

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFEDOL, 40 mg/ml, solution for injection for cattle, pigs, cats and dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Tolfenamic acid ..... 40 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E 1519)	10.4 mg
Sodium formaldehyde sulfoxylate	5 mg
Diethylene glycol monoethylether	
Ethanolamine	
Water for injections	

A clear yellowish solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle, pigs, cats and dogs.

### 3.2 Indications for use for each target species

**In cattle:** as an adjunct in the treatment of pneumonia by improving general conditions and nasal discharge and as an adjunct in the treatment of acute mastitis.

**In pigs:** as an adjunct in the treatment of Metritis Mastitis Agalactia syndrome.

**In dogs:** for the treatment of inflammation associated with musculo-skeletal disorders and for the reduction of post-operative pain.

**In cats:** as an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate.

### **3.3 Contraindications**

Do not use in cases of cardiac disease.

Do not use in cases of impaired hepatic function or acute renal insufficiency.

Do not use in cases of ulceration or digestive bleeding, in case of blood dyscrasia.

Do not inject intramuscularly in cats.

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

Do not use in dehydrated, hypovolemic or hypotonic animals (due to its potential risk of increasing renal toxicity).

Do not administer other steroidal or non – steroidal anti – inflammatory drugs concurrently or within 24 hours of each other.

### **3.4 Special warnings**

NSAIDS can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections appropriate concurrent antimicrobial therapy should be instigated.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

Use in animals less than 6 weeks of age, or in aged animals, may involve additional risk. If such a use cannot be avoided animals may require a reduced dosage and careful clinical management is essential. Reduced metabolism and excretion in these animals should be considered.

Concurrent administration of potential nephrotoxic drugs should be avoided.

It is preferable that the product is not administered to cats undergoing general anaesthesia until fully recovered.

Do not exceed the prescribed dosage or duration of treatment. The scale of pain relief after pre-operative administration may be influenced by the severity and duration of the operation.

Animals suffering from a chronic renal insufficiency and requiring an anti-inflammatory treatment may be treated with tolafenamic acid without requiring an adjustment of the dosage.

However, the use of this product is contra-indicated in acute cases of renal insufficiency.

In case of undesirable effects (anorexia, vomiting, diarrhoea, presence of blood in faeces) occurring during the treatment, your veterinarian should be contacted for advice and the possibility of stopping treatment should be considered.

Use aseptic precautions when administering the product.

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

The product may cause skin sensitisation. People with known hypersensitivity to non-steroidal anti inflammatory (NSAID) or to any of the excipients should avoid contact with the veterinary medicinal product.

Administer the veterinary medicinal product with caution to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

This product may cause skin and eye irritation. Avoid contact with skin or eyes. In case of accidental contact, wash immediately exposed area with plenty of clean water.

Seek medical attention if irritation persists.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polydipsia <sup>1</sup> Polyuria/pollakiuria <sup>1</sup>  Diarrhoea <sup>2</sup> Vomiting <sup>2</sup>  Injection site reaction
Uncommon (1 to 10 animals / 1,000 animals treated):	Collapse <sup>3</sup>

<sup>1</sup> Signs cease spontaneously after treatment in most cases.

<sup>2</sup> Where either persists, treatment should be discontinued.

<sup>3</sup> Following rapid intravenous injection.

Pigs, cats and dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polydipsia <sup>1</sup> Polyuria/pollakiuria <sup>1</sup>  Diarrhoea <sup>2</sup> Vomiting <sup>2</sup>  Injection site reaction
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<sup>1</sup> Signs cease spontaneously after treatment in most cases.

<sup>2</sup> Where either persists, treatment should be discontinued.

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 its 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**

Cats and dogs:

Pregnancy:

Do not use during pregnancy.

Cattle and pigs:

Pregnancy and lactation:

Use only according to the benefit-risk assessment by the responsible veterinarian.

Can be used during lactation.

