

KEYTRUDA Inf Konz 100 mg/4ml Durchstf

Keytruda, Konzentrat zur Herstellung einer Infusionslösung

Quelle

Compendium

[Keytruda Inf Konz 100 mg/4ml](#)

compendium.ch®

SAI

[KEYTRUDA Inf Konz 100 mg/4ml Durchstf](#)



Medicinal Product

MPID

CH-7601001001138-6623101

Approved Dose Form
(EXT)

KOINF

Konzentrat zur Herstellung einer Infusionslösung

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]

Product Classification

ATC

(Code System)

L01FF02

Heilmittelcode
(Value)

BT – Biotechnologika

Product Classification

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

Medicinal Product Name

Type
(EXT)

Original

Full Name

KEYTRUDA Inf Konz 100 mg/4ml Durchstf

Invented Name
Part

KEYTRUDA

Strength Part

100 mg/4ml

Pharmaceutical
Dose Form
Part

Inf Konz

Container or
Pack Part

Durchstf

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

Medicinal Product Name		
Type (EXT)	BAG	
Full Name	KEYTRUDA Inf Konz 100 mg/4ml	
Invented Name Part	KEYTRUDA	
Strength Part	100 mg/4ml	
Pharmaceutical Dose Form Part	Inf Konz	

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	6623101	
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)
Authorisation Status	Z	Zugelassen
Authorisation Status Date	22.02.2017	
Validity Period End	31.12.9999	
Date of First Authorisation	22.02.2017	

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	MSD Merck Sharp & Dohme AG	
GLN	7601001001138	

Marketing Authorisation Holder (Organisation)

Hinweis: Pack Size, 1 Durchstechflasche.

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

Packaged Medicinal Product

- PCID: II
- Package Description: ST

Data Carrier Identifier		
GTIN (Code System)	7680662310018	<div> Data Carrier Identifier <ul style="list-style-type: none"> - Code System: CD.codeSystem - Value: CD.code </div>

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	30069000	Vial
Package Item (Container) Quantity	1	
Material	Glas	

Package Item (Container)

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

Package (Component)		
Component Type	30064000	Stopper
Component Material	200000003200	Aluminium,
	200000003226	Rubber

Package (Component)

- Component Type: CD
- Component Material: CD [0..*]
- Component Alternate Material: CD [0..*]

Packaged Item (Manufactured Item)		
Manufactured Item Quantity	4	ml

Manufactured Item

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

Marketing Authorisation (Packaged Medicinal Product)		
Marketing Authorisation Number	66231001	
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)
Authorisation Status	Z	Zugelassen
Authorisation Status Date	22.02.2017	

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

Packaged Medicinal Product

- PCID: II
- Package Description: ST

0..1

Shelf Life / Storage			
Shelf Life Type	100000073403	Closed package	<div> Shelf Life / Storage <ul style="list-style-type: none"> - Shelf Life Type: CD - Shelf Life Time Period: PQ - Special Precautions for Storage: CD [0..*] </div>
Shelf Life Time Period	tbd		
Special Precautions of Storage	2	Im Kühlschrank (2°C – 8°C)	
	L	vor Licht Schützen	
	NF	Nicht einfrieren	
	Bei Swissmedic angefragt	Nicht schütteln	
	OVP	In der Originalverpackung aufbewahren.	

Manufactured Item			
Manufactured Dose Form	11210000	Solution for infusion	<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	15060000	Vial	

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 --> Strength SpecifiedSubstance --> ReferenceStrength[Reference Strength] Strength --> ReferenceStrength </pre>
Substance	DPT003T46P	Pembrolizumabum	
Strength (presentation)	100 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 --> Strength SpecifiedSubstance --> ReferenceStrength[Reference Strength] Strength --> ReferenceStrength </pre>
Substance	4QD397987E	Histidinum	
	X573657P6P	Histidini hydrochloridum monohydricum	
	6OZP39ZG8H	Polysorbatum 80	
	FST467XS7D	Saccharum	
	059QF0KO0R	Aqua ad iniectionabile	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	11210000	Solution for infusion	<div>Pharmaceutical Product</div> <ul style="list-style-type: none"> - Administrable Dose Form: CD - Unit of Presentation: CD [0..1] <div>Route of Administration</div> <ul style="list-style-type: none"> - Route of Administration: CD
Unit of Presentation	15060000	Vial	
Route of Administration	20045000	Intravenous use	
Methode of Administration (Swissmedic)	200000002043	Infusion	

Therapeutic Indication			
Indication as	10027400	Melanom	<div>Therapeutic Indication</div> <ul style="list-style-type: none"> - 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]
Intended Effect	200000003194	Therapy	

Therapeutic Indication			
Indication as	10028881	Nicht-kleinzelliges Lungenkarzinom	<div>Therapeutic Indication</div> <ul style="list-style-type: none"> - 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]
Intended Effect	200000003194	Therapy	

Therapeutic Indication			
Indication as	10021782	Kopf- und Halskarzinom	<div>Therapeutic Indication</div> <ul style="list-style-type: none"> - 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]
Intended Effect	200000003194	Therapy	

Therapeutic Indication			
Indication as	10019927	Klassisches Hodgkin Lymphom	<div>Therapeutic Indication</div> <ul style="list-style-type: none"> - 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]
Intended Effect	200000003194	Therapy	

Therapeutic Indication			
Indication as	10043971	Primäres mediastinales grosszelliges B-Zell-Lymphom	<div>Therapeutic Indication</div> <ul style="list-style-type: none"> - 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]
Intended Effect	200000003194	Therapy	