Substance	83D19O7250	Silicone adhesive	Substance - Secified Substance - Secified Substance CD			
	180M9K3GHP	acrylic adhesive	- Substance CD - Specified Substance Group: CD - Confiderability Indicator: CD [0, 1]			
	U725QWY32X	povidonum K 30	Strength - Sterngth - Reference Strength - Reference Strength - Reference Substance: CD (0.1)			
	2UMI9U37CP	acidum oleicum	- Strugth (Concentration): RTO-PO-PO-PO-ID.1] - Measurement Point ST [01] - Country: CD [01] - Country: CD [01] - Reference Strength: RTO-PO-PO-ID.5 [11] - Reference Strength: Resurement Point: ST [01] - Reference Strength: Measurement Point: ST [01]			
	E107L85C40	dipropylenglycolum				



Pharmaceutica	I Product / Route	of Administration	
Administrable Dose Form	10519000	Transdermales Pflaster	Pharmaceutical Product
Unit of Presentation	15036000	Pflaster	- Administrable Dose Form: CD - Unit of Presentation: CD [01]
Route of Administration	20070000	Transdermale Anwendung	
Methode of Administration (Swissmedic)	200000002039	Application	Route of Administration - Route of Administration: CD

Therapeutic Ind	lication		
Indication as	10030247	Oestrogenmangel	
Comorbidity	10027308	Menopause	
Intended Effect	200000003192	Prophylaxis	

Therapeutic Inc	lication		
Indication as	10031285	Osteoporose postmenopausal	
Intended Effect	200000003194	Therapy	
Intended Effect	200000003192	Prophylaxis	



KEYTRUDA Inf Konz 100 mg/4ml Durchstf



Quelle		
Compendium	Keytruda Inf Konz 100 mg/4ml	compendium.ch®
SAI	KEYTRUDA Inf Konz 100 mg/4ml Durchstf	

Medicinal Product						
MPID	CH-7601001001138-6623101		Medicinal Product			
Approved Dose Form (EXT)	KOINF	Konzentrat zur Herstellung einer Infusionslösung	- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01] - Special Measures: ST [0*] - Paediatric Use Indicator: CD [01] - Orphan Designation Status: CD [01]			

Product Classification				
ATC (Code System)	L01FF02	Product Classification		
Heilmittelcode (Value)	BT – Biotechnologika	- Code System: CD.codeSystem - Value: CD.code		



Medicinal Produ	uct Name		
Type (EXT)	Original		
Full Name	KEYTRUDA Inf Konz 100 mg/4ml Durchstf		Medicinal Product Name - Full Name: ST
Invented Name Part	KEYTRUDA		- Invented Name Part: ENXP [0*] - Scientific Name Part: ENXP [0*] - Strength Part: ENXP [0*] - Pharmaceutical Dose Form Part: ENXP [0*] - Formulation Part: ENXP [0*]
Strength Part	100 mg/-	4ml	Intended Use Part: ENXP [0*] Target Population Part: ENXP [0*]
Pharmaceutical Dose Form Part	Inf Konz		Container or Pack Part: ENXP [0*] Device Part: ENXP [0*] Trademark or Company Name Part: ENXP [0*] Time / Period Part: ENXP [0*] Flavour Part: ENXP [0*] Delimiter Part: ENXP [0*]
Container or Pack Part	Durchstf		
Country / Langu	ıage		
Language	de	Deutsch	Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD
Medicinal Produ	uct Name		
Type (EXT)	BAG		Medicinal Product Name - Full Name: ST
Full Name	KEYTRU	JDA Inf Konz 100 mg/4ml	Invented Name Part: ENXP [0*] Scientific Name Part: ENXP [0*]
Invented Name Part	KEYTRU	JDA	Strength Part: ENXP [0*] Pharmaceutical Dose Form Part: ENXP [0*] Formulation Part: ENXP [0*] Intended Use Part: ENXP [0*] Target Population Part: ENXP [0*]
Strength Part	100 mg/-	4ml	- Container or Pack Part: ENXP [0*] - Device Part: ENXP [0*]
Pharmaceutical Dose Form Part	Inf Konz		Trademark or Company Name Part: ENXP [0*] Time / Period Part: ENXP [0*] Flavour Part: ENXP [0*] Delimiter Part: ENXP [0*]
Country / Langu	uage		
Language	de	Deutsch	Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD



Marketing Auth	orisation	(Medicinal Product)	
Marketing Authorisation Type (EXT)	tbd		Marketing Authorisation
Marketing Authorisation Number	6623101		- Marketing Authorisation Number: II - Country: CD [1*] - Legal Status of Supply: CD - Authorisation Status: CD - Authorisation Status Date: TS - Validity Period Start: TS
Legal Status of Supply	А	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	- Validity Period End; TS - Data Exclusivity Start Date; TS [01] - Data Exclusivity End Date; TS [01] - Date of First Authorisation; TS [01]
Authorisation Status	Z	Zugelassen	- International Birth Date: TS Medicinal Product
Authorisation Status Date	22.02.20	017	- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01]
Validity Period End	31.12.99	999	Special Measures: ST [0.*] Paediatric Use Indicator: CD [0.1] Orphan Designation Status: CD [01]
Date of First Authorisation	22.02.2017		
Spezialitätenlis	te (BAG)	(Medicinal Product)	
Selbstbehalt (BAG)	-		Spezialitätenliste [BAG] - IT-Limitation [BAG]: BL
Preismodell (BAG)	PM -		Selbstbehalt [BAG]: INT Preismodel [BAG]: BL Befristete Aufnahme [BAG]: BL
Original Generika Code (BAG)			Original Generica Code [BAG]: CD LOA-Regel Berechnung Ppub [BAG]: CD Überprüfung nach Patentablauf [BAG]: BL Freiwillige Preisserkung nach 1.8 Monaten [BAG]: BL Gamme (für APV) [BAG]: ST [01]
BAG Dossier- Nr. (BAG)	20416		- Gammen-FR (für APV) [BAG]: INT [01] - Allgemeine Kommentare [BAG]: ST [01]
Status (BAG) (N	dedicinal	Product)	
Integriert am (BAG)	01.09.20	017	
gültig ab (BAG)	01.01.20	023	Status [BAG] - Status [BAG]: CD - Ingegriert am [BAG]: TS [01]
gültig bis (befr. Aufnahme) (BAG)	31.12.2024		- Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS



Marketing Authorisation Holder (Organisation)				
Name	MSD Merck Sharp & Dohme AG	Marketing Authorisation Holder (Organisation)		
GLN	7601001001138			

Hinweis: Pack Size, 1 Durchstechflasche.			
Packaged Medicinal Product			
PCID	CH-7601001001138-6623101-001	Packaged Medicinal Product	
Package Description	KEYTRUDA Inf Konz 100 mg/4ml Durchstf	- PCID: II - Package Description: ST	
Pack Size (EXT)	1 Durchstechflasche(n)		

Data Carrier Identifier			
GTIN (Code System)	7680662310018	Data Carrier Identifier - Code System: CD.codeSystem - Value: CD.code	

Packaged Item (Container)			
Package Item (Container) Type	30009000	Вох	Package Item (Container) - Package Item (Container) Type: CD
Package Item (Container) Quantity	1		- Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]
Material	Karton		

Packaged Item (Container)			
Package Item (Container) Type	30069000	Vial	Package Item (Container) - Package Item (Container) Type: CD
Package Item (Container) Quantity	1		- Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]
Material	Glas		



Package (Component)			
Component Type	30064000	Stopper	Package (Component)
Component Material	20000003200	Aluminium,	- Component Type: CD - Component Material: CD [0*]
	200000003226	Rubber	- Component Alternate Material: CD [0*]

Packaged Item (Manufactured Item)			
Manufactured Item Quantity	4	ml Manufactured	Item
		- Manufactured Dose - Unit of Presentation:	
		- Manufactured Item C	

Marketing Auth	norisation	(Packaged Medicinal Product)	
Marketing Authorisation Number	66231001		Marketing Authorisation - Marketing Authorisation Number: II - Country: CD [1*]
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	Legal Status of Supply: CD Authorisation Status: CD Authorisation Status Date: TS Validity Period Start: TS Validity Period End: TS Data Exclusivity Start Date: TS [01]
Authorisation Status	Z	Zugelassen	Data Exclusivity End Date: TS [01] Date of First Authorisation: TS [01] International Birth Date: TS
Authorisation Status Date	22.02.2017		Packaged Medicinal Product - PCID: II - Package Description: ST
Preis (BAG) (Pa	ackaged M	ledicinal Product)	
FAP (BAG)	CHF 44	107.68	Preis [BAG] - Preis-Typ [BAG]: MO
PP (BAG)	CHF 4763.85		- Preis BAG]: MO - Letzte Preisänderung [BAG]: TS - SB [BAG]: CD.code
Preis- änderungstyp (BAG)	Normale Preismutation		
Limitation (BA	G) (Packag	ged Medicinal Product)	
Limitation (BAG)	L		Limitation [BAG] - Limitation [BAG]: CD
Beschreibung (BAG)	xxx		- Change Type [BAG]: CD - Type [BAG]: CD - Niveau [BAG]: CD - Wert [BAG]: INT - Beschreibung [BAG]: ST - Indikationscode [BAG]: II [1*]
Status (BAG) (Packaged	Medicinal Product)	
Gültig ab (BAG)	01.09.2	017	



Gültig bis (BAG)	28.02.2018	Status [BAG]	
(B/C)		 Status [BAG]: CD Ingegriert am [BAG]: TS [01] Gültig ab [BAG]: TS Gültig bis (befr. Aufnahme) [BAG]: TS	

Shelf Life / Storag	je		
Shelf Life Type	100000073403	Closed package	
Shelf Life Time Period	tbd		
Special Precautions of Storage	2	Im Kühlschrank (2°C – 8°C)	Shelf Life / Storage
Storage	L	vor Licht Schützen	- Shelf Life Type: CD - Shelf Life Time Period: PQ
	NF	Nicht einfrieren	- Special Precautions for Storage: CD [0*]
	Bei Swissmedic angefragt	Nicht schütteln	
	OVP	In der Originalverpackung aufbewahren.	

Manufactured Item						
Manufactured Dose Form	11210000	Solution for infusion	Manufactured Item - Manufactured Dose Form: CD			
Unit of Presentation	15060000	Vial	- Unit of Presentation: CD [01] - Manufactured Item Quantity: PQ			

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength						
Ingredient Role	WIRKS	Wirkstoff	Ingredient Ingredient Role: CD Altergenic Indicator: EL [0.1]			
Substance	DPT0O3T46P	Pembrolizumabum	Specified Substance - Specified Substance CD			
Strength (presentation)	100 mg		- Substance: CD - Specified Substance Group: CD - Confidentially Sedicator: CD [0.1]			
(presentation)	(per UoP)		Strength Reference Strength			
			- Streigh (Presentation; PTO-PD-PD- Breight (Concentration): RTO-PD-PD- [0,1] - Measurement Point ST [0,1] - Country CD [0,1] - Country CD [0,1] - Reference Streight Resourcement Point ST [0,1] - Reference Streight Resourcement Point ST [0,1]			

Ingredient (Mai	Ingredient (Manufactured Item) / Substance / Strength / Reference Strength					
Ingredient Role	HNIDK	Hilfsstoff				
Substance	4QD397987E	Histidinum				
	X573657P6P	Histidini hydrochloridum monohydricum				
	60ZP39ZG8H	Polysorbatum 80				



FST467XS7D	Saccharum	Ingredient - Ingredient Role: CD	
059QF0KO0R	Aqua ad iniectabile	- Allergenic Indicator: BL [0.1]	
		Substance - Specified 5 - Specified 5	ecified Substance Substance: CD Substance Group: CD substance Group: CD Judicator: CD [01]
		Strength (Presentation): RTO-PO_PO> Strength (Concentration): RTO-PO_PO> [0,1] Measurement Point: ST [0,1] Country: CD [0,1]	Reference Strength Reference Special Substance: CD [01] Reference Special Substance: CD [0.1] Reference Strength: RTO-PQ_PQ> Reference Strength Resuscement Point: ST [01] Reference Strength Resuscement Point: ST [01]



Pharmaceutica	Product / Route	of Administration	
Administrable Dose Form	11210000	Solution for infusion	Pharmaceutical Product
Unit of Presentation	15060000	Vial	- Administrable Dose Form: CD - Unit of Presentation: CD [01]
Route of Administration	20045000	Intravenous use	
Methode of Administration (Swissmedic)	200000002043	Infusion	Route of Administration: CD