### **3.8 Interaction with other medicinal products and other forms of interaction**

Do not administer with other non-steroidal anti-inflammatory drugs simultaneously or with an interval of 24 hours between them. Other NSAIDs, diuretics, anticoagulants and substances with high affinity to plasma proteins may compete for binding and produce toxic effects.

Do not administer in conjunction with anticoagulants.

Avoid simultaneous administration of potentially nephrotoxic drugs.

Do not administer in conjunction with glucocorticoids.

### **3.9 Administration routes and dosage**

Cattle: intramuscular (IM) or intravenous (IV) routes.

Pigs: intramuscular (IM) route.

Dogs: intramuscular (IM) or subcutaneous (SC) routes.

Cats: subcutaneous (SC) route.

Cats and dogs: The recommended dose is 4 mg/kg bodyweight (1 ml/10 kg bodyweight) given as a single injection and repeated once after 24 to 48 hours if required and depending upon clinical assessment. Alternatively, a single injection of 1 ml/10 kg can be given with the treatment being continued by the oral route, using tablets.

In dogs, administer by intramuscular or subcutaneous injection.

For the reduction of post-operative pain, this is best given pre-operatively, at the time of premedication one hour before induction of anaesthesia.

In cats, administer by the subcutaneous route only.

Cattle: For inflammation associated with respiratory disease in cattle, the recommended dosage is 2 mg/kg (1 ml/20 kg bodyweight) by intramuscular injection into the neck area. Treatment may be repeated once after 48 hours.

For use in mastitis, the recommended dosage is 4 mg/kg bodyweight (1ml per 10 kg bodyweight) as a single intravenous injection.

When administering intravenously, the product should be injected slowly. At the first signs of intolerance, the injection should be interrupted.

Pigs: the recommended dosage is 2 mg/kg (1ml/20kg bodyweight) as a single intramuscular injection.

The maximum injected volume is 20 ml per injection site.

The stopper for the 20 ml, 50 ml and 100 ml vial sizes may be safely punctured up to 20 times. The stopper for the 250 ml vial size may be safely punctured up to 50 times. The user should choose the most appropriate vial size according to the target species to be treated.

The use of an insulin-type needle/syringe is advisable particularly in low-weight animals to ensure an accurate dose.

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

At high dosages, neurological disorders have been observed.

In case of overdose, administer symptomatic treatment.

### **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**

#### **Cattle:**

Intramuscular injection

Meat and offal: 12 days.

Milk: zero hours.

Intravenous injection

Meat and offal: 4 days.

Milk: 24 hours.

#### **Pigs:**

Meat and offal: 16 days.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QM01AG02.

## 4.2 Pharmacodynamics

Tolfenamic acid (N-(2-methyl-3-chlorophenyl) anthranilic acid) is a non-steroidal anti-inflammatory drug belonging to the fenamate group. Tolfenamic acid possesses anti-inflammatory, analgesic and antipyretic properties.

The anti-inflammatory activity of tolfenamic acid is due to inhibition of cyclooxygenase leading to a reduction in prostaglandin and thromboxane synthesis, which are important inflammatory mediators.

## 4.3 Pharmacokinetics

In dogs, tolfenamic acid is readily absorbed by injectable administration. By injection, maximum plasma concentrations of about 4 µg/ml (subcutaneously) and about 3 µg/ml (intramuscularly) are obtained 2 hours after administration at 4 mg/kg.

In cats, absorption is quite rapid. By injection, a peak of 3.9 µg/ml is obtained within 1 hour of administration at 4 mg/kg.

In dogs and cats, over 99% of tolfenamic acid is bound to plasma proteins.

In the dog, only tolfenamic acid and its conjugate with glucuronic acid are found in urine.

The hydroxylated metabolites and their conjugates are mainly excreted by the kidneys. The unchanged tolfenamic acid and its glucuronides are predominantly excreted into the bile. Moreover, tolfenamic acid undergoes an intensive enterohepatic recycling.

Tolfenamic acid is distributed to all organs with high concentrations in plasma, digestive tract, liver, lungs and kidneys. The concentration in the brain however is low.

