ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepeloron 10 mg chewable tablets for dogs Cepeloron 40 mg chewable tablets for dogs Cepeloron 80 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet contains:

Active substance:

Spironolactone 10 mg Spironolactone 40 mg Spironolactone 80 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Cellulose, microcrystalline
Sodium laurilsulfate
Crospovidone (type A)
Silica, colloidal hydrated
Magnesium stearate
Yeast (dried)
Chicken flavour

Off-white to light brown with brown spots, round and convex chewable tablet with a cross-shaped break line on one side.

The tablet can be divided into equal halves and quarters.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of congestive heart failure caused by degenerative mitral valve disease, in combination with standard therapy (including diuretic support, where necessary) in dogs.

3.3 Contraindications

Do not use during pregnancy and lactation.

Do not use in animals used for or intended for use in breeding.

Do not use in dogs suffering from hypoadrenocorticism, hyperkalaemia or hyponatraemia.

Do not administer spironolactone in conjunction with NSAIDs to dogs with renal insufficiency.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Kidney function and plasma potassium levels should be evaluated before initiating combined treatment with spironolactone and Angiotensin Converting Enzyme (ACE) inhibitors. Unlike in humans, an increased incidence of hyperkalaemia was not observed in clinical trials performed in dogs with this combination.

However, in dogs with renal impairment, regular monitoring of renal function and plasma potassium levels is recommended as there may be an increased risk of hyperkalaemia.

Dogs treated concomitantly with spironolactone and NSAIDs should be correctly hydrated. Monitoring of their renal function and plasma potassium levels is recommended before initiation and during treatment with combined therapy (see 3.3 'Contraindications').

As spironolactone has an antiandrogenic effect, it is not recommended to administer the product to growing dogs.

As spironolactone undergoes extensive hepatic biotransformation, care should be taken when using the product to treat dogs with hepatic dysfunction.

The chewable tablets are flavoured. In order to avoid accidental ingestion, store these tablets out of the reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The product may cause skin sensitization. People with known hypersensitivity to spironolactone or other components of the final formulation should avoid contact with the veterinary medicinal product. Handle this product with great care to avoid unnecessary exposure, taking all recommended precautions.

Wash hands after use.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Common	Vomiting, diarrhoea
(1 to 10 animals / 100 animals treated):	Prostatic disorder*

^{*}A reversible prostatic atrophy is often observed in entire male dogs.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or the local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Spironolactone had developmental toxicity in laboratory animals.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 3.3 'Contraindications').

3.8 Interaction with other medicinal products and other forms of interaction

In clinical studies, the product was co-administered with ACE-inhibitors, furosemide and pimobendan without evidence of associated adverse reactions.

Spironolactone decreases digoxin elimination and hence raises digoxin plasma concentration. As the therapeutic index for digoxin is very narrow, it is advisable to monitor closely dogs receiving both digoxin and spironolactone.

The administration of either deoxycorticosterone or NSAIDs with spironolactone may lead to a moderate reduction of the natriuretic effects (reduction of urinary sodium excretion) of spironolactone. Concomitant administration of spironolactone with ACE-inhibitors and other potassium-sparing drugs (as angiotensin receptor blockers, \beta-blockers, calcium channels blockers, etc.) may potentially lead to hyperkalaemia (see section 3.5 'Special precautions for use').

Spironolactone may cause both induction and inhibition of cytochrome P450 enzymes and could therefore affect the metabolism of other drugs utilizing these metabolic pathways.

3.9 Administration routes and dosage

Oral use.

2 mg of spironolactone per kg of body weight once daily. The product should be administered with a meal.

Cepeloron 10 mg: 1 tablet per 5 kg bw of body weight

Bodyweight (kg)	Cepeloron 10 mg Number of tablets per day
> 1 – 1.25	1/4
> 1.25 – 2.5	1/2
> 2.5 – 3.75	3/4
> 3.75 – 5	1
> 5 - 6.25	11/4
> 6.25 – 7.5	1½
> 7.5 – 8.75	13/4
> 8.75 – 10	2

Cepeloron 40 mg: 1 tablet per 20 kg of body weight

Bodyweight (kg)	Cepeloron 40 mg Number of tablets per day
> 3.75 – 5	1/4
> 5 – 10	1/2
> 10 – 15	3/4
> 15 – 20	1
> 20 – 25	11/4

> 25 – 30	1½
> 30 – 35	13/4
> 35 – 40	2

Cepeloron 80 mg: 1 tablet per 40 kg of body weight

Bodyweight (kg)	Cepeloron 80 mg
	Number of tablets per day
> 5 – 10	1/4
> 10 – 20	1/2
> 20 – 30	3/4
> 30 – 40	1
> 40 – 50	11/4
> 50 - 60	1½
> 60 – 70	13/4
> 70 – 80	2

The tablets are flavoured. If the dog does not accept the tablet from hand or bowl, then the tablets may be mixed with a small amount of food offered prior to the main meal, or administered directly into the mouth after feeding.

