



## ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk

Entocort Enema, Klistier Lösung + Tabletten		
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<b>Quelle</b>		
Compendium	<a href="#">ENTOCORT Enema Klistier Lösung + Tabletten</a>	
SAI	<a href="#">ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk</a>	

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

**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]

<b>Product Classification</b>		
ATC (Code System)	A07EA06	<div data-bbox="956 896 1362 1025" data-label="Complex-Block"> <p><b>Product Classification</b></p> <ul style="list-style-type: none"> <li>- Code System: CD.codeSystem</li> <li>- Value: CD.code</li> </ul> </div>
Heilmittelcode (Value)	S – Synthetika	

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

**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..\*]

<b>Country / Language</b>		
Language	de	Deutsch

**Country / Language**

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

Medicinal Product Name		
Type (EXT)	BAG	
Full Name	ENTOCORT Enema Klistier Lösung + Tabletten	
Invented Name Part	ENTOCORT Enema	
Pharmaceutical Dose Form Part	Klistier Lösung + Tabletten	
<div> <b>Medicinal Product Name</b> <ul style="list-style-type: none"> <li>- Full Name: ST</li> <li>- Invented Name Part: ENXP [0..*]</li> <li>- Scientific Name Part: ENXP [0..*]</li> <li>- Strength Part: ENXP [0..*]</li> <li>- Pharmaceutical Dose Form Part: ENXP [0..*]</li> <li>- Formulation Part: ENXP [0..*]</li> <li>- Intended Use Part: ENXP [0..*]</li> <li>- Target Population Part: ENXP [0..*]</li> <li>- Container or Pack Part: ENXP [0..*]</li> <li>- Device Part: ENXP [0..*]</li> <li>- Trademark or Company Name Part: ENXP [0..*]</li> <li>- Time / Period Part: ENXP [0..*]</li> <li>- Flavour Part: ENXP [0..*]</li> <li>- Delimiter Part: ENXP [0..*]</li> </ul> </div>		
Country / Language		
Language	de	Deutsch
<div> <b>Country / Language</b> <ul style="list-style-type: none"> <li>- Country: CD</li> <li>- Jurisdiction: CD [0..1]</li> <li>- Language: CD</li> </ul> </div>		
Marketing Authorisation (Medicinal Product)		
Marketing Authorisation Type (EXT)	tbd	
Marketing Authorisation Number	5204201	
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)
Authorisation Status	Z	Zugelassen
Authorisation Status Date	18.06.1993	
Validity Period End	31.12.9999	
Date of First Authorisation	18.06.1993	
<div> <b>Marketing Authorisation</b> <ul style="list-style-type: none"> <li>- Marketing Authorisation Number: II</li> <li>- Country: CD [1..*]</li> <li>- Legal Status of Supply: CD</li> <li>- Authorisation Status: CD</li> <li>- Authorisation Status Date: TS</li> <li>- Validity Period Start: TS</li> <li>- Validity Period End: TS</li> <li>- Data Exclusivity Start Date: TS [0..1]</li> <li>- Data Exclusivity End Date: TS [0..1]</li> <li>- Date of First Authorisation: TS [0..1]</li> <li>- International Birth Date: TS</li> </ul> </div> <div> <b>Medicinal Product</b> <ul style="list-style-type: none"> <li>- MPID: II</li> <li>- Combined Pharmaceutical Dose Form: CD [0..1]</li> <li>- Additional Monitoring Indicator: CD [0..1]</li> <li>- Special Measures: ST [0..*]</li> <li>- Paediatric Use Indicator: CD [0..1]</li> <li>- Orphan Designation Status: CD [0..1]</li> </ul> </div>		
Marketing Authorisation Holder (Organisation)		
Name	Tillotts Pharma AG	
GLN	7601001346451	
<div> <b>Marketing Authorisation Holder (Organisation)</b> </div>		