In dogs with renal insufficiency, the elimination of tolfenamic acid is unchanged and accumulation does not occur.

In cattle and pigs, tolfenamic acid injected intramuscularly at a dose of 2mg/kg is rapidly absorbed from the injection site with mean maximum plasma concentrations of about 1.4 µg/ml in cattle and 2.3 µg/ml in pigs obtained at about 1 hour.

The volume of distribution is about 1.3 l/kg.

Tolfenamic acid is extensively bound to plasma albumin (>97%).

Tolfenamic acid is distributed in all the organs with a high concentration in the plasma, digestive tract, liver, lungs and kidneys. However, the concentration in the brain is low. Tolfenamic acid and its metabolites do not cross the placenta to any great extent.

Tolfenamic acid distribution involves extracellular fluids where concentrations similar to plasma are achieved both in healthy and inflamed peripheral tissues. It also appears in milk in the active form, mainly associated with the curds.

Tolfenamic acid undergoes extensive enterohepatic recirculation and, as a result prolonged concentrations are found in plasma.

The elimination half-life varies from 3-5 hours in pigs to 8 - 15 hours in cattle.

In cattle and pigs, tolfenamic acid is eliminated mainly unchanged in faeces (~30%) and urine (~70%).

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major Incompatibilities**

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

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.  
Shelf life after first opening the immediate packaging: 28 days.

### **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**

Amber polypropylene vials of 20 ml, 50 ml, 100 ml and 250 ml provided with a grey (20 ml, 50 ml and 100 ml) or pink (250 ml) bromobutyl stopper and aluminium seal with a flip-off sealing. Each vial is packaged in an outer carton.

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal product 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**

S.P. VETERINARIA, S.A.

## **7. MARKETING AUTHORISATION NUMBER(S)**

## **8. DATE OF FIRST AUTHORISATION**

<Date of first authorisation:> <{DD/MM/YYYY}><{DD month YYYY}>.



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

<{MM/YYYY}>

## **10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

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

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Individual boxes for 20 ml, 50 ml, 100 ml and 250 ml**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

TOLFEDOL, 40 mg/ml, solution for injection for cattle, pigs, cats and dogs

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Tolfenamic acid

40 mg

**3. PACKAGE SIZE**

20 ml

50 ml

100 ml

250 ml

**4. TARGET SPECIES**

Cattle, pigs, cats and dogs.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Cattle: intramuscular (IM) or intravenous (IV) routes.

Pigs: intramuscular (IM) route.

Dogs: intramuscular (IM) or subcutaneous (SC) routes.

Cats: subcutaneous (SC) route.

**7. WITHDRAWAL PERIODS**

**Cattle:**

Intramuscular route

Meat and offal: 12 days.

Milk: zero hours.

Intravenous route

Meat and offal: 4 days.

Milk: 24 hours.

**Pigs:**

Meat and offal: 16 days.

<b>8. EXPIRY DATE</b>
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Exp. {mm/yyyy}

Once broached use by 28 days.

Once broached use by...

<b>9. SPECIAL STORAGE PRECAUTIONS</b>
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<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
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Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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S.P. VETERINARIA, S.A.

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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<b>15. BATCH NUMBER</b>
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Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Labels for 100 ml and 250 ml vials**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

TOLFEDOL, 40 mg/ml, solution for injection for cattle, pigs, cats and dogs

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Tolfenamic acid

40 mg

**3. TARGET SPECIES**

Cattle, pigs, cats and dogs.

**4. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

Cattle: intramuscular (IM) or intravenous (IV) routes.

Pigs: intramuscular (IM) route.

Dogs: intramuscular (IM) or subcutaneous (SC) routes.

Cats: subcutaneous (SC) route.

**5. WITHDRAWAL PERIODS**

**Cattle:**

Intramuscular route

Meat and offal: 12 days.

Milk: zero hours.

Intravenous route

Meat and offal: 4 days.

Milk: 24 hours.

