ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Convenia 80 mg/ml powder and solvent for solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 23 ml vial of lyophilised powder contains:

Active substance:
852 mg cefovecin (as sodium salt)

Excipients:
19.17 mg methyl parahydroxybenzoate (E218)
2.13 mg propyl parahydroxybenzoate (E216)

Each 19 ml vial of diluent contains:

Excipients:
13 mg/ml benzyl alcohol
10.8 ml water for injections

Each 5 ml vial of lyophilised powder contains:

Active substance:
340 mg cefovecin (as sodium salt)

Excipients:
7.67 mg methyl parahydroxybenzoate (E218)
0.85 mg propyl parahydroxybenzoate (E216)

Each 10 ml vial of diluent contains:

Excipients:
13 mg/ml benzyl alcohol
4.45 ml water for injections

When reconstituted according to label instructions, the solution for injection contains:
80.0 mg/ml cefovecin (as sodium salt)
1.8 mg/ml methyl parahydroxybenzoate (E218)
0.2 mg/ml propyl parahydroxybenzoate (E216)
12.3 mg/ml benzyl alcohol

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

The powder is off-white to yellow and the diluent (solvent) is a clear, colourless liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

For use only for the following infections which require prolonged treatment. The antimicrobial activity of Convenia following a single injection lasts for up to 14 days.

Dogs:
For the treatment of skin and soft tissue infections including pyoderma, wounds and abscesses associated with *Staphylococcus pseudintermedius,* β-haemolytic Streptococci*, Escherichia coli* and/or *Pasteurella multocida*.

For the treatment of urinary tract infections associated with *Escherichia coli* and/or *Proteus* spp.

As adjunctive treatment to mechanical or surgical periodontal therapy in the treatment of severe infections of the gingiva and periodontal tissues associated with *Porphyromonas* spp. and *Prevotella* spp. (See also Section 4.5 'Special Precautions for Use'.)

Cats:
For the treatment of skin and soft tissue abscesses and wounds associated with *Pasteurella multocida*, *Fusobacterium* spp., *Bacteroides* spp., *Prevotella oralis*, β haemolytic Streptococci and/or *Staphylococcus pseudintermedius*.

For the treatment of urinary tract infections associated with *Escherichia coli*.

4.3 Contraindications

Do not use in cases of hypersensitivity to cephalosporin or penicillin antibiotics.
Do not use in small herbivores (including guinea pigs and rabbits).
Do not use in dogs and cats less than 8 weeks old.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

It is prudent to reserve third generation cephalosporins for the treatment of clinical conditions, which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials or first generation cephalosporins. Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

The fundamental requirement of the treatment of periodontal disease is mechanical and/or surgical intervention by the veterinarian.

The safety of Convenia has not been assessed in animals suffering from severe renal dysfunction.

Pyoderma is often secondary to an underlying disease. It is, therefore, advisable to determine the underlying cause and to treat the animal accordingly.

Caution should be exercised in patients that have previously shown hypersensitivity reactions to cefovecin, other cephalosporins, penicillins, or other drugs. If an allergic reaction occurs, no further administrations of cefovecin should be administered and appropriate therapy for beta-lactam hypersensitivity should be instituted. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamine, corticosteroids, and airway management, as clinically indicated. Veterinarians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

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

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 in breathing are more serious symptoms and require urgent medical attention.

If you know you are allergic to penicillins or cephalosporins, avoid contact with contaminated litter. In the event of contact, wash skin with soap and water.

4.6 Adverse reactions (frequency and seriousness)

On very rare occasions gastrointestinal signs, including emesis and/or diarrhoea, have been observed.

In very rare cases neurological signs and injection site reactions have been reported after the use of the product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of Convenia in dogs and cats has not been established during pregnancy and lactation.

Treated animals should not be used for breeding for 12 weeks after the last administration.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent use of other substances that have a high degree of protein binding (e.g. furosemide, ketoconazole, or non-steroidal anti-inflammatory drugs (NSAIDs)) may compete with cefovecin binding and thus may cause adverse effects.