*Hinweis: Pack Size, Tablette und Lösungsmittel für Klistier Lösung*

#### Packaged Medicinal Product

PCID	CH-7601001346451-5204201-011	<div> <b>Packaged Medicinal Product</b> <ul style="list-style-type: none"> <li>- PCID: II</li> <li>- Package Description: ST</li> </ul> </div>
Package Description	ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk	
Pack Size (EXT)	7 Lösung 7 Tablette	

#### Data Carrier Identifier

GTIN (Code System)	7680520420118	<div> <b>Data Carrier Identifier</b> <ul style="list-style-type: none"> <li>- Code System: CD.codeSystem</li> <li>- Value: CD.code</li> </ul> </div>
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#### Packaged Item (Container)

Package Item (Container) Type	30009000	Box	<div> <b>Package Item (Container)</b> <ul style="list-style-type: none"> <li>- Package Item (Container) Type: CD</li> <li>- Package Item (Container) Quantity: PQ</li> <li>- Material: CD [1..*]</li> <li>- Alternate Material: CD [0..*]</li> </ul> </div>
Package Item (Container) Quantity	1		
Material	Karton		

#### Packaged Item (Container)

Package Item (Container) Type	30007000	Blister	<div> <b>Package Item (Container)</b> <ul style="list-style-type: none"> <li>- Package Item (Container) Type: CD</li> <li>- Package Item (Container) Quantity: PQ</li> <li>- Material: CD [1..*]</li> <li>- Alternate Material: CD [0..*]</li> </ul> </div>
Package Item (Container) Quantity	5		
Material	Aluminium, Aluminium		

#### Packaged Item (Container)

Package Item (Container) Type	30008000	Bottle	<div> <b>Package Item (Container)</b> <ul style="list-style-type: none"> <li>- Package Item (Container) Type: CD</li> <li>- Package Item (Container) Quantity: PQ</li> <li>- Material: CD [1..*]</li> <li>- Alternate Material: CD [0..*]</li> </ul> </div>
Package Item (Container) Quantity	7		
Material	200000003214	Polyethylen	

#### Package (Component)

Component Type	30013000	Cap	<div> <b>Package (Component)</b> <ul style="list-style-type: none"> <li>- Component Type: CD</li> <li>- Component Material: CD [0..*]</li> <li>- Component Alternate Material: CD [0..*]</li> </ul> </div>
Component Material	200000003214	Polyethylen	

Device			
Device Type	30012000	Rektalkanüle (Applikator Enema)	<div> <b>Device</b> <ul style="list-style-type: none"> <li>- Device Type: CD</li> <li>- Device Trade Name: ST [0..1]</li> <li>- Device Quantity: PQ</li> <li>- Device Listing Number: ST [0..1]</li> <li>- Device Identifier: II [0..1]</li> <li>- Model Number: ST [0..1]</li> <li>- Sterility Indicator: CD [0..1]</li> <li>- Sterilisation Requirement Indicator: CD [0..1]</li> <li>- Device Usage: CD [0..1]</li> </ul> </div>
Device Quantity	7		

Device			
Device Type	tbd	Plastikhandschutz	<div> <b>Device</b> <ul style="list-style-type: none"> <li>- Device Type: CD</li> <li>- Device Trade Name: ST [0..1]</li> <li>- Device Quantity: PQ</li> <li>- Device Listing Number: ST [0..1]</li> <li>- Device Identifier: II [0..1]</li> <li>- Model Number: ST [0..1]</li> <li>- Sterility Indicator: CD [0..1]</li> <li>- Sterilisation Requirement Indicator: CD [0..1]</li> <li>- Device Usage: CD [0..1]</li> </ul> </div>
Device Quantity	7		

Packaged Item (Manufactured Item)			
Manufactured Item Quantity	7	Tabletten (per blister)	<div> <b>Manufactured Item</b> <ul style="list-style-type: none"> <li>- Manufactured Dose Form: CD</li> <li>- Unit of Presentation: CD [0..1]</li> <li>- Manufactured Item Quantity: PQ</li> </ul> </div>
Manufactured Item Quantity	7	Lösungsmittel (per box)	

Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Number	52042011		<div> <b>Marketing Authorisation</b> <ul style="list-style-type: none"> <li>- Marketing Authorisation Number: II</li> <li>- Country: CD [1..*]</li> <li>- Legal Status of Supply: CD</li> <li>- Authorisation Status: CD</li> <li>- Authorisation Status Date: TS</li> <li>- Validity Period Start: TS</li> <li>- Validity Period End: TS</li> <li>- Data Exclusivity Start Date: TS [0..1]</li> <li>- Data Exclusivity End Date: TS [0..1]</li> <li>- Date of First Authorisation: TS [0..1]</li> <li>- International Birth Date: TS</li> </ul> </div> <div> <b>Packaged Medicinal Product</b> <ul style="list-style-type: none"> <li>- PCID: II</li> <li>- Package Description: ST</li> </ul> </div>
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	18.06.1993		

Shelf Life / Storage			
Shelf Life Type	100000073403	Closed Package	<div> <b>Shelf Life / Storage</b> <ul style="list-style-type: none"> <li>- Shelf Life Type: CD</li> <li>- Shelf Life Time Period: PQ</li> <li>- Special Precautions for Storage: CD [0..*]</li> </ul> </div>
Shelf Life Time Period	60 mo		
Special Precautions of Storage	NO30	Nicht über 30°C lagern	

Manufactured Item			
Manufactured Dose Form	11012000	Tablet for rectal suspension	<div> <b>Manufactured Item</b> <ul style="list-style-type: none"> <li>Manufactured Dose Form: CD</li> <li>Unit of Presentation: CD [0..1]</li> <li>Manufactured Item Quantity: PQ</li> </ul> </div>
Unit of Presentation	15054000	Tablette	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	<div> <pre> graph TD     Ingredient --&gt; Substance     Ingredient --&gt; SpecifiedSubstance     Substance --&gt; Strength     SpecifiedSubstance --&gt; ReferenceStrength     Strength --&gt; ReferenceStrength </pre> </div>
Substance	Q3OKS62Q6X	Budesonidum	
Strength (presentation)	2.3 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	<div> <pre> graph TD     Ingredient --&gt; Substance     Ingredient --&gt; SpecifiedSubstance     Substance --&gt; Strength     SpecifiedSubstance --&gt; ReferenceStrength     Strength --&gt; ReferenceStrength </pre> </div>
Substance	3SY5LH9PMK	Lactosum	
	957E53WV42	Riboflavini natrii phosphas	
	2S7830E561	Crospovidonum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	70097M6I30	Magnesii stearas	