**Pigs:**

Meat and offal: 16 days.

<b>6. EXPIRY DATE</b>
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Exp. {mm/yyyy}  
Once broached use by 28 days.  
Once broached use by...

<b>7. SPECIAL STORAGE PRECAUTIONS</b>
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<b>8. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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S.P. VETERINARIA, S.A.

<b>9. BATCH NUMBER</b>
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Lot {number}



**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Labels for 20 ml and 50 ml**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

TOLFEDOL, 40 mg/ml, solution for injection for cattle, pigs, cats and dogs

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Tolfenamic acid 40 mg/ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}>

Once broached use by 28 days.

Once broached use by...

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

TOLFEDOL, 40 mg/ml, solution for injection for cattle, pigs, cats and dogs

### 2. Composition

Each ml contains:

#### Active substance:

Tolfenamic acid ..... 40 mg

#### Excipients:

Benzyl alcohol (E 1519)..... 10.4 mg

Sodium formaldehyde sulfoxylate        5 mg

A clear yellowish solution.

### 3. Target species

Cattle, pigs, cats and dogs.

### 4. Indications for use

**In cattle:** as an adjunct in the treatment of pneumonia by improving general conditions and nasal discharge and as an adjunct in the treatment of acute mastitis.

**In pigs:** as an adjunct in the treatment of Metritis Mastitis Agalactia syndrome.

**In dogs:** for the treatment of inflammation associated with musculo-skeletal disorders and for the reduction of post-operative pain.

**In cats:** as an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate.

### 5. Contraindications

Do not use in cases of cardiac disease.

Do not use in cases of impaired hepatic function or acute renal insufficiency.

Do not use in cases of ulceration or digestive bleeding, in case of blood dyscrasia.  
Do not inject intramuscularly in cats.  
Do not use in cases of hypersensitivity to the active substance or any of the excipients.  
Do not use in dehydrated, hypovolemic or hypotonic animals (due to its potential risk of increasing renal toxicity).  
Do not administer other steroidal or non-steroidal anti-inflammatory drugs concurrently or within 24 hours of each other.

## **6. Special warnings**

### Special warnings:

NSAIDS can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections appropriate concurrent antimicrobial therapy should be instigated.

### Special precautions for safe use in the target species:

Use in animals less than 6 weeks of age, or in aged animals, may involve additional risk. If such a use cannot be avoided animals may require a reduced dosage and careful clinical management is essential. Reduced metabolism and excretion in these animals should be considered.

Concurrent administration of potential nephrotoxic drugs should be avoided.

It is preferable that the product is not administered to cats undergoing general anaesthesia until fully recovered.

Do not exceed the prescribed dosage or duration of treatment. The scale of pain relief after pre-operative administration may be influenced by the severity and duration of the operation.

Animals suffering from a chronic renal insufficiency and requiring an anti-inflammatory treatment may be treated with tolafenamic acid without requiring an adjustment of the dosage. However, the use of this product is contra-indicated in acute cases of renal insufficiency.

In case of undesirable effects (anorexia, vomiting, diarrhoea, presence of blood in faeces) occurring during the treatment, your veterinarian should be contacted for advice and the possibility of stopping treatment should be considered.

Use aseptic precautions when administering the product.

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

The product may cause skin sensitisation. People with known hypersensitivity to non-steroidal anti inflammatory (NSAID) or to any of the excipients should avoid contact with the veterinary medicinal product.

Administer the veterinary medicinal product with caution to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

This product may cause skin and eye irritation. Avoid contact with skin or eyes. In case of accidental contact, wash immediately exposed area with plenty of clean water.

Seek medical attention if irritation persists.

Wash hands after use.

Pregnancy and lactation:

Cats and dogs:

Pregnancy: Do not use during pregnancy.

Cattle and pigs:

Pregnancy: Use only according to the benefit-risk assessment by the responsible veterinarian.

Lactation: The product can be used during lactation.