Instructions on how to divide the tablet: Put the tablet on an even surface, with its scored side facing up (convex side facing down). With the tip of the forefinger, exert slight vertical pressure on the middle of the tablet to break it along its width into halves. Then, in order to obtain quarters, exert slight pressure on the middle of one half with the forefinger to break it into two parts.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After administration of up to 5 times the recommended dose (10 mg/kg) to healthy dogs, dose-dependent adverse effects were noted, see section 3.6 'Adverse events'.

In case of an accidental massive ingestion by a dog, there is no specific antidote or treatment. It is therefore recommended to induce vomiting, lavage the stomach (depending on risk assessment) and monitor electrolytes. Symptomatic treatment, e.g., fluid therapy, should be provided.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QC03DA01

4.2 Pharmacodynamics

Spironolactone and its active metabolites (including 7α -thiomethyl-spironolactone and canrenone) act as specific antagonists of aldosterone, and exert their effects by binding competitively to the mineralocorticoid receptor located in the kidneys, heart and blood vessels.

Spironolactone is a natriuretic drug (historically described as a soft diuretic). In the kidney, spironolactone inhibits the aldosterone-induced sodium retention leading to increase in sodium and subsequently water excretion, and potassium retention. The renal effects of spironolactone and its metabolites lead to a decrease in extracellular volume and consequently in a decrease of cardiac preload and left atrial pressure. The result is an improvement in heart function.

In the cardiovascular system, spironolactone prevents the detrimental effects of aldosterone.

Although the precise mechanism of action is not yet clearly defined, aldosterone promotes myocardial fibrosis, myocardial and vascular remodelling and endothelial dysfunction.

In experimental models in dogs, it was shown that long term therapy with an aldosterone antagonist prevents progressive left ventricle dysfunction and attenuates left ventricle remodelling in dogs with chronic heart failure.

When used in combination with ACE-inhibitors, spironolactone may counteract the effects of "aldosterone escape".

A slight increase in aldosterone blood levels may be observed in animals on treatment. This is thought to be due to activation of feedback mechanisms without adverse clinical consequence. There may be a dose related hypertrophy of the adrenal zona glomerulosa at high dose rates.

4.3 Pharmacokinetics

The pharmacokinetics of spironolactone are based on its metabolites, as the parent compound is rapidly metabolised.

Absorption

In dogs, oral bioavailability of spironolactone as measured by canrenone AUCs was 83% relative to the iv route. It has been shown that feeding significantly increases the oral bioavailability of all measured metabolites resulting from dosing dogs with spironolactone.

After multiple oral doses of 2 mg spironolactone per kg for 5 consecutive days, steady-state conditions are reached by day 3 and only a slight accumulation of canrenone is observed.

After oral administration of spironolactone in dogs at 2 mg/kg, a mean C_{max} of 41 ng/mL is achieved for the primary metabolites, canrenone, after 4 hours.

Distribution

The mean apparent volume of distribution during elimination phase after oral dosing in dogs was 41 L/kg for canrenone.

The mean residence time of the metabolites is about 11 hours.

The protein binding is about 90%.

Metabolism

Spironolactone is rapidly and completely metabolised by the liver into its active metabolites, canrenone, 7α -thiomethyl-spironolactone and 6β -hydroxy- 7α -thiomethyl-spironolactone, which are the primary metabolites in the dog.

Elimination

Spironolactone is mainly excreted via its metabolites. Plasma clearance of canrenone is 3 L/h/kg for canrenone, in dogs. After oral administration of radiolabelled spironolactone to the dog, 66 % of the dose is recovered in faeces and 12 % in the urine. 74% of the dose is excreted within 48 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

oPA/Alu/PVC-Alu blister, containing 10 tablets each.

Pack sizes:

Cardboard box containing 10 tablets

Cardboard box containing 30 tablets

Cardboard box containing 50 tablets

Cardboard box containing 100 tablets

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/321/001-012

8. DATE OF FIRST AUTHORISATION

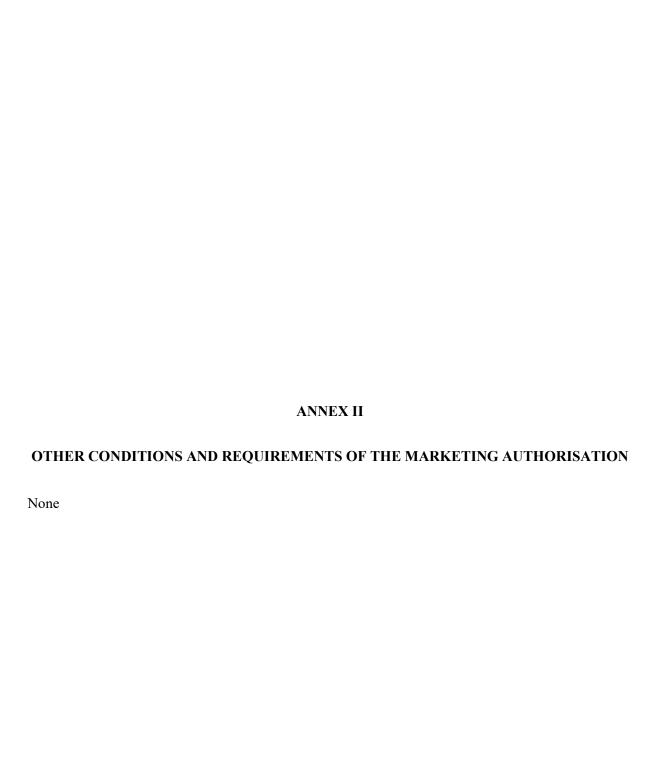
Date of first authorisation: 12/09/2024.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the <u>Union Product Database</u> (<u>https://medicines.health.europa.eu/veterinary</u>).



ANNEX III LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO	APPEAR ON THE OUTER PACKAGE	
Cardboard box	Cardboard box	
1. NAME OF THE	E VETERINARY MEDICINAL PRODUCT	
Cepeloron 10 mg chew	able tablets	
Cepeloron 40 mg chewa		
Cepeloron 80 mg chew		
2. STATEMENT (OF ACTIVE SUBSTANCES	
Each tablet contains:		
Spironolactone	10 mg	
	40 mg	
Spironolactone	80 mg	
3. PACKAGE SIZ	E .	
10 tablets		
30 tablets		
50 tablets		
100 tablets		
4. TARGET SPEC	TIES	
Dogs.		
5		
5. INDICATIONS		
6. ROUTES OF A	DMINISTRATION	
Oral use.		
7. WITHDRAWA	I DEDIONS	
" WIIIDRAWA		
8. EXPIRY DATE		
o. EATIKI DATE		
Exp. {mm/yyyy}		
9. SPECIAL STO	RAGE PRECAUTIONS	
SILCIME SIOI	ALGE ALECTICATION	

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/321/001 (10 mg, 10 tablets)

EU/2/24/321/002 (10 mg, 30 tablets)

EU/2/24/321/003 (10 mg, 50 tablets)

EU/2/24/321/004 (10 mg, 100 tablets)

EU/2/24/321/005 (40 mg, 10 tablets)

EU/2/24/321/006 (40 mg, 30 tablets)

EU/2/24/321/007 (40 mg, 50 tablets)

EU/2/24/321/008 (40 mg, 100 tablets)

E0/2/24/321/008 (40 mg, 100 tablets

EU/2/24/321/009 (80 mg, 10 tablets) EU/2/24/321/010 (80 mg, 30 tablets)

EU/2/24/321/011 (80 mg, 50 tablets)

EU/2/24/321/012 (80 mg, 100 tablets)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

oPA/Alu/PVC-Alu blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepeloron

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains:

Spironolactone 10 mg Spironolactone 40 mg Spironolactone 80 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cepeloron 10 mg chewable tablets for dogs Cepeloron 40 mg chewable tablets for dogs Cepeloron 80 mg chewable tablets for dogs

2. Composition

One chewable tablet contains:

Active substance:

Spironolactone 10 mg Spironolactone 40 mg Spironolactone 80 mg

Off-white to light brown with brown spots, round and convex chewable tablet with a cross-shaped break line on one side.

The tablet can be divided into equal halves and quarters.

3. Target species

Dogs.

4. Indications for use

Treatment of congestive heart failure caused by degenerative mitral valve disease, in combination with standard therapy (including diuretic support, where necessary) in dogs.

5. Contraindications

Do not use during pregnancy and lactation.

Do not use in animals used for or intended for use in breeding.

Do not use in dogs suffering from hypoadrenocorticism, hyperkalaemia or hyponatraemia.

Do not administer spironolactone in conjunction with NSAIDs to dogs with renal insufficiency.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

Kidney function and plasma potassium levels should be evaluated before initiating combined treatment with spironolactone and Angiotensin Converting Enzyme (ACE) inhibitors. Unlike in humans, an increased incidence of hyperkalaemia was not observed in clinical trials performed in dogs with this combination.

However, in dogs with renal impairment, regular monitoring of renal function and plasma potassium levels is recommended as there may be an increased risk of hyperkalaemia.

