



ESTALIS Matrixpfl 50/250

Estalis, transdermale Pflaster		
Quelle		
Compendium	ESTALIS Matrixpfl 50/250 	
SAI	ESTALIS Matrixpfl 50/250 8 Stk ESTALIS Matrixpfl 50/250 24 Stk 	
Medicinal Product		
MPID	CH-7601001029439-5470402	
Approved Dose Form (EXT)	TRAP	Transdermales Pflaster
<div><div>Medicinal Product</div><div><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]</div></div>		
Product Classification		
ATC (Code System)	G03FA01	
Heilmittelcode (Value)	S – Synthetika	
<div><div>Product Classification</div><div><ul style="list-style-type: none">- Code System: CD.codeSystem- Value: CD.code</div></div>		
Medicinal Product Name		
TYPE (EXT)	Original	
Full Name	ESTALIS Matrixpfl 50/250 8 Stk	
Invented Name Part	ESTALIS	
Strength Part	50/250	
Pharmaceutical Dose Form Part	Matrixpfl	
Container or Pack Part	8 Stk	
<div><div>Medicinal Product Name</div><div><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..*]</div></div>		
Country / Language		
Language	de	Deutsch
<div><div>Country / Language</div><div><ul style="list-style-type: none">- Country: CD- Jurisdiction: CD [0..1]- Language: CD</div></div>		

Medicinal Product Name			
TYPE (EXT)	Original		<div> 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..*] </div>
Full Name	ESTALIS Matrixpfl 50/250 24 Stk		
Invented Name Part	ESTALIS		
Strength Part	50/250		
Pharmaceutical Dose Form Part	Matrixpfl		
Container or Pack Part	24 Stk		
Country / Language			
Language	de	Deutsch	<div> Country / Language <ul style="list-style-type: none"> - Country: CD - Jurisdiction: CD [0..1] - Language: CD </div>

Medicinal Product Name			
Type (EXT)	BAG		<div> 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..*] </div>
Full Name	ESTALIS Matrixpfl 50/250		
Invented Name Part	ESTALIS		
Strength Part	50/250		
Pharmaceutical Dose Form Part	Matrixpfl		
Container or Pack Part			
Country / Language			
Language	de	Deutsch	<div> Country / Language <ul style="list-style-type: none"> - Country: CD - Jurisdiction: CD [0..1] - Language: CD </div>

Marketing Authorisation (Medicinal Product)		
Marketing Authorisation Type (EXT)	tbd	
Marketing Authorisation Number	5470402	
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)
Authorisation Status	Z	Zugelassen
Authorisation Status Date	17.08.1999	
Validity Period End	31.12.9999	
Date of First Authorisation	17.08.1999	

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	Sandoz Pharmaceuticals AG	
GLN	7601001029439	

Marketing Authorisation Holder (Organisation)

Hinweis: Pack Size, 8 Pflaster. Mehrere Packungsgrößen werden wie folgt separat erfasst

Packaged Medicinal Product		
PCID	CH-7601001029439-5470402-089	
Package Description	ESTALIS Matrixpfl 50/250 8 Stk	
Pack Size (EXT)	8 Pflaster	

Packaged Medicinal Product

- PCID: II
- Package Description: ST

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	Box
Package Item (Container) Quantity	1	
Material	Karton	

Package Item (Container)

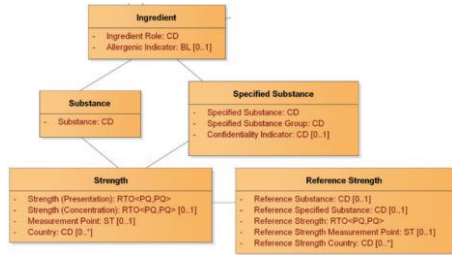
- Package Item (Container) Type: CD
- Package Item (Container) Quantity: PQ
- Material: CD [1..*]
- Alternate Material: CD [0..*]

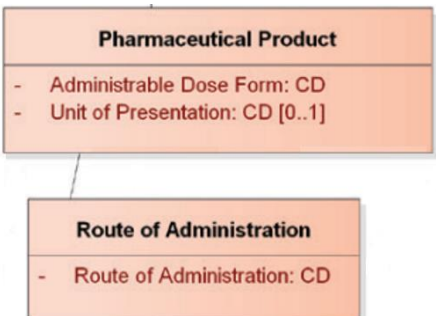
Shelf Life / Storage			
Shelf Life Type	100000073403	Closed Package	<div> Shelf Life / Storage <ul style="list-style-type: none"> - Shelf Life Type: CD - Shelf Life Time Period: PQ - Special Precautions for Storage: CD [0..*] </div>
Shelf Life Time Period	6 mo		
Special Precautions of Storage	NO25	Nicht über 25°C	
	L	vor Licht Schützen	
	2	Im Kühlschrank (2°C - 8°C)	

Manufactured Item			
Manufactured Dose Form	10519000	Transdermal patch	<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	15036000	Patch	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	<pre> graph TD Ingredient --> Substance Ingredient --> SpecifiedSubstance[Specified Substance] Substance --> Strength SpecifiedSubstance --> ReferenceStrength[Reference Strength] </pre>
Substance	CXY7B3Q98Z	Estradiolum hemihydricum	
Strength (presentation)	0.512 mg (per UoP)		
Reference Substance	ENB39R14VF	Estradiol	
Reference Strength	0.496 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	<pre> graph TD Ingredient --> Substance Ingredient --> SpecifiedSubstance[Specified Substance] Substance --> Strength SpecifiedSubstance --> ReferenceStrength[Reference Strength] </pre>
Substance	9S44LIC7OJ	Norethisteroni acetat	
Strength (presentation)	4.8 mg (per UoP)		
Reference Substance	T18F433X4S	Norethisteronum	
Reference Strength	4.2073 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+ [0..1] - 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+ [0..1] - Reference Strength Measurement Point: ST [0..1] - Reference Strength Country: CD [0..1]] Ingredient --> Substance Ingredient --> SpecifiedSubstance Substance --> Strength SpecifiedSubstance --> Strength SpecifiedSubstance --> ReferenceStrength Strength --> ReferenceStrength </pre>
Substance	83D19O7250	Silicone adhesive	
	180M9K3GHP	acrylic adhesive	
	U725QWY32X	povidonum K 30	
	2UMI9U37CP	acidum oleicum	
	E107L85C40	dipropylenglycolum	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	10519000	Transdermales Pflaster	 <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	15036000	Pflaster	
Route of Administration	20070000	Transdermale Anwendung	
Methode of Administration (Swissmedic)	200000002039	Application	

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

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