Interaction with other medicinal products and other forms of interaction:

Do not administer with other non-steroidal anti-inflammatory drugs simultaneously or with an interval of 24 hours between them. Other NSAIDs, diuretics, anticoagulants and substances with high affinity to plasma proteins may compete for binding and produce toxic effects.

Do not administer in conjunction with anticoagulants.

Avoid simultaneous administration of potentially nephrotoxic drugs.

Do not administer in conjunction with glucocorticoids.

Overdose:

At high dosages, neurological disorders have been observed.

In case of overdose, administer symptomatic treatment.

Major incompatibilities:

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

**7. Adverse events**

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polydipsia (Increased drinking) <sup>1</sup> Polyuria/pollakiuria (Increased urination/frequent, abnormal urination) <sup>1</sup>  Diarrhoea <sup>2</sup> Vomiting <sup>2</sup>  Injection site reaction
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Uncommon (1 to 10 animals / 1,000 animals treated):	Collapse <sup>3</sup>
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<sup>1</sup> Signs cease spontaneously after treatment in most cases.

<sup>2</sup> Where either persists, treatment should be discontinued.

<sup>3</sup> Following rapid intravenous injection.

Pigs, cats and dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polydipsia <sup>1</sup> (Increased drinking) <sup>1</sup> Polyuria/pollakiuria <sup>1</sup> (Increased urination/frequent, abnormal urination) <sup>1</sup>  Diarrhoea <sup>2</sup> Vomiting <sup>2</sup>  Injection site reaction
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<sup>1</sup> Signs cease spontaneously after treatment in most cases.

<sup>2</sup> Where either persists, treatment should be discontinued.

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: {national system details}

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

Cattle: intramuscular (IM) or intravenous (IV) routes.

Pigs: intramuscular (IM) route.

Dogs: intramuscular (IM) or subcutaneous (SC) routes.

Cats: subcutaneous (SC) route.

Cats and dogs: The recommended dose is 4 mg/kg bodyweight (1 ml/10 kg bodyweight) given as a single injection and repeated once after 24 to 48 hours if required and depending upon clinical assessment. Alternatively, a single injection of 1 ml/10 kg can be given with, the treatment being continued by the oral route, using tablets.

In dogs administer by intramuscular or subcutaneous injection. For the reduction of post-operative pain, this is best given pre-operatively, at the time of premedication one hour before induction of anaesthesia.

In cats, administer by the subcutaneous route only.

Cattle: For inflammation associated with respiratory disease in cattle, the recommended dosage is 2 mg/kg (1 ml/20 kg bodyweight) by intramuscular injection into the neck area. Treatment may be repeated once after 48 hours.

For use in mastitis, the recommended dosage is 4 mg/kg bodyweight (1ml per 10 kg bodyweight) as a single intravenous injection.

Pigs: the recommended dosage is 2 mg/kg (1ml/20kg bodyweight) as a single intramuscular injection.

## **9. Advice on correct administration**

The maximum injected volume is 20 ml per injection site.

The stopper for the 20 ml, 50 ml and 100 ml vial sizes may be safely punctured up to 20 times. The stopper for the 250 ml vial size may be safely punctured up to 50 times. The user should choose the most appropriate vial size according to the target species to be treated.

When administering intravenously, the product should be injected slowly. At the first signs of intolerance, the injection should be interrupted.

The use of an insulin-type needle/syringe is advisable particularly in low-weight animals to ensure an accurate dose.

## **10. Withdrawal periods**

### **Cattle:**

Intramuscular route

Meat and offal: 12 days.

Milk: zero hours.

Intravenous route

Meat and offal: 4 days.

Milk: 24 hours.

### **Pigs:**

Meat and offal: 16 days.

## **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 and on the vial after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

## **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 national collection systems applicable to the veterinary medicinal product concerned.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Pack sizes:

20 ml.

50 ml.

100 ml.

250 ml.

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 Union Product Database (<https://medicines.health.europa.eu/veterinary>).

## **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

<Local representatives and contact details to report suspected adverse reactions>:>



## **17. Other information**