Dogs treated concomitantly with spironolactone and NSAIDs should be correctly hydrated. Monitoring of their renal function and plasma potassium levels is recommended before initiation and during treatment with combined therapy (see 'Contraindications').

As spironolactone has an antiandrogenic effect, it is not recommended to administer the product to growing dogs.

As spironolactone undergoes extensive hepatic biotransformation, care should be taken when using the product to treat dogs with hepatic dysfunction.

The chewable tablets are flavoured. In order to avoid accidental ingestion, store these tablets out of the reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The product may cause skin sensitization.

People with known hypersensitivity to spironolactone or other components of the final formulation should avoid contact with the veterinary medicinal product.

Handle this product with great care to avoid unnecessary exposure, taking all recommended precautions.

Wash hands after use.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

Spironolactone had developmental toxicity in laboratory animals.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see 'Contraindications').

Interaction with other medicinal products and other forms of interaction:

In clinical studies, the product was co-administered with ACE-inhibitors, furosemide and pimobendan without evidence of associated adverse reactions.

Spironolactone decreases digoxin elimination and hence raises digoxin plasma concentration. As the therapeutic index for digoxin is very narrow, it is advisable to monitor closely dogs receiving both digoxin and spironolactone.

The administration of either deoxycorticosterone or NSAIDs with spironolactone may lead to a moderate reduction of the natriuretic effects (reduction of urinary sodium excretion) of spironolactone. Concomitant administration of spironolactone with ACE-inhibitors and other potassium-sparing drugs (as angiotensin receptor blockers, \(\beta\)-blockers, calcium channels blockers, etc.) may potentially lead to hyperkalaemia (see 'Special precautions for safe use in the target species').

Spironolactone may cause both induction and inhibition of cytochrome P450 enzymes and could therefore affect the metabolism of other drugs utilizing these metabolic pathways.

Overdose:

After administration of up to 5 times the recommended dose (10 mg/kg) to healthy dogs, dose-dependent adverse effects were noted, see 'Adverse events'.

In case of an accidental massive ingestion by a dog, there is no specific antidote or treatment. It is therefore recommended to induce vomiting, lavage the stomach (depending on risk assessment) and monitor electrolytes. Symptomatic treatment, e.g., fluid therapy, should be provided.

Dogs:

Common	Vomiting, diarrhoea
(1 to 10 animals / 100 animals treated):	Prostatic disorder*

^{*}A reversible prostatic atrophy (decrease in size) is often observed in entire male dogs.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

Oral use.

2 mg of spironolactone per kg of body weight once daily. The product should be administered with a meal.

Cepeloron 10 mg: 1 tablet per 5 kg bw of body weight

Bodyweight (kg)	Cepeloron 10 mg Number of tablets per day
> 1 – 1.25	1/4
> 1.25 – 2.5	1/2
> 2.5 – 3.75	3/4
> 3.75 – 5	1
> 5 - 6.25	11/4
> 6.25 – 7.5	1½
> 7.5 – 8.75	13/4
> 8.75 – 10	2

Cepeloron 40 mg: 1 tablet per 20 kg bw of body weight

Bodyweight (kg)	Cepeloron 40 mg
	Number of tablets per day
> 3.75 – 5	1/4
> 5 – 10	1/2
> 10 – 15	3/4
> 15 – 20	1
> 20 – 25	11/4
> 25 – 30	1½
> 30 – 35	13/4
> 35 – 40	2

Cepeloron 80 mg: 1 tablet per 40 kg bw of body weight

Bodyweight (kg)	Cepeloron 80 mg
	Number of tablets per day
> 5 – 10	1/4
> 10 – 20	1/2

> 20 – 30	3/4
> 30 – 40	1
> 40 – 50	11/4
> 50 - 60	1½
> 60 – 70	13/4
> 70 – 80	2

9. Advice on correct administration

The tablets are flavoured. If the dog does not accept the tablet from hand or bowl, then the tablets may be mixed with a small amount of food offered prior to the main meal, or administered directly into the mouth after feeding.

Instructions on how to divide the tablet: Put the tablet on an even surface, with its scored side facing up (convex side facing down). With the tip of the forefinger, exert slight vertical pressure on the middle of the tablet to break it along its width into halves. Then, in order to obtain quarters, exert slight pressure on the middle of one half with the forefinger to break it into two parts.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/24/321/001-012

oPA/Alu/PVC-Alu blister, containing 10 tablets each.

Pack sizes:

Cardboard box containing 10 tablets

Cardboard box containing 30 tablets Cardboard box containing 50 tablets Cardboard box containing 100 tablets

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

 $\{MM/YYYY\}$

Detailed information on this veterinary medicinal product is available in the <u>Union Product Database</u> (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release: CP Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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Norge

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Österreich

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România

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Sloveniia

CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany

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Slovenská republika

CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany

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