

1.1 PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk

Paxlovid, Filmtabletten		
Quelle		
Compendium	PAXLOVID Filmtabl 4x150mg/2x100mg	compendium.ch®
SAI	PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk	rofil.ch
Medicinal Product		
MPID	CH-7601001010604-6879301	
Approved Dose Form (EXT)	FILM	Filmtablette
		Medicinal Product <ul style="list-style-type: none"> - MPID: II - Combined Pharmaceutical Dose Form: CD [0..1] - Additional Monitoring Indicator: CD [0..1] - Special Measures: ST [0..*] - Paediatric Use Indicator: CD [0..1] - Orphan Designation Status: CD [0..1]
Product Classification		
ATC (Code System)	J05AE30	
Heilmittelcode (Value)	S – Synthetika	
		Product Classification <ul style="list-style-type: none"> - Code System: CD.codeSystem - Value: CD.code
Medicinal Product Name		
Type (EXT)	Original	
Full Name	PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk	
Invented Name Part	PAXLOVID	
Strength Part	150mg	
Strength Part	100mg	
Pharmaceutical Dose Form Part	Filmtabl	
Container or Pack Part	4x	
Container or Pack Part	2x	
Container or Pack Part	5 x 6 Stk	
Delimiter Part	/	
		Medicinal Product Name <ul style="list-style-type: none"> - 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..*] - 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..*] - Delimiter Part: ENXP [0..*]
Country / Language		
Language	de	Deutsch
		Country / Language <ul style="list-style-type: none"> - Country: CD - Jurisdiction: CD [0..1] - Language: CD

Medicinal Product Name		
Type (EXT)	BAG	
Full Name	PAXLOVID Filmtabl 4x150mg/2x100mg	
Invented Name Part	PAXLOVID	
Strength Part	150mg	
Strength Part	100mg	
Pharmaceutical Dose Form Part	Filmtabl	
Container or Pack Part	4x	
Container or Pack Part	2x	
Delimiter Part	/	

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..*]
- 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..*]
- Delimiter Part: ENXP [0..*]

Country / Language		
Language	de	Deutsch

Country / Language

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

Marketing Authorisation (Medicinal Product)		
Marketing Authorisation Type (EXT)	tbd	
Marketing Authorisation Number	6879301	
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)
Authorisation Status	B	Befristet
Authorisation Status Date	15.06.2022	
Validity Period End	15.06.2024	
Date of First Authorisation	15.06.2022	

Marketing Authorisation

- Marketing Authorisation Number: II
- Country: CD [1..*]
- 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 [0..1]
- Data Exclusivity End Date: TS [0..1]
- Date of First Authorisation: TS [0..1]
- International Birth Date: TS

Medicinal Product

- MPID: II
- Combined Pharmaceutical Dose Form: CD [0..1]
- Additional Monitoring Indicator: CD [0..1]
- Special Measures: ST [0..*]
- Paediatric Use Indicator: CD [0..1]
- Orphan Designation Status: CD [0..1]

Marketing Authorisation Holder (Organisation)		
Name	Pfizer AG	
GLN	7601001010604	

Marketing Authorisation Holder (Organisation)

Hinweis: Pack Size, eine Verpackung: 4x150mg und 2x100mg in einem Blister, 5 Blister pro Box.

Packaged Medicinal Product

PCID	CH-7601001010604-6879301-001
Package Description	PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk
Pack Size (EXT)	30 Filmtabletten

Packaged Medicinal Product

- PCID: II
- Package Description: ST

Data Carrier Identifier

GTIN (Code System)	7680687930017
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Data Carrier Identifier

- Code System: CD.codeSystem
- Value: CD.code

Packaged Item (Container)

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

Package Item (Container)

- Package Item (Container) Type: CD
- Package Item (Container) Quantity: PQ
- Material: CD [1..*]
- Alternate Material: CD [0..*]

Packaged Item (Container)

Package Item (Container) Type	30007000	Blister
Package Item (Container) Quantity	1	
Material	Aluminium, Aluminium	

Package Item (Container)

- Package Item (Container) Type: CD
- Package Item (Container) Quantity: PQ
- Material: CD [1..*]
- Alternate Material: CD [0..*]

Packaged Item (Manufactured Item)

Manufactured Item Quantity	20	Tabletten (150 mg nirmatrelvirum) 4 Tabletten pro Blister
Manufactured Item Quantity	10	Tabletten (100 mg ritonavirum) 2 Tabletten pro Blister

Manufactured Item

- Manufactured Dose Form: CD
- Unit of Presentation: CD [0..1]
- Manufactured Item Quantity: PQ

Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Number	68793001		
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	
Authorisation Status	B	Befristet	
Authorisation Status Date	15.06.2022		

Marketing Authorisation

- Marketing Authorisation Number: II
- Country: CD [1..*]
- 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 [0..1]
- Data Exclusivity End Date: TS [0..1]
- Date of First Authorisation: TS [0..1]
- International Birth Date: TS

0..1

Packaged Medicinal Product

- PCID: II
- Package Description: ST

Shelf Life / Storage		
Shelf Life Type	100000073403	Closed package
Shelf Life Time Period	tbd	
Special Precautions of Storage	OVP	Im Originalkarton aufbewahren
	NO25	Nicht über 25 °C
	2	Im Kühlschrank (2°C - 8°C)
	NF	Nicht einfrieren

Shelf Life / Storage

- Shelf Life Type: CD
- Shelf Life Time Period: PQ
- Special Precautions for Storage: CD [0..*]