Therapeutic Indication						
Indication as	10027400	Melanom	Therapeutic Indication			
Intended Effect	20000003194	Therapy	- Indication Text: ST - Indication as "Disease / Symptom / Procedure": CD [01] - Disease Status: CD [01] - Comorbidity: CD [01] - Intended Effect: CD [01] - Timing / Duration: PQ [01]			

Therapeutic Ind	Therapeutic Indication					
Indication as	10028881	Nicht-kleinzelliges Lungenkarzinom		Therapeutic Indication		
Intended Effect	20000003194	Therapy		Indication as "Disease / Symptom / Procedure": CD [01] Disease Status: CD [01] Comorbidity: CD [01] Intended Effect: CD [01] Timing / Duration: PQ [01]		

Therapeutic Indication					
Indication as	10021782	Kopf- und Halskarzinom	Therapeutic Indication		
Intended Effect	20000003194	Therapy	Indication Text: ST Indication as "Disease / Symptom / Procedure": CD [01] Disease Status: CD [01] Comorbidity: CD [01] Intended Effect: CD [01] Timing / Duration: PQ [01]		

Therapeutic Ind	Therapeutic Indication					
Indication as	10019927	Klassisches Hodgkin Lymphom	Therapeutic Indication - Indication Text: ST			
Intended Effect	20000003194	Therapy	Indication as "Disease / Symptom / Procedure": CD [01] Disease Status: CD [01] Comorbidity: CD [01] Intended Effect: CD [01] Timing / Duration: PQ [01]			

Therapeutic Indication				
Indication as	10043971	Primäres mediastinales grosszelliges B-Zell- Lymphom		



Intended Effect	200000003194	Therapy	Therapeutic Indication
			 Indication Text: ST Indication as "Disease / Symptom / Procedure": CD [01] Disease Status: CD [01] Comorbidity: CD [0*] Intended Effect: CD [01] Timing / Duration: PQ [01]



PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk



Quelle				
Compendium	PAXLOVID Filmtabl 4x150mg/2x100mg	compendium.ch®		
SAI	PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk			

Medicinal Produ	uct			
MPID	CH-7601	001010604-6879301	1	Medicinal Product
Approved Dose Form (EXT)	FILM	Filmtablette		- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01] - Special Measures: ST [0*] - Paediatric Use Indicator: CD [01] - Orphan Designation Status: CD [01]

Product Classification			
ATC (Code System)	J05AE30	Product Classification	
Heilmittelcode (Value)	S – Synthetika	- Code System: CD.codeSystem - Value: CD.code	



Medicinal Produ	ıct Name		
Type (EXT)	Original		
Full Name	PAXLOV	/ID Filmtabl 4x150mg/2x100mg 5 x 6 Stk	
Invented Name Part	PAXLOV	/ID	
Strength Part	150mg		Medicinal Product Name - Full Name: ST
Strength Part	100mg		Invented Name Part: ENXP [0*] Scientific Name Part: ENXP [0*] Strength Part: ENXP [0*]
Pharmaceutical Dose Form Part	Filmtabl		- Pharmaceutical Dose Form Part: ENXP [0*] - Formulation Part: ENXP [0*] - Intended Use Part: ENXP [0*] - Target Population Part: ENXP [0*] - Container or Pack Part: ENXP [0*] - Device Part: ENXP [0*]
Container or Pack Part	4x		- Trademark or Company Name Part: ENXP [0*] - Time / Period Part: ENXP [0*] - Flavour Part: ENXP [0*] - Delimiter Part: ENXP [0*]
Container or Pack Part	2x		
Container or Pack Part	5 x 6 Stk		
Delimiter Part	/		
Country / Langu	ıage		
Language	de	Deutsch	Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD
Medicinal Produ	ıct Name		
Type (EXT)	BAG		
Full Name	PAXLOV	/ID Filmtabl 4x150mg/2x100mg	
Invented Name Part	PAXLOV	/ID	Medicinal Product Name
Strength Part	150mg		Invented Name Part: ENXP [0*] Scientific Name Part: ENXP [0*]
Strength Part	100mg		Strength Part: ENXP [0*] Pharmaceutical Dose Form Part: ENXP [0*] Formulation Part: ENXP [0*]
Pharmaceutical Dose Form Part	Filmtabl		Intended Use Part: ENXP [0*] Target Population Part: ENXP [0*] Container or Pack Part: ENXP [0*] Device Part: ENXP [0*] Trademark or Company Name Part: ENXP [0*] Time / Period Part: ENXP [0*]
Container or Pack Part	4x		- Flavour Part: ENXP [0*] - Delimiter Part: ENXP [0*]
			=

2x

Container or

Country / Language

Pack Part Delimiter Part



Language	e de	Deutsch	Country / Language
			- Country: CD - Jurisdiction: CD [01] - Language: CD

	ı				
Marketing Auth	orisation	(Medicinal Product)			
Marketing Authorisation Type (EXT)	tbd		Marketing Authorisation		
Marketing Authorisation Number	6879301		- Marketing Authorisation Number: III - Country: CD [1*] - Legal Status of Supply: CD - Authorisation Status: CD - Authorisation Status: TS - Validity Period Start: TS - Validity Period Start: TS		
Legal Status of Supply	А	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	- Validity Period End: TS - Data Exclusivity Start Date: TS [01] - Data Exclusivity End Date: TS [01] - Date of First Authorisation: TS [01]		
Authorisation Status	В	Befristet	- International Birth Date: TS Medicinal Product		
Authorisation Status Date	15.06.20)22	- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01]		
Validity Period End	15.06.20	024	- Special Measures: ST [01] - Paediatric Use Indicator: CD [01] - Orphan Designation Status: CD [01]		
Date of First Authorisation	15.06.20)22			
Spezialitätenlis	te (BAG)	(Medicinal Product)			
Selbstbehalt (BAG)	-		Spezialitätenliste [BAG]		
Preismodell (BAG)	PM		- IT-Limitation [BAG]: BL - Selbstbehalt [BAG]: INT - Preismodel [BAG]: BL - Befristete Aufnahme [BAG]: BL		
Original Generika Code (BAG)	-		Original Generica Code [BAG]: CD LOA-Regel Berechnung Ppub [BAG]: CD Überprüfung nach Patentablauf [BAG]: BL Freiwillige Preisserkung nach 18 Monaten [BAG]: BL Gamme (für APV) [BAG]: ST [01]		
BAG Dossier- Nr. (BAG)	21529		- Gammen-FR (für APV) [BAG]: INT [01] - Allgemeine Kommentare [BAG]: ST [01]		
Status (BAG) (N	ledicinal	Product)			
Integriert am (BAG)	01.12.20)23			
gültig ab (BAG)	01.12.2023 31.12.2025		- Status [BAG] - Status [BAG]: CD - Ingegriert am [BAG]: TS [01]		
gültig bis (befr. Aufnahme) (BAG)			- Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS		