4.9 Amounts to be administered and administration route

Skin and soft tissue infections in dogs:
A single subcutaneous injection of 8 mg/kg bodyweight (1 ml per 10 kg bodyweight). If required, treatment may be repeated at 14 day intervals up to a further three times. In accordance with good veterinary practice, treatment of pyoderma should be extended beyond complete resolution of clinical signs.

Severe infections of the gingival and periodontal tissues in dogs:
A single subcutaneous injection of 8 mg/kg bodyweight (1 ml per 10 kg bodyweight).

Skin and soft tissue abscesses and wounds in cats:
A single subcutaneous injection of 8 mg/kg bodyweight (1 ml per 10 kg bodyweight). If required, an additional dose may be administered 14 days after the first injection.

Urinary tract infections in dogs and cats:
A single subcutaneous injection of 8 mg/kg bodyweight (1 ml per 10 kg bodyweight).

To reconstitute, withdraw the required volume of the supplied diluent from its vial (for 23 ml vial containing 852 mg of lyophilised powder reconstitute using 10 ml of diluent, or for 5 ml vial containing 340 mg of lyophilised powder reconstitute using 4 ml of diluent) and add to the vial containing the lyophilised powder. Shake the vial until the powder is seen to have fully dissolved.

Dosing Table

Animal Weight (Dogs and Cats)	Volume to be Administered
2.5 kg	0.25 ml
5 kg	0.5 ml
10 kg	1.0 ml
20 kg	2.0 ml
40 kg	4.0 ml
60 kg	6.0 ml

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Repeated dosing (eight administrations) in 14-day intervals at five times the recommended dose was tolerated well in young dogs. Slight and transient injection site swellings were observed after the first and second administration. A single administration of 22.5 times the recommended dose caused transient oedema and discomfort at the injection site.

Repeated dosing (eight administrations) in 14-day intervals at five times the recommended dose was tolerated well in young cats. A single administration of 22.5 times the recommended dose caused transient oedema and discomfort at the injection site.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use (cephalosporins).
ATCvet code: QJ01DD91.

5.1 Pharmacodynamic properties

Cefovecin is a third generation cephalosporin with a broad-spectrum of activity against Gram-positive and Gram-negative bacteria. It differs from other cephalosporins in that it is highly protein bound and has a long duration of activity. As with all cephalosporins, the action of cefovecin results from the inhibition of bacterial cell wall synthesis; cefovecin has bactericidal activity.

Cefovecin exhibits *in-vitro* activity against *Staphylococcus pseudintermedius* and *Pasteurella multocida* which are associated with canine and feline skin infections. Anaerobic bacteria such as *Bacteroides* spp. and *Fusobacterium* spp. collected from feline abscesses were shown to be susceptible. *Porphyromonas gingivalis* and *Prevotella intermedia* collected from canine periodontal disease were also shown to be susceptible. In addition, cefovecin exhibits *in-vitro* activity against *Escherichia coli* which is associated with canine and feline urinary tract infections.

In-vitro activity against these pathogens as well as against other skin and urinary tract pathogens collected during a European (Denmark, France, Germany, Italy and United Kingdom) MIC survey (1999 – 2000)

and during European (France, Germany, Spain and United Kingdom) clinical efficacy and safety field studies (2001 – 2003) are listed below. Periodontal isolates were collected during a European (France and Belgium) clinical efficacy and safety field study (2008).