Manufactured Item			
Manufactured Dose Form	13035000	Lösungsmittel	<div> <b>Manufactured Item</b> <ul style="list-style-type: none"> <li>Manufactured Dose Form: CD</li> <li>Unit of Presentation: CD [0..1]</li> <li>Manufactured Item Quantity: PQ</li> </ul> </div>
Unit of Presentation	15009000	Bottle	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	<div> <pre> graph TD     Ingredient --&gt; Substance     Ingredient --&gt; SpecifiedSubstance     Substance --&gt; Strength     SpecifiedSubstance --&gt; ReferenceStrength     Strength --&gt; ReferenceStrength </pre> </div>
Substance	A2I8C7HI9T	METHYLPARABEN E 218	
	Z8IX2SC1OH	Propylis parahydroxybenzoas	
	451W47IQ8X	Natrii chloridum	
	059QF0KO0R	Aqua purificata	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	11006000	Rectal suspension	<div> <b>Pharmaceutical Product</b> <ul style="list-style-type: none"> <li>- Administrable Dose Form: CD</li> <li>- Unit of Presentation: CD [0..1]</li> </ul> </div> <div> <b>Route of Administration</b> <ul style="list-style-type: none"> <li>- Route of Administration: CD</li> </ul> </div>
Unit of Presentation	15009000	Bottle	
Route of Administration	20061000	Rectal use	
Methode of Administration (Swissmedic)	200000002039	Application	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	<div> <b>Ingredient</b> <ul style="list-style-type: none"> <li>- Ingredient Role: CD</li> <li>- Allergenic Indicator: BL [0..1]</li> </ul> </div> <div> <b>Substance</b> <ul style="list-style-type: none"> <li>- Substance: CD</li> </ul> </div> <div> <b>Specified Substance</b> <ul style="list-style-type: none"> <li>- Specified Substance: CD</li> <li>- Specified Substance Group: CD</li> <li>- Confidentiality Indicator: CD [0..1]</li> </ul> </div> <div> <b>Strength</b> <ul style="list-style-type: none"> <li>- Strength (Presentation): RTO=PQ,PQ&gt;</li> <li>- Strength (Concentration): RTO=PQ,PQ&gt; [0..1]</li> <li>- Measurement Point: ST [0..1]</li> <li>- Country: CD [0..1]</li> </ul> </div> <div> <b>Reference Strength</b> <ul style="list-style-type: none"> <li>- Reference Substance: CD [0..1]</li> <li>- Reference Specified Substance: CD [0..1]</li> <li>- Reference Strength: RTO=PQ,PQ&gt;</li> <li>- Reference Strength Measurement Point: ST [0..1]</li> <li>- Reference Strength Country: CD [0..1]</li> </ul> </div>
Substance	Q3OKS62Q6X	Budesonidum	
Strength (presentation)	2.0 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	<div> <b>Ingredient</b> <ul style="list-style-type: none"> <li>- Ingredient Role: CD</li> <li>- Allergenic Indicator: BL [0..1]</li> </ul> </div> <div> <b>Substance</b> <ul style="list-style-type: none"> <li>- Substance: CD</li> </ul> </div> <div> <b>Specified Substance</b> <ul style="list-style-type: none"> <li>- Specified Substance: CD</li> <li>- Specified Substance Group: CD</li> <li>- Confidentiality Indicator: CD [0..1]</li> </ul> </div> <div> <b>Strength</b> <ul style="list-style-type: none"> <li>- Strength (Presentation): RTO=PQ,PQ&gt;</li> <li>- Strength (Concentration): RTO=PQ,PQ&gt; [0..1]</li> <li>- Measurement Point: ST [0..1]</li> <li>- Country: CD [0..1]</li> </ul> </div> <div> <b>Reference Strength</b> <ul style="list-style-type: none"> <li>- Reference Substance: CD [0..1]</li> <li>- Reference Specified Substance: CD [0..1]</li> <li>- Reference Strength: RTO=PQ,PQ&gt;</li> <li>- Reference Strength Measurement Point: ST [0..1]</li> <li>- Reference Strength Country: CD [0..1]</li> </ul> </div>
Substance	3SY5LH9PMK	Lactosum	
	957E53WV42	Riboflavini natrii phosphas	
	2S7830E561	Crospovidonum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	70097M6I30	Magnesii stearas	
	A2I8C7HI9T	METHYLPARABEN E 218	
	Z8IX2SC1OH	Propylis parahydroxybenzoas	
	451W47IQ8X	Natrii chloridum	
	059QF0KO0R	Aqua purificata	

Therapeutic Indication			
Indication Text	Leichte bis mittelschwere Colitis ulcerosa des Rectums sowie des Colon sigmoideum		<div> <b>Therapeutic Indication</b> <ul style="list-style-type: none"> <li>- Indication Text: ST</li> <li>- Indication as "Disease / Symptom / Procedure": CD [0..1]</li> <li>- Disease Status: CD [0..1]</li> <li>- Comorbidity: CD [0..1]</li> <li>- Intended Effect: CD [0..1]</li> <li>- Timing / Duration: PQ [0..1]</li> </ul> </div>
Indication as	10009900	Colitis ulcerative	
Intended Effect	200000003194	Therapie	