Marketing Authorisation Holder (Organisation)			
Name	Pfizer AG	Marketing Authorisation Holder (Organisation)	
GLN	7601001010604		

Hinweis: Pack Size, eine Verpackung: 4x150mg und 2x100mg in einem Blister, 5 Blister pro Box.				
Packaged Me	edicinal Product			
PCID	CH-7601001010604-6879301-001	Packaged Medicinal Product		
Package Description	PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk	- PCID: II - Package Description: ST		
Pack Size (EXT)	30 Filmtabletten			

Data Carrier Identifier			
GTIN (Code System)	7680687930017	Data Carrier Identifier - Code System: CD.codeSystem - Value: CD.code	

Packaged Item	(Container)			
Package Item (Container) Type	30009000	Вох		Package Item (Container) Package Item (Container) Type: CD
Package Item (Container) Quantity	1			Package Item (Container) Quantity: PQ Material: CD [1*] Alternate Material: CD [0*]
Material	Karton			

Packaged Item	Packaged Item (Container)				
Package Item (Container) Type	30007000	Blister	Package Item (Container) - Package Item (Container) Type: CD		
Package Item (Container) Quantity	1		- Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]		
Material	Aluminium, A	luminium			



Packaged Item (Manufactured Item)			
Manufactured Item Quantity	20	Tabletten (150 mg nirmatrelvirum) 4 Tabletten pro Blister	Manufactured Item - Manufactured Dose Form: CD - Unit of Presentation: CD [01]
Manufactured Item Quantity	10	Tabletten (100 mg ritonavirum) 2 Tabletten pro Blister	- Manufactured Item Quantity: PQ

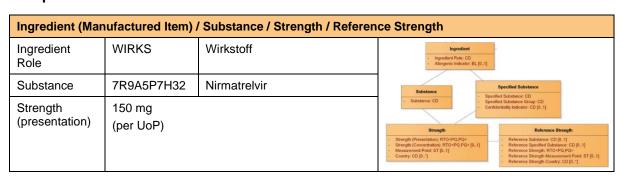
Marketing Auth	orisati	on (Packaged Medicinal Product)			
Marketing Authorisation Number	6879	3001	Marketing Authorisation - Marketing Authorisation Number: II - Country: CD [1*]		
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	Legal Status of Supply: CD Authorisation Status; CD Authorisation Status Date: TS Validity Period Start: TS Validity Period End: TS		
Authorisation Status	В	Befristet	Data Exclusivity Start Date: TS [01] Data Exclusivity End Date: TS [01] Date of First Authorisation: TS [01]		
Authorisation Status Date	15.06	3.2022	Packaged Medicinal Product PCID: II Package Description: ST		
Preis (BAG) (Pa	ckage	d Medicinal Product)			
FAP (BAG)	СНІ	- 958.62	Preis [BAG] - Preis-Typ [BAG]: MO		
PP (BAG)	CHI	F 1112.85	- Preis Badg: NO O - Preis Badg: MO O - Letzte Preisänderung [BAG]: TS - SB [BAG]: CD.code		
Preis- änderungstyp (BAG)	Pre	ismutation bei Erstaufnahme			
Limitation (BAC	3) (Pac	kaged Medicinal Product)			
Limitation (BAG)	L		Limitation [BAG] - Limitation [BAG]: CD		
Beschreibung (BAG)	xxx		- Change Type [BAG]: CD - Type [BAG]: CD - Niveau [BAG]: CD - Wert [BAG]: NT - Beschreibung [BAG]: ST - Indikationscode [BAG]: II [1*]		
Status (BAG) (F	Packag	ed Medicinal Product)			
Gültig ab (BAG)	01.1	12.2023	Status [BAG]		
Gültig bis (BAG)	31.	12.2025	- Status [BAG]: CD - Ingegriert am [BAG]: TS [01] - Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS		



Shelf Life / Stora	ge		
Shelf Life Type	100000073403	Closed package	
Shelf Life Time Period	tbd	1	
Special Precautions of	OVP	Im Originalkarton aufbewahren	Shelf Life / Storage - Shelf Life Type: CD - Shelf Life Time Period: PQ
Storage	NO25	Nicht über 25 °C	- Special Precautions for Storage: CD [0*]
	2	Im Kühlschrank (2°C - 8°C)	
	NF	Nicht einfrieren	

Manufactured	ltem		
Manufactured Dose Form	10221000	Filmtablette	Manufactured Item - Manufactured Dose Form: CD
Unit of Presentation	15054000	Tablette	- Unit of Presentation: CD [01] - Manufactured Item Quantity: PQ
Description (EXT)	Komponente /	A: Rosafarbene, ovale Filmtablette	Manufactured Item
Description (EXT)	Komponente I	3: Weisse kapselförmige Tablette	Manufactured Dose Form: CD Unit of Presentation: CD [01] Manufactured Item Quantity: PQ Description [EXT]: ST [01]

Komponente A



Ingredient (M	Ingredient (Manufactured Item) / Substance / Strength / Reference Strength					
Ingredient Role	HNIDK	Hilfsstoff	Ingredient Ingredient Roke: CD Altergenic Indicator: BL [01]			
Substance	OP1R32D61U	Cellulosum microcristallinum	Substance	Specified Substance cified Substance CD		
	EWQ57Q8I5X	185 mg lactosum monohydricum	- Substance: CD - Spe	cared scientarios (CD) indentiality indicator: CD [0, 1] Reference Strength		
	M28OL1HH48	Carmellosum natricum conexum	Strength (Presentation): RTO <p0.p0> Strength (Concentration): RTO<p0.p0> [01] Measurement Point: ST [01] Country: CD [07]</p0.p0></p0.p0>	Reference Substance: CD [0, 1] Reference Specified Substance: CD [0, 1] Reference Steepth: RTO-4PLPQ: Reference Strength Remove Steepth Stream (1, 1) Reference Strength Country: CD [0, 1] Reference Strength Country: CD [0, 1]		
	ETJ7Z6XBU4	Silica colloidalis anhydrica				
	7CV7WJK4UI	Natrii stearylis fumaras				