Bacterial Pathogen	Origin	No. of Isolates	cefovecin MIC (µg/ml)			
			Min	Max	MIC_{50} [1]	MIC_{90} [2]
Staphylococcus pseudintermedius	Dog Cat	226 44	≤0.06 ≤0.06	8 8	0.12 0.12	0.25 0.25
β haemolytic *Streptococcus* spp.	Dog Cat	52 34	≤0.06 ≤0.06	16 1	≤0.06 ≤0.06	0.12 0.12
Coagulase negative *Staphylococcus* spp.[4]	Cat	16	0.12	32	0.25	8
Staphylococcus aureus[3, 4]	Dog[4] Cat[4]	16 20	0.5 0.5	1 >32	1 1	1 16
Coagulase positive *Staphylococcus* spp.[3, 4]	Dog[4] Cat[4]	24	0.12	>32	0.25	0.5
Escherichia coli	Dog Cat	167 93	0.12 0.25	>32 8	0.5 0.5	1 1
Pasteurella multocida	Dog Cat	47 146	≤0.06 ≤0.06	0.12 2	≤0.06 ≤0.06	0.12 0.12
Proteus spp.	Dog Cat[4]	52 19	0.12 0.12	8 0.25	0.25 0.12	0.5 0.25
Enterobacter spp.[4]	Dog[4] Cat[4]	29 10	0.12 0.25	>32 8	1 2	>32 4
Klebsiella spp.[4]	Dog[4] Cat[4]	11	0.25	1	0.5	1
Prevotella spp. (2003 survey)	Dog[4] Cat	25 50	≤0.06 ≤0.06	8 4	0.25 0.25	2 0.5
Fusobacterium spp.	Cat	23	≤0.06	2	0.12	1
Bacteroides spp.	Cat	24	≤0.06	8	0.25	4
Prevotella spp. (periodontal 2008)	Dog	29	≤0.008	4	0.125	1
Porphyromonas spp.	Dog	272	≤0.008	1	0.031	0.062

[1] Lowest concentration, which completely inhibits visible growth of at least 50 % of isolates
[2] Lowest concentration, which completely inhibits visible growth of at least 90 % of isolates
[3] Some of these pathogens (e.g. *S. aureus*) exhibited natural *in vitro* resistance to cefovecin
[4] The clinical significance of these *in vitro* data has not been demonstrated.

Resistance to cephalosporins results from enzymatic inactivation (β-lactamase production), from reduced permeability by porin mutations or change in efflux, or by selection of low-affinity penicillin-binding proteins. Resistance may be chromosomal or plasmid-encoded and may be transferred if associated with transposons or plasmids. Cross resistance with other cephalosporins and other beta-lactam antibacterial agents can be observed.

When applying a proposed microbiological breakpoint of S ≤ 2 µg/ml, no resistance to cefovecin was detected in *Pasteurella multocida, Fusobacterium* spp. or *Porphyromonas* spp. field isolates. When applying a proposed microbiological breakpoint of I ≤ 4 µg/ml, cefovecin resistance in *S. pseudintermedius* and beta-haemolytic Streptococci isolates was less than 0.02 % and 3.4 % in *Prevotella intermedia* isolates. The percentage of cefovecin resistant isolates in *E. coli*, *Prevotella oralis*, *Bacteroides* spp. and *Proteus* spp. were 2.3 %, 2.7 %, 3.1 % and 1.4 %, respectively. The percentage of cefovecin resistant isolates in coagulase negative *Staphylococcus* spp. (e.g. *S. xylosus*, *S. schleiferi*, *S. epidermidis*) is 9.5 %. *Pseudomonas* spp., *Enterococcus* spp., and *Bordetella bronchiseptica* isolates are inherently resistant to cefovecin.

5.2 Pharmacokinetic particulars

Cefovecin has unique pharmacokinetic properties with extremely long elimination half-lives in both dogs and cats.

In dogs, when cefovecin was administered as a single subcutaneous dose of 8 mg/kg bodyweight, absorption was rapid and extensive; peak plasma concentration at 6 hours was 120 μg/ml and bioavailability approximately 99 %. Peak concentrations in tissue cage fluid of 31.9 μg/ml were measured 2 days after administration. Fourteen days after administration, the mean cefovecin concentration in plasma was 5.6 μg/ml. Plasma protein binding is high (96.0 % to 98.7 %) and the volume of distribution is low (0.1 l/kg). Elimination half-life is long – approximately 5.5 days. Cefovecin is primarily eliminated unchanged via the kidneys. At fourteen days after administration, urine concentrations were 2.9 μg/ml.