Manufactured Item			
Manufactured Dose Form	10221000	Filmtablette	<div>Manufactured Item<ul style="list-style-type: none">- Manufactured Dose Form: CD- Unit of Presentation: CD [0..1]- Manufactured Item Quantity: PQ</div>
Unit of Presentation	15054000	Tablette	
Description (EXT)	Komponente A: Rosafarbene, ovale Filmtablette		<div>Manufactured Item<ul style="list-style-type: none">- Manufactured Dose Form: CD- Unit of Presentation: CD [0..1]- Manufactured Item Quantity: PQ- Description [EXT]: ST [0..1]</div>
Description (EXT)	Komponente B: Weisse kapselförmige Tablette		

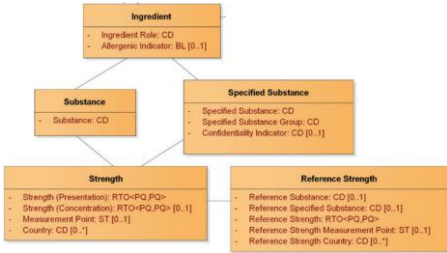
Komponente A

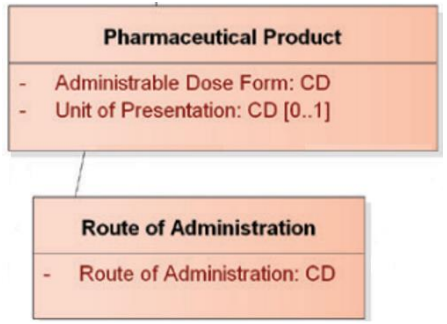
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	<pre> graph TD Ingredient[Ingredient] --> Substance[Substance] Ingredient --> SpecifiedSubstance[Specified Substance] Substance --> Strength[Strength] SpecifiedSubstance --> ReferenceStrength[Reference Strength] Strength --> ReferenceStrength </pre>
Substance	7R9A5P7H32	Nirmatrelvir	
Strength (presentation)	150 mg (per UoP)		

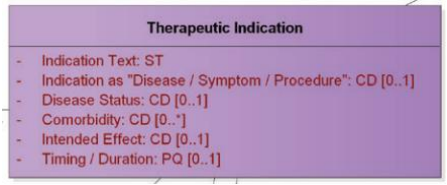
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	<pre> graph TD Ingredient[Ingredient] --> Substance[Substance] Ingredient --> SpecifiedSubstance[Specified Substance] Substance --> Strength[Strength] SpecifiedSubstance --> ReferenceStrength[Reference Strength] Strength --> ReferenceStrength </pre>
Substance	OP1R32D61U	Cellulosum microcristallinum	
	EWQ57Q8I5X	185 mg lactosum monohydricum	
	M28OL1HH48	Carmellosum natricum conexum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	7CV7WJK4UI	Natrii stearyl is fumaras	
	3NXW29V3WO	Hypromellosem	
	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 (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	<pre> graph TD Ingredient[Ingredient] --> Substance[Substance] Ingredient --> SpecifiedSubstance[Specified Substance] Substance --> Strength[Strength] SpecifiedSubstance --> ReferenceStrength[Reference Strength] Strength --> ReferenceStrength </pre>
Substance	O3J8G9O825	Ritonavirum	
Strength (presentation)	150 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	 <pre> graph TD Ingredient[Ingredient - Ingredient Role: CD - Allergenic Indicator: BL [0..1]] Substance[Substance - Substance: CD] SpecifiedSubstance[Specified Substance - Specified Substance: CD - Specified Substance Group: CD - Confidentiality Indicator: CD [0..1]] Strength[Strength - Strength (Presentation): RTO=PQ,PQ> - Strength (Concentration): RTO=PQ,PQ> [0..1] - Measurement Point: ST [0..1] - Country: CD [0..1]] ReferenceStrength[Reference Strength - Reference Substance: CD [0..1] - Reference Specified Substance: CD [0..1] - Reference Strength: RTO=PQ,PQ> - Reference Strength Measurement Point: ST [0..1] - Reference Strength Country: CD [0..1]] Ingredient --> Substance Ingredient --> SpecifiedSubstance Substance --> Strength SpecifiedSubstance --> ReferenceStrength </pre>
Substance	9E63551N1O	Copovidonum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	6W9PS8B71J	Sorbitani lauras	
	L11K75P92J	Calcii hydrogenophosphas	
	7CV7WJK4UI	Natrii stearyl is fumaras	
	3NXW29V3WO	Hypromellose	
	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	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	10221000	Film-coated tablet	 <pre> graph TD PharmaceuticalProduct[Pharmaceutical Product - Administrable Dose Form: CD - Unit of Presentation: CD [0..1]] RouteOfAdministration[Route of Administration - Route of Administration: CD] PharmaceuticalProduct --> RouteOfAdministration </pre>
Unit of Presentation	15054000	Tablette	
Route of Administration	20053000	Oral use	
Method of Administration (Swissmedic)	200000002052	Swallowing	

Therapeutic Indication			
Indication as	10084529	Coronavirus-Krankheit 2019 (COVID-19)	 <pre> graph TD TherapeuticIndication[Therapeutic Indication - Indication Text: ST - Indication as "Disease / Symptom / Procedure": CD [0..1] - Disease Status: CD [0..1] - Comorbidity: CD [0..1] - Intended Effect: CD [0..1] - Timing / Duration: PQ [0..1]] </pre>
Intended Effect	200000003194	Therapy	