	3NXW29V3WO	Hypromellosum
	15FIX9V2JP	TITANII DIOXIDUM CL 77891 E 171
	B697894SGQ	Macrogolum 400
	1K09F3G675	Red Iron Oxide Dehydrate E 172
	9NEZ333N27	0.99 mg Natrium

Komponente B

Ingredient (Mar	Ingredient (Manufactured Item) / Substance / Strength / Reference Strength					
Ingredient Role	WIRKS	Wirkstoff	Ingredient - Ingredient Role: CD - Altergenic Indicator: BL [0.1]			
Substance	O3J8G9O825	Ritonavirum	Substance Specific Substance - Specified Substance	ied Substance		
Strength 150 mg (presentation) (per LIOP)			- Substance: CD - Specified Subs	stance Group: CD Indicator: CD [01]		
(procentation)	(per UoP)		- Strength (Concentration): RTO <pq.pq> [0.1] - R: - Measurement Point: ST [0.1] - R: - Country: CD [0.7] - R:</pq.pq>	Reference Strength inference Substance: CD [01] leference Specified Substance: CD [01] leference Strength RTO-PD-PD- leference Strength Measurement Point: ST [01] leference Strength Country: CD [07]		

Ingredient (Ma	anufactured Item) / S	Substance / Strength / Referen	nce Strength	
Ingredient Role	HNIDK	Hilfsstoff	Ingredient Ingredient Role: CD Allergenic Indicator: BL [0,1]	
Substance	9E63551N1O	Copovidonum	Substance	Specified Substance Specified Substance: CD
	ETJ7Z6XBU4	Silica colloidalis anhydrica	- Substance: CD - S	specified Substance Group: CD Confidentiality Indicator: CD [01]
	6W9PS8B71J	Sorbitani lauras	Strength Strength (Presentation): RTO <pq.pq></pq.pq>	Reference Strength - Reference Substance: CD [0.1]
	L11K75P92J	Calcii hydrogenophosphas	- Strength (Concentration): RTO <pq.pq> [01] - Measurement Point: ST [01] - Country: CD [0*]</pq.pq>	Reference Specified Substance: CD [01] Reference Strength: RTO-PO_PO> Reference Strength Measurement Point: ST [01] Reference Strength Country: CD [01]
	7CV7WJK4UI	Natrii stearylis fumaras		produce the second seco
	3NXW29V3WO	Hypromellosum		
	15FIX9V2JP	TITANII DIOXIDUM CL 77891 E 171		
	B697894SGQ	Macrogolum 400		
	YIN83H0ESV	Macrogolum 3350		
	9XZ8H6N6OH	Hydroxypropylcellulosum		
	7SEV7J4R1U	Talc		
	ETJ7Z6XBU4	Silica colloidalis anhydrica		
	6OZP39ZG8H	Polysorbatum 80		
	9NEZ333N27	0.388 mg Natrium		

Pharmaceutica	Pharmaceutical Product / Route of Administration				
Administrable Dose Form	10221000	Film-coated tablet			

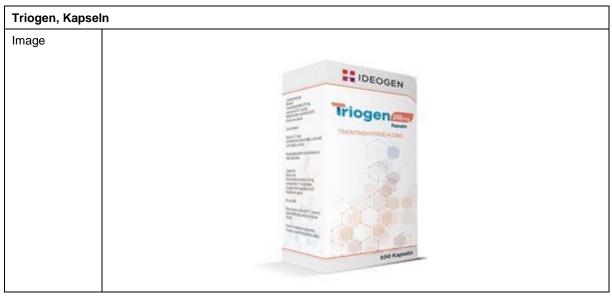


Unit of Presentation	15054000	Tablette	Pharmaceutical Product
Route of Administration	20053000	Oral use	- Administrable Dose Form: CD - Unit of Presentation: CD [01]
Methode of Administration (Swissmedic)	20000002052	Swallowing	Route of Administration - Route of Administration: CD

Therapeutic Ind	Therapeutic Indication					
Indication as	10084529	Coronavirus-Krankheit 2019 (COVID-19)		Therapeutic Indication		
Intended Effect	20000003194	Therapy		Indication as "Disease / Symptom / Procedure": CD [01] Disease Status: CD [01] Comorbidity: CD [07] Intended Effect: CD [01] Timing / Duration: PQ [01]		



TRIOGEN Kaps 250 mg Ds 100 Stk



Quelle		
Compendium	TRIOGEN Kaps 250 mg	compendium.ch®
SAI	TRIOGEN Kaps 250 mg Ds 100 Stk	rofinia.

Medicinal Produ	Medicinal Product					
MPID	CH-7601	1001403062-6743101	Medicinal Product			
Approved Dose Form (EXT)	KAPS	Kapsel	- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01] - Special Measures: ST [0*] - Paediatric Use Indicator: CD [01] - Orphan Designation Status: CD [01]			

Product Classification				
ATC	A16AX12	Product Classification		
Heilmittelcode	S – Synthetika	- Code System: CD.codeSystem - Value: CD.code		



Medicinal Produ	uct Name		
Type (EXT)	Original		
Full Name	TRIOGE	N Kaps 250 mg Ds 100 Stk	Medicinal Product Name - Full Name: ST
Invented Name Part	TRIOGE	in .	Invented Name Part: ENXP [0*] Scientific Name Part: ENXP [0*] Strength Part: ENXP [0*] Pharmaceutical Dose Form Part: ENXP [0*] Formulation Part: ENXP [0*]
Pharmaceutical Dose Form Part	Kaps		- Intended Use Part: ENXP [0*] - Target Population Part: ENXP [0*] - Container or Pack Part: ENXP [0*] - Device Part: ENXP [0*] - Trademark or Company Name Part: ENXP [0*] - Time / Period Part: ENXP [0*]
Strength Part	250 mg		- Flavour Part: ENXP [0*] - Delimiter Part: ENXP [0*]
Container or Pack Part	Ds 100 S	Stk	
Country / Langu	ıage		
Language	de	Deutsch	Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD

Medicinal Produ	uct Name				
Type (EXT)	BAG			Medicinal Product Name	
Full Name	TRIOGE	N Kaps 250 mg	- Full Name: ST - Invented Name Part: ENXP [0*] - Scientific Name Part: ENXP [0*]		
Invented Name Part	TRIOGE	N		Strength Part: ENXP [0*] Pharmaceutical Dose Form Part: ENXP [0*] Formulation Part: ENXP [0*] Intended Use Part: ENXP [0*]	
Pharmaceutical Dose Form Part	Kaps			Target Population Part: ENXP [0*] Container or Pack Part: ENXP [0*] Device Part: ENXP [0*] Trademark or Company Name Part: ENXP [0*] Time / Period Part: ENXP [0*] Flavour Part: ENXP [0*]	
Strength Part	250 mg			Delimiter Part: ENXP [0*]	
Country / Langu	ıage				
Language	de	Deutsch		Country / Language - Country: CD - Jurisdiction: CD [01] - Language: CD	



Marketing Auth	orisation	(Medicinal Product)	
Marketing Authorisation Type (EXT)	tbd		Marketing Authorisation
Marketing Authorisation Number	6743101	1	- Marketing Authorisation Number: II - Country: CD [1.**] - Legal Status of Supply: CD - Authorisation Status: CD - Authorisation Status Date: TS - Validity Period Statt: TS
Legal Status of Supply	В	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	- Validity Period End: TS - Data Exclusivity Start Date: TS [01] - Data Exclusivity End Date: TS [01] - Date of First Authorisation: TS [01]
Authorisation Status	Z	Zugelassen	- International Birth Date: TS Medicinal Product
Authorisation Status Date	28.05.20)20	- MPID: II - Combined Pharmaceutical Dose Form: CD [01] - Additional Monitoring Indicator: CD [01]
Validity Period End	27.05.20	025	Special Measures: ST [0*] Paediatric Use Indicator: CD [01] Orphan Designation Status: CD [01]
Date of First Authorisation	28.05.20	020	
Spezialitätenlis	te (BAG) ((Medicinal Product)	
Selbstbehalt (BAG)	-		Spezialitätenliste [BAG] - IT-Limitation [BAG]: BL
Preismodell (BAG)	-		- Selbstbehalt [BAG]: INT - Preismodel [BAG]: BL - Befristete Aufnahme [BAG]: BL
Original Generika Code (BAG)	-		- Original Generica Code [BAG]: CD - LOA-Regel Berechnung Ppub [BAG]: CD - Überprüfung nach Patentablauf [BAG]: BL - Freiwillige Preisserkung nach 18 Monaten [BAG]: BL - Gamme (für APV) [BAG]: ST [01]
BAG Dossier- Nr. (BAG)	21070		- Gammen-FR (für APV) [BAG]: INT [01] - Allgemeine Kommentare [BAG]: ST [01]
Status (BAG) (N	/ledicinal	Product)	
Integriert am (BAG)	01.09.20	020	
gültig ab (BAG)	01.09.20	020	Status [BAG]: CD - Ingegriert am [BAG]: TS [01]
gültig bis (befr. Aufnahme) (BAG)	31.12.99	999	- Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS



Marketing Authorisation Holder (Organisation)					
Name	IDEOGEN AG	Marketing Authorisation Holder (Organisation)			
GLN	7601001403062				
Hinweis: I	Pack Size, 100 Kapseln				

Hinweis: Pack Size, 100 Kapseln					
Packaged Medicinal Product					
PCID	CH-7601001403062-6743101-001	Packaged Medicinal Product			
Package Description	TRIOGEN Kaps 250 mg Ds 100 Stk	- PCID: II - Package Description: ST			
Pack Size (EXT)	100 Kapseln(n)				

Data Carrier Identifier			
GTIN (Code System)	7680674310013	- Code System: CD.codeSystem - Value: CD.code	

Packaged Item	(Container)			
Package Item (Container) Type	30009000	Box		Package Item (Container) Package Item (Container) Type: CD
Package Item (Container) Quantity	1		1-	Package Item (Container) Quantity: PQ Material: CD [1*] Alternate Material: CD [0*]
Material	Karton			

Packaged Item (Container)			
Package Item (Container) Type	30008000	Bottle	Package Item (Container) - Package Item (Container) Type: CD
Package Item (Container) Quantity	1		- Package Item (Container) Quantity: PQ - Material: CD [1*] - Alternate Material: CD [0*]
Material	unknown		

Packaged Item (Manufactured Item)				
Manufactured Item Quantity	100	Kapseln (per box)	Manufactured Item - Manufactured Dose Form: CD - Unit of Presentation: CD [01] - Manufactured Item Quantity: PQ	



Marketing Auth	orisation ((Packaged	Medicinal Product)	
Marketing Authorisation Number	6743100	1		Marketing Authorisation - Marketing Authorisation Number: II - Country: CD [1*]
Legal Status of Supply	В		auf ärztliche oder iche Verschreibung (B)	- Legal Status of Supply: CD - Authorisation Status; CD - Authorisation Status Date: TS - Validity Period Start: TS - Validity Period End: TS
Authorisation Status	Z	Zugelas	ssen	Data Exclusivity Start Date: TS [01] Data Exclusivity End Date: TS [01] Date of First Authorisation: TS [01] International Birth Date: TS
Authorisation Status Date	28.05.2020			O1 Packaged Medicinal Product PCID: II Package Description: ST
Preis (BAG) (Pa	ackaged M	edicinal P	roduct)	
FAP (BAG)	CHF 41	17.12		Preis [BAG] - Preis-Typ [BAG]: MO - Preisänderungstyp [BAG]: II
PP (BAG)	CHF 44	66.05		- Preis [BAG]: MO - Letzte Preisänderung [BAG]: TS - SB [BAG]: CD.code
Preis- änderungstyp (BAG)	Preismu	utation bei	Erstaufnahme	
Limitation (BAC	G) (Packag	ed Medici	nal Product)	
Limitation (BAG)	L			Limitation [BAG] - Limitation [BAG]: CD
Beschreibung (BAG)	xxx			- Change Type [BAG]: CD - Type [BAG]: CD - Niveau [BAG]: CD - Wert [BAG]: INT - Beschreibung [BAG]: ST - Indikationscode [BAG]: II [1*]
Status (BAG) (F	Packaged I	Medicinal	Product)	
Gültig ab (BAG)	01.09.2	020		Status [BAG] - Status [BAG]: CD
Gültig bis (BAG)	31.12.9	999		- Ingegriert am [BAG]: TS [01] - Gültig ab [BAG]: TS - Gültig bis (befr. Aufnahme) [BAG]: TS
Shelf Life / Stor	age			
Shelf Life Type	100000	0073403	Closed Package	
Shelf Life Time Period	tbd			Shelf Life / Storage - Shelf Life Type: CD
Special Precautions of Storage	NO30		Nicht über 30°C lagern	- Shelf Life Time Period: PQ - Special Precautions for Storage: CD [0*]
Storago	F		vor Feuchtigkeit schützen	