In cats, when cefovecin was administered as a single subcutaneous dose of 8 mg/kg bodyweight, absorption was rapid and extensive; peak plasma concentration at 2 hours was 141 μg/ml and bioavailability approximately 99 %. Fourteen days after administration the mean cefovecin concentration in plasma was 18 μg/ml. Plasma protein binding is high (more than 99 %) and the volume of distribution is low (0.09 l/kg). Elimination half-life is long – approximately 6.9 days. Cefovecin is primarily eliminated unchanged via the kidneys. At ten and fourteen days after administration, urine concentrations were 1.3 μg/ml and 0.7 μg/ml, respectively. Following repeated administrations at the recommended dose, elevated concentrations of cefovecin were observed in plasma.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Benzyl alcohol
Sodium citrate
Citric acid
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injection

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 28 days.

As with other cephalosporins, the colour of the reconstituted solution may darken during this period. However, if stored as recommended, potency is not affected.

6.4 Special precautions for storage

Before reconstitution:
Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Store in the original package in order to protect from light.

After reconstitution:
Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Store in the original package in order to protect from light.

6.5 Nature and composition of immediate packaging

Powder:
Type I glass vial of either 5 ml or 23 ml with butyl rubber stopper sealed with an aluminium flip-off seal.

Diluent:
Type I glass vial of either 10 ml or 19 ml with chlorobutyl rubber stopper sealed with an aluminium flip-off seal.

Pack size: 1 vial of powder and 1 vial of diluent.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/059/001 (23 ml vial)
EU/2/06/059/002 (5 ml vial)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19/06/2006
Date of last renewal: 15/06/2011

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Haupt Pharma Latina S.r.l.
S.S. 156 Km 47,600
04100 Borgo San Michele
Latina
ITALY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON (CONTAINING LYOPHILISED POWDER VIAL AND DILUENT VIAL)

23 ml Vial – 5 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Convenia 80 mg/ml powder and solvent for solution for injection for dogs and cats
cefovecin

2. STATEMENT OF ACTIVE SUBSTANCES

The reconstituted solution for injection contains:
80.0 mg/ml cefovecin (as sodium salt)

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. PACKAGE SIZE

10 ml (after reconstitution)
4 ml (after reconstitution)

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

For certain skin, soft tissue, urinary tract and severe periodontal infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
After reconstitution, use within 28 days.
Discard date:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Store in the original package in order to protect from light (before and after reconstitution).

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/059/001 (23 ml)
EU/2/06/059/002 (5 ml)

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL (23 ml LYOPHILISED POWDER VIAL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Convenia 80 mg/ml powder for solution for injection for dogs and cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each vial contains 852 mg cefovecin.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml (after reconstitution)

4. ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP: {mm/yyyy}
After reconstitution, use within 28 days.
Discard date:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL (19 ml DILUENT VIAL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diluent for Convenia

2. QUANTITY OF OTHER SUBSTANCES

13 mg/ml benzyl alcohol in water for injections.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP: {mm/yyyy}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL (5 ml LYOPHILISED POWDER VIAL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Convenia 80 mg/ml powder for solution for injection for dogs and cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

340 mg cefovecin

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4 ml (after reconstitution)

4. ROUTE(S) OF ADMINISTRATION

s.c.

Read the package leaflet

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {mm/yyyy}
After reconstitution, use within 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL (10 ml DILUENT VIAL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diluent for Convenia.

2. QUANTITY OF OTHER SUBSTANCES

13 mg/ml benzyl alcohol

3. CONTENTS BY WEIGHT, BY VOLUME OR NUMBER OF DOSES

4 ml

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP: {mm/yyyy}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Convenia 80 mg/ml powder and solvent for solution for injection for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Manufacturer responsible for batch release:
Haupt Pharma Latina S.r.l.
S.S. 156 Km 47,600
04100 Borgo San Michele
Latina
ITALY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Convenia 80 mg/ml powder and solvent for solution for injection for dogs and cats
cefovecin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 23 ml vial of lyophilised powder contains:

Active substance:
852 mg cefovecin (as sodium salt)

Excipients:
19.17 mg methyl parahydroxybenzoate (E218)
2.13 mg propyl parahydroxybenzoate (E216)

Each 19 ml vial of diluent contains:

Excipients:
13 mg/ml benzyl alcohol
10.8 ml water for injections

Each 5 ml vial of lyophilised powder contains:

Active substance:
340 mg cefovecin (as sodium salt)

Excipients:
7.67 mg methyl parahydroxybenzoate (E218)
0.85 mg propyl parahydroxybenzoate (E216)

Each 10 ml vial of diluent contains:

Excipients:
13 mg/ml benzyl alcohol
4.45 ml water for injections

When reconstituted according to label instructions, the solution for injection contains:
80.0 mg/ml cefovecin (as sodium salt)
1.8 mg/ml methyl parahydroxybenzoate (E218)
0.2 mg/ml propyl parahydroxybenzoate (E216)
12.3 mg/ml benzyl alcohol

4. INDICATION(S)

For use only for the following infections requiring prolonged treatment. The antimicrobial activity of Convenia following a single injection lasts for up to 14 days.

Dogs:
For the treatment of skin and soft tissue infections including pyoderma, wounds and abscesses associated with *Staphylococcus pseudintermedius,* β haemolytic Streptococci*, Escherichia coli* and/or *Pasteurella multocida*.

For the treatment of urinary tract infections associated with *Escherichia coli* and/or *Proteus* spp.

As adjunctive treatment to mechanical or surgical periodontal therapy in the treatment of severe infections of the gingiva and periodontal tissues associated with *Porphyromonas* spp. and *Prevotella* spp. (See also Section 12 'Special Warnings – For the animal'.)

Cats:
For the treatment of skin and soft tissue abscesses and wounds associated with *Pasteurella multocida*, *Fusobacterium* spp., *Bacteroides* spp., *Prevotella oralis*, β haemolytic Streptococci and/or *Staphylococcus pseudintermedius*.

For the treatment of urinary tract infections associated with *Escherichia coli*.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to cephalosporin or penicillin antibiotics.
Do not use in small herbivores (including guinea pigs and rabbits).
Do not use in dogs and cats less than 8 weeks old.

6. ADVERSE REACTIONS

On very rare occasions gastrointestinal signs, including emesis and/or diarrhoea, have been observed.

In very rare cases neurological signs and injection site reactions have been reported after the use of the product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dogs and cats: 8 mg cefovecin/kg body weight (1 ml/10 kg body weight).

Dosing Table:

Animal Weight (Dogs and Cats)	Volume to be Administered
2.5 kg	0.25 ml
5 kg	0.5 ml
10 kg	1.0 ml
20 kg	2.0 ml
40 kg	4.0 ml
60 kg	6.0 ml

To reconstitute, withdraw of the required volume of the supplied diluent from its vial (for 23 ml vial containing 852 mg of lyophilised powder reconstitute using 10 ml of diluent, or for 5 ml vial containing 340 mg of lyophilised powder reconstitute using 4 ml of diluent) and add to the vial containing the lyophilised powder. Shake the vial until the powder is seen to have fully dissolved.

Skin and soft tissue infections in dogs:
A single subcutaneous injection. If required, treatment may be repeated at 14 day intervals up to a further three times. In accordance with good veterinary practice, treatment of pyoderma should be extended beyond complete resolution of clinical signs.

Severe infections of the gingival and periodontal tissues in dogs:
A single subcutaneous injection of 8 mg/kg bodyweight (1 ml per 10 kg bodyweight).

Skin and soft tissue abscesses and wounds in cats:
A single subcutaneous injection. If required, an additional dose may be administered 14 days after the first injection.

Urinary tract infections in dogs and cats:
A single subcutaneous injection.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Pyoderma is often secondary to an underlying disease. It is, therefore, advisable to determine the underlying cause and to treat the animal accordingly.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton.

Shelf-life after reconstitution according to directions: 28 days.

As with other cephalosporins, the colour of the reconstituted solution may darken during this period. However, if stored as recommended, potency is not affected.

Before reconstitution:
Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Store in the original package in order to protect from light.

After reconstitution:
Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Store in the original package in order to protect from light.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

It is prudent to reserve third generation cephalosporins for the treatment of clinical conditions, which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials or first generation cephalosporins. Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

The fundamental requirement of the treatment of periodontal disease is mechanical and/or surgical intervention by the veterinarian.

