Veterinary medicine package leaflet

This medicine is dispensed with a veterinarian's prescription only

For use in animals only

1. Name, form and strength of the veterinary medicine

Convenia Veterinary

2. Active ingredients

Each vial of lyophilised powder contains: cefovecin (as sodium salt) 852 mg.

After reconstitution according to the instructions, the solution for injection contains: cefovecin as sodium salt 80 mg/ml.

The list of inactive ingredients is provided in section 13.

3. What is this medicine intended for

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

Dogs:

For the treatment of skin and soft tissue infections including pyoderma, wounds and abscesses associated with *Staphylococcus intermedius*, 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 of severe infections of the gingival and periodontal tissues associated with *Porphyromonas* spp. and *Prevotella* spp.

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 intermedius*.

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

4. Contraindications

Do not use in cases of hypersensitivity to cephalosporin or penicillin antibiotics.

Do not use in small herbivores (including rabbits and guinea pigs).

Do not use in dogs and cats less than 8 weeks old.

5. Side effects

Gastrointestinal signs, including emesis, diarrhoea and/or anorexia have been observed on very rare occasions.

Neurological signs (ataxia, convulsion or seizure) and injection site reactions have been reported in very rare cases after use of the product.

Hypersensitivity reactions (e.g. anaphylaxis, dyspnoea and shock) may occur very rarely. If such a reaction occurs, appropriate treatment should be administered without delay.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il/

6. Target animals

Cats and dogs

7. Dosage and method of administration

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

Skin and soft tissue infections in dogs:

A single subcutaneous injection of 8 mg cefovecin/kg body weight (1 ml/10 kg body weight). If required, treatment should be repeated at 14-day intervals up to three additional times.

In accordance with good veterinary practice, treatment of pyoderma should be extended beyond complete recovery.

Severe infections of the gingival and periodontal tissues in dogs:

A single subcutaneous injection of 8 mg cefovecin/kg body weight (1 ml/10 kg body weight).

Skin and soft tissue abscesses and wounds in cats:

A single subcutaneous injection of 8 mg cefovecin/kg body weight (1 ml/10 kg body weight). If required, treatment may be repeated 14 days after the first injection.

Urinary tract infections in dogs and cats:

A single subcutaneous injection of 8 mg cefovecin/kg body weight (1 ml/10 kg body weight).

Animal weight in kg (dog or cat)	**Volume for injection in ml**
2.5	0.25
5	0.5
10	1.0
20	2.0
40	4.0
60	6.0

8. How to use this medicine

To reconstitute the solution, withdraw 10 ml from the diluent vial and add to the vial containing the powder. Shake the vial until the powder is fully dissolved.

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

9. Withdrawal period

Not applicable

10. Warnings

- **Special warnings about use of the medicine for treating the target animal:**

  It is important to reserve third generation cephalosporins for the treatment of clinical conditions which do not respond or are not expected to respond to other classes of antibiotics or first generation cephalosporins. The treatment should be based on susceptibility tests. The fundamental requirement for 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 renal failure.

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

  Caution should be exercised in animals that have previously shown signs of sensitivity to cefovecin, other cephalosporins, penicillins or other drugs. If an allergic reaction occurs, no further administration of cefovecin should be performed and appropriate therapy for beta-lactam hypersensitivity should be administered.

Serious hypersensitivity reactions sometimes require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, and airway opening as clinically indicated.
The veterinarian should be aware that reappearance of allergic signs may occur when symptomatic therapy is discontinued.

Occasionally, cephalosporins have been associated with myelosuppression, thereby causing toxic neutropenia. Other haematological reactions associated with cephalosporins include neutropenia, anaemia, hypoprothrombinemia, thrombocytopenia, prolonged prothrombin time (PT) and partial thromboplastin time (PTT) and platelet dysfunction.

- **Special warnings related to safety of the person treating with the medicine:**
  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.
  An allergic reaction to these substances may occasionally be serious.
  Do not handle this product if you know that you are sensitive or if you have been advised not to work with such preparations.
  Use this product with care to avoid exposure, using all the recommended precautions.
  If you develop symptoms following exposure, such as a rash, you should seek medical attention and show the doctor this warning.
  Swelling of the face, lips or eyes or difficulties breathing are more serious effects and require urgent medical attention.
  If you know that you are sensitive to penicillins or cephalosporins, avoid contact with contaminated waste. In the event of contact, wash the skin with soap and water.

- **Pregnancy and lactation of the treated animal:**
  The safety of use 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.

- **Interactions with other drugs and other types of interactions:**
  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 for binding, and thus may cause side effects.

- **Overdose:**
  Repeated dosing (eight administrations) in 14-day intervals at five times the recommended dose was tolerated in young dogs and cats. In 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 in dogs and cats.

- **Incompatibility:**

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

11. Storage instructions

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Shelf life after solution reconstitution according to the instructions: 28 days.
- Storage conditions:
  Before solution reconstitution:
  Store in a refrigerator (2°C–8°C). Do not freeze.
  Store in the original package in order to protect from light.
  After solution reconstitution:
  Store in a refrigerator (2°C–8°C). Do not freeze.
  Store in the original package in order to protect from light.

12. Instructions for disposal of the product/ remaining product at the end of use

Dispose of any remaining veterinary medicinal product or waste obtained from using a veterinary medicinal product in the same manner as toxic waste; do not discard into a sewer.

13. Additional information

- In addition to the active ingredient, this medicine also contains:
  Sodium Citrate Dihydrate
  Methylparaben
  Propylparaben
  Citric Acid Monohydrate
  Sodium Hydroxide
  Hydrochloric Acid

  The diluent contains:
  Benzyl Alcohol
  Water for Injection

- What the medicine looks like and contents of the pack:
  Product: a 23 ml glass vial.
  Diluent: a 10 ml glass vial.

Registration holder: Zoetis Israel Holding B.V., 5 Atir Yeda st., Kfar Saba
Manufacturer: Haupt Pharma Latina S.R.L, Italy, S.S. 156 KM, 04010 Borgo San Michele, Latina, Italy

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 144-77-92447-01

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