CLOS Den Behälter fest
verschlossen halten

Manufactured Item						
Manufactured Dose Form	10210000	Capsule, hard	Manufactured Item - Manufactured Dose Form: CD - Unit of Presentation: CD [01] - Manufactured Item Quantity: PQ			

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength				
Ingredient Role	WIRKS	Wirkstoff	Ingredient - Ingredient Role: CD - Allergenic Indicator: BL [0.1]	
Substance		Trientini dihydrochloridum	Substance Specified Substance	
Strength (presentation)	250 mg (per UoP)		Substance: CD Specified Substance: CD Specified Substance: Group: CD Confidentiality Indicator: CD [0,1]	
u sasany			Strength (Pesentation): RTO-PD/PD> Strength (Concentration): RTO-PD/PD> Strength (Concentration): RTO-PD/PD- [0.1] - Measurement Point: ST [0.1] - Country: CD [0.1] - Reference Strength: RTO-PD/PD- Reference Strength: RTO-PD-PD- Reference Strength: RTO-PD-PD- Reference Strength: RTO-PD-PD-PD-PD-PD-PD-PD-PD-PD-PD-PD-PD-PD-	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	Ingredient - Ingredient Relo: CD - Allergenie Indicator: BL [0.1]
Substance	ETJ7Z6XBU4	Silica colloidalis anhydrica	Substance - Specified Substance CD - Substance: CD - Specified Substance: CD - Specified Substance: CD - Conditionally indicator C(0):1
	4ELV7Z65AP	Acidum stearicum	Strength Reference Strength
	2G86QN327L	Gelatina	Strength (Presentation); RTO-PQ-PQ> Strength (Concentration); RTO-PQ-PQ> [0.1] Strength (Concentration); RTO-PQ-PQ> [0.1] Measurement Point: \$T1 = [1] Reference Specified Substance: CD [0.1] Reference Strength; RTO-PQ-PQ-PQ>
	059QF0KO0R	Aqua purificata	- Country: CD [07] - Reference Strength Measurement Point: ST [01] - Reference Strength Country: CD [07]
	368GB5141J	Natrii laurilsulfas	
	9NEZ333N27	0.0048 mg natrium	
	EX438O2MRT	YELLOW LAKE CLF 3076 (E104 AND E172) E 172 (flavum)	
	1K09F3G675	RED IRON OXIDE DEHYDRATE (E172) E 172 (rubum)	
	15FIX9V2JP	TITANII DIOXIDUM CL 77891 E 171	
	J601Y25Y5H	Lacca	
	3N8O9D1K5W	Alcohol butylicus	
	6DC9Q167V3	Propylenglycolum	
	1K09F3G675	BLACK IRON OXIDE - SYNTHETIC (E172)	
		E 172 (nigrum)	-
	WZH3C48M4T	Kalii hydroxidum	





Pharmaceutical Product / Route of Administration			
Administrable Dose Form	10210000	Capsule, hard	Pharmaceutical Product
Unit of Presentation	15012000	Capsule	- Administrable Dose Form: CD - Unit of Presentation: CD [01]
Route of Administration	20053000	Oral use	
Methode of Administration (Swissmedic)	200000002052	Swallowing	Route of Administration - Route of Administration: CD

Therapeutic Indication			
Indication as	100000019583	Copper metabolism disorder (Morbus Wilson)	Therapeutic Indication - Indication Text: ST
Intended Effect	20000003194	Therapy	- Indication as "Disease / Symptom / Procedure": CD [01] - Disease Status: CD [01] - Comorbidity: CD [01] - Intended Effect: CD [01] - Timing / Duration: PQ [01]



3 Abkürzungsverzeichnis

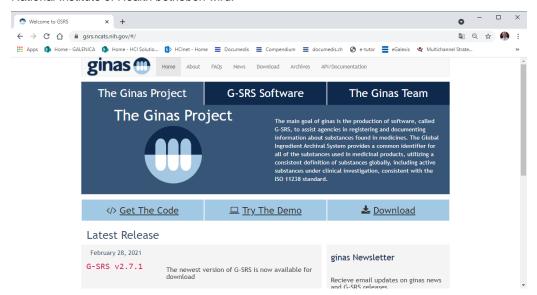
CD	Concept Descriptor (Werteliste)
EMA	European Medicines Agency
EU	Europäische Union
FHIR	Fast Healthcare Interoperability Resources
GSRS	Global Substance Registration System
1/0	Input / Output
IDMP	Identification of Medicinal Product
II	Instance Identifier (Identifikationsnummer)
JSON	JavaScript Object Notation
MPID	Medicinal Product Identifier
NCATS	
SPOR	Substances, Products, Organisations, Referencials
ST	String
TS	Time Stamp (Datumsangabe)
UNII	Unique Ingredient Identifier
XML	Extensible Markup Language



4 Websites

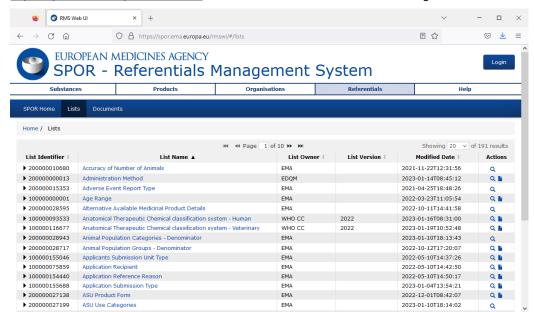
4.1.1 GSRS

https://gsrs.ncats.nih.gov/ ist die Globale Substanz-Registrierungs-Datenbank welche vom NCATS des US National Institute of Health betrieben wird.