The safety of Convenia in dogs and cats has not been established during pregnancy and lactation. Treated animals should not be used for breeding for 12 weeks after the last administration.

The safety of Convenia has not been assessed in animals suffering from severe renal dysfunction.

Caution should be exercised in patients that have previously shown hypersensitivity reactions to cefovecin, other cephalosporins, penicillins, or other drugs. If an allergic reaction occurs, no further administrations of cefovecin should be administered and appropriate therapy for beta-lactam hypersensitivity should be instituted. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamine, corticosteroids, and airway management, as clinically indicated. Veterinarians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

Concurrent use of other substances that have a high degree of protein binding (e.g. furosemide, ketoconazole, or non-steroidal anti-inflammatory drugs (NSAIDs)) may compete with cefovecin binding and thus may cause adverse effects.

Repeated dosing (eight administrations) in 14-day intervals at five times the recommended dose was tolerated well in young dogs. Slight and transient injection site swellings were observed after the first and second administration. A single administration of 22.5 times the recommended dose caused transient oedema and discomfort at the injection site.

Repeated dosing (eight administrations) in 14-day intervals at five times the recommended dose was tolerated well in young cats. A single administration of 22.5 times the recommended dose caused transient oedema and discomfort at the injection site.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious:

Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

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

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 in breathing are more serious symptoms and require urgent medical attention.

If you know you are allergic to penicillins or cephalosporins, avoid contact with contaminated litter. In the event of contact, wash skin with soap and water.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Cefovecin is a third generation cephalosporin with a broad-spectrum of activity against Gram-positive and Gram-negative bacteria. It differs from other cephalosporins in that it is highly protein bound and has a long duration of activity. As with all cephalosporins, the action of cefovecin results from the inhibition of bacterial cell wall synthesis; cefovecin has bactericidal activity.

Cefovecin exhibits *in vitro* activity against *Staphylococcus pseudintermedius* and *Pasteurella multocida* which are associated with canine and feline skin infections. Anaerobic bacteria such as *Bacteroides* spp. and *Fusobacterium* spp. collected from feline abscesses were shown to be susceptible. *Porphyromonas gingivalis* and *Prevotella intermedia* collected from canine periodontal disease were also shown to be susceptible. In addition, cefovecin exhibits *in-vitro* activity against *Escherichia coli* which is associated with canine and feline urinary tract infections.

Resistance to cephalosporins results from enzymatic inactivation (β-lactamase production) or from other mechanisms. Resistance may be chromosomal or plasmid-encoded and may be transferred if associated with transposons or plasmids. Cross resistance with other cephalosporins and other beta-lactam antibacterial agents can be observed. When applying a proposed microbiological breakpoint of S ≤ 2 µg/ml, no resistance to cefovecin was detected in *Pasteurella multocida*, *Fusobacterium* spp. and *Porphyromonas* spp. field isolates. When applying a proposed microbiological breakpoint of I ≤ 4 µg/ml, cefovecin resistance in *S. pseudintermedius* and beta-haemolytic Streptococci isolates was less than 0.02 % and 3.4 % in *Prevotella intermedia* isolates. The percentage of cefovecin resistant isolates in *E. coli*, *Prevotella oralis*, *Bacteroides* spp. and *Proteus* spp. were 2.3 %, 2.7 %, 3.1 % and 1.4 %,

respectively. The percentage of cefovecin resistant isolates in coagulase negative Staphylococci spp. (e.g. *S. xylosus*, *S. schleiferi*, *S. epidermidis*) is 9.5 %. *Pseudomonas* spp., *Enterococcus* spp., and *Bordetella bronchiseptica* isolates are inherently resistant to cefovecin.

Cefovecin has unique pharmacokinetic properties with extremely long elimination half-lives in both dogs and cats.

The product is available in a single pack of either 5 ml or 23 ml, composed of a vial containing the freeze-dried powder, and a second vial containing the diluent. Reconstitution yields either 4 ml or 10 ml of solution for injection respectively. Not all pack sizes may be marketed.