4.1.2 EMA RMS

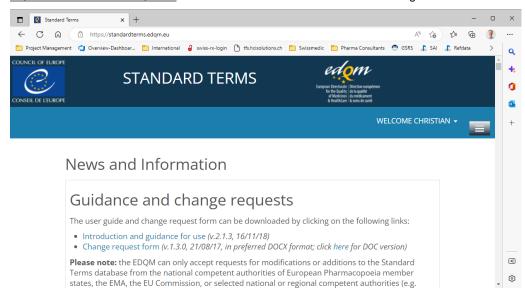
https://spor.ema.europa.eu/rmswi/#/ ist die Website der EMA mit der Auflistung all ihrer Wertelisten.





4.1.3 EDQM Standardterms

https://standardterms.edqm.eu/ ist die Website des EDQM mit der Auflistung ihrer Wertelisten.





4.2 Gesetze und Vorgaben

4.2.1 Antwort des Bundesrates vom 7.3.2022 betreffend der Einführung von IDMP in der Schweiz

Auf Anfrage der Nationalrätin Edith Graf-Litscher antwortet der Bundesrat wie folgt:

Die Einführung von ISO IDMP ist in der Schweiz vorgesehen. Ein entsprechender Vorgehensplan für die schrittweise Einführung ist bei Swissmedic in Erarbeitung. Die Einführung soll mit den betroffenen Kreisen abgestimmt werden. Die Arzneimittelsicherheit und Patientensicherheit sind während der schrittweisen Einführung jederzeit gewährleistet. Um mit der Europäischen Arzneimittelagentur und anderen Behörden bei relevanten Arzneimitteldaten kompatibel zu sein, wurden gewisse Massnahmen bereits umgesetzt. Ob Ausnahmen für Tierarzneimittel oder Komplementär- und Phytoarzneimittel denkbar sind, ist Bestandteil der gegenwärtigen Abklärungen. Zum aktuellen Zeitpunkt geht der Bundesrat davon aus, dass weder eine Anpassung des Heilmittelgesetzes noch der entsprechenden Verordnungen nötig sein wird.

Link zum vollständigen Artikel:

https://www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?Affairld=20227054

4.2.2 Commission Implementing Regulation (EU) No 520/2012

Beiliegend die gesetzlichen Bestimmungen der Europäischen Union zur Einführung von IDMP in der EEA.

Article 25 of Commission Implementing Regulation (EU) No 520/2012 (terminology)

MedDRA, Standard Terms published by European Pharmacopeia Commission and terminology set out in **EN ISO 11615, 11616, 11238, 11239 and 11240 must be used** for the classification, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of **pharmacovigilance and medicinal product information** by Member States, marketing authorisation holders and the Agency.

Article 26 of Commission Implementing Regulation (EU) No 520/2012 (formats and standards)

XEVMPD, EN ISO 27953-2:2011 ICSR as well as formats and standards set out in **EN ISO 11615**, **11616**, **11238**, **11239** and **11240** must be used for the description, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of pharmacovigilance and medicinal product information by national competent authorities, marketing authorisation holders and the Agency.

Article 40 of Commission Implementing Regulation (EU) No 520/2012 (due date)

The obligation on the part of marketing authorisation holders, national competent authorities and the Agency to use the terminology provided for in Art 25 and Art 26(2)shall apply from **1 July 2016**



Official Journal of the European Union

L 159/5

COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012

of 19 June 2012

on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council

EN

Having regard to the Treaty on the Functioning of the European Union.

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veserinary use and establishing a European Medicines Agency (³), and in particular Article 87a thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (?), and in particular Article 108 thereof.

- Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 Regulation (EU) No 1233/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veerinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (?) strengthened and rationalised the monitoring of the safety of medicines that have been placed on the market in the Union. Similar provisions were incroduced by Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (4) into Directive 2001/83/EC.
- Pharmacovigilance activities cover the whole life-cycle management of medicinal products for human use in relation to safety.
- Regulation (EU) No 1235/2010 and Directive 2010/84/EU introduced the concept of the pharmacovigilance system master file. In order to accurately reflect the pharmacovigilance system used by the

(*) OJ L 136, 30.4.2004, p. 1. (*) OJ L 311, 28.11.2001, p. 67. (*) OJ L 348, 31.12.2010, p. 1. (*) OJ L 348, 31.12.2010, p. 74.

marketing authorisation holder, the pharmacovigilance system master file should contain key information and documents covering all aspects of pharmacovigilance activities, including information on tasks that have been subcontracted. It should contribute to the appropriate planning and conduct of audits by the marketing authorisation holder and the supervision of pharmacovigilance activities by the qualified person responsible for pharmacovigilance. At the same time it should enable national competent authorities to verify compliance concerning all aspects of the system.

- The information contained in the pharmacovigilance system master file should be maintained so as to reflect any modifications that have been made and ensure easy accessibility and availability by national competent authority. orities for the purpose of inspections.
- Quality systems should form an integral part of the pharmacovigalance system. The minimum requirements for the quality system for the performance of pharmacovigilance activities should ensure that marketing authorisation holders, national competent authorisies and the European Medicines Agency (hereinafter 'the Agency') establish an adequate and effective quality system, which provides for an effective monitoring of compiliance and the accurate and proper documentation of all measures taken. They should also ensure that marketing authorisation holders, national competent authorities and the Agency have at their disposal sufficient competent, appropriately qualified and trained staff.
- Adherence to a well-defined quality system should ensure that all pharmacovigilance activities are conducted in such a way that they are likely to produce the desired results or quality objectives for the fulfilment of phar-macovigilance tasks.
- As pare of their qualisy system, national competent authorities and the Agency should establish contact points to facilitate interaction between national competent authorities, the Agency, the Commission, marketing authorities and the Agency description of the facilitate of the Agency description of the facilitate of the Agency description of the facilitate of the Agency description of the Agency descript
- If markeeing authorisation holders, national competent authorities and the Agency use performance indicators to monitor the good performance of pharmacovigilance activities, those indicators should be documented.

Abbildung 1 Commission Implementing Regulation (EU) No 520/2012

Siehe: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000491.jsp



5 Versionierung

Version	Erstellt	Änderungen	Autor
1.0	12.12.2023	Initial Draft	MBK
1.1	19.12.2023	Update nach Reviews Ergänzung weiterer Produkte	CKR
1.2	10.01.2024	Ergänzung IDMP – BAG Datenmodel Erweiterungen der Daten	CKR