

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animeloxan 1.5 mg/ml oral suspension for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Meloxicam 1.5 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium benzoate	1.5 mg
Microcrystalline cellulose	
Carmellose sodium	
Glycerol	
Sorbitol, Liquid (non-crystallising)	
Xylitol	
Sodium dihydrogen phosphate dihydrate	
Saccharin Sodium	
Honey Flavour IFF RS 80008	
Citric acid monohydrate	
Purified Water	

The veterinary medicinal product is a pale yellow viscous suspension.

## 3. CLINICAL INFORMATION

### 3.1. Target species

Dogs

### 3.2. Indications for use for each target species

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

### 3.3. Contraindications

Do not use in pregnant or lactating animals.

Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.

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

Do not use in dogs less than 6 weeks of age.

### **3.4. Special warnings**

None.

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

Special precautions for safe use in the target species:

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

In case of prolonged use, monitoring during treatment should be carried out.

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

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

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**

Dog:

Undetermined frequency (cannot be estimated from the available data):	Appetite loss <sup>1</sup> , vomiting <sup>1</sup> , diarrhoea <sup>1</sup> , blood in faeces <sup>1,2</sup> , apathy <sup>1</sup>
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<sup>1</sup>These typical adverse drug reactions of NSAIDs occur occasionally and generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

<sup>2</sup>occult

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 also the package leaflet for respective contact details.

### **3.7. Use during pregnancy, lactation or lay**

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy:

Do not use during pregnancy.

Lactation:

Do not use for nursing bitches.

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

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Meloxicam must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the veterinary medicinal products used previously.

Meloxicam may antagonise the antihypertensive effects of ACE inhibitors.

**3.9. Administration routes and dosage**

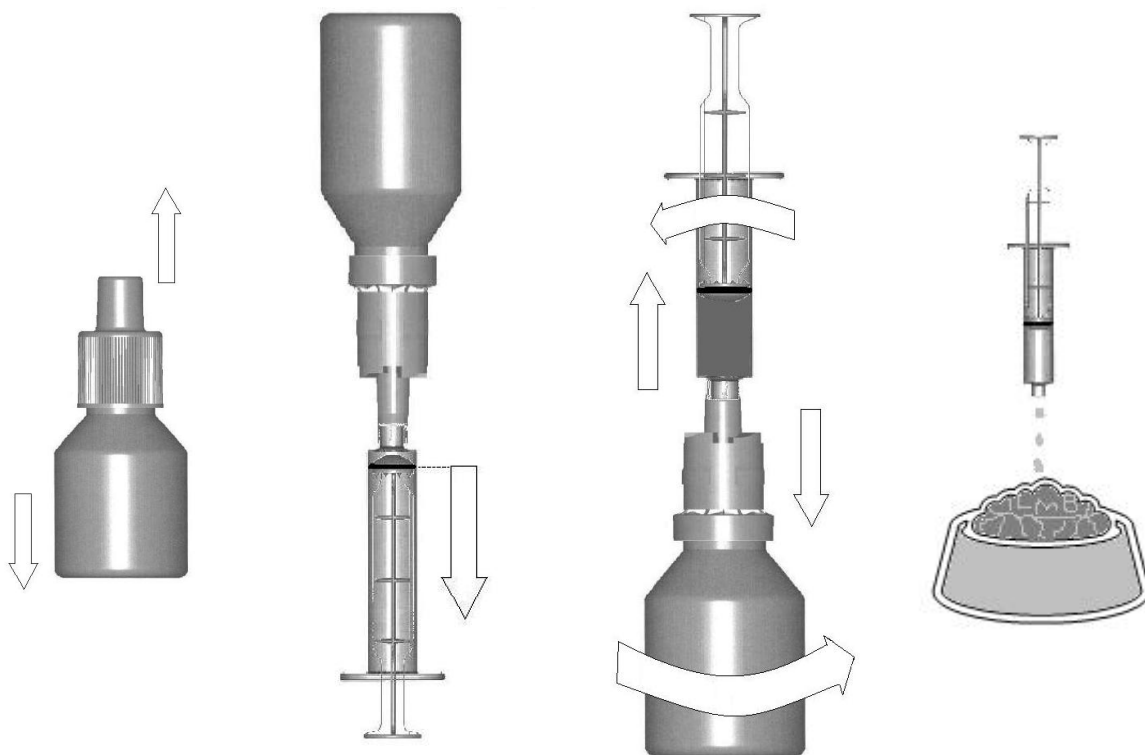
Shake well before use.

To be administered mixed with food or directly into the mouth.

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight (equivalent to 0,07 ml/kg).

Particular care should be taken with regard to the accuracy of dosing.

The suspension can be given using the measuring syringe provided in the package. The syringe provided allows dosing for dogs with a body weight of 2.5 – 45 kg. For dosing for dogs with a body weight of less than 2.5 kg, a syringe with a smaller volume (0.5 ml, 1 ml) must be used. The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg body weight corresponds to 0,07 ml/kg bodyweight). Thus for the first day, twice the maintenance volume will be required.



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle.

Turn the bottle/syringe upside down. Pull the plunger out until the line on the plunger corresponds to your dog's bodyweight in kilograms

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle

Empty the contents of the syringe onto the food by pushing the plunger in or directly into the mouth.

A clinical response is normally seen within 3 - 4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

For longer term treatment, once clinical response has been observed (after  $\geq 4$  days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Avoid introduction of contamination during use.

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

In the case of overdosage symptomatic treatment should be initiated. Please refer to Section 3.6 (Adverse events) for details of symptoms.

### **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:**

QM 01 AC 06

### **4.2. Pharmacodynamics**

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. In vitro and in vivo studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

### **4.3. Pharmacokinetics**

#### Absorption

Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 7.5 hours. When the veterinary medicinal product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

#### Distribution

There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg.

#### Metabolism

Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

#### Elimination

Meloxicam is eliminated with a half-life of 24 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

## **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: 6 months

### **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**

High density polyethylene bottle with polyethylene inner and outer cap.  
Measuring device: Polypropylene syringe

Pack size(s): Bottles of 10 ml, 25 ml, 50ml, 100 and 125 ml

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**

aniMedica GmbH

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

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation:

**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**  
**(CARDBOARD CARTON)**

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

Animeloxan 1.5 mg/ml oral suspension

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Active substance:  
Meloxicam 1.5 mg

**3. PACKAGE SIZE**

10 ml bottle  
25 ml bottle  
50 ml bottle  
100 ml bottle  
125 ml bottle

A measuring device (a plastic syringe) is also included in the pack.

**4. TARGET SPECIES**

Dogs

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Shake well before use.  
To be administered mixed with food or directly into the mouth.  
Read the package leaflet before use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}  
Shelf-life after first opening the immediate packaging: 6 months  
Once opened, use by: .....

**9. SPECIAL STORAGE PRECAUTIONS**

**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**

aniMedica GmbH

*{Name or company name or logo name of the marketing authorisation holder}*

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE  
(100 ml, 125 ml)**

**VIA ADHESIVE LABEL ON BOTTLE**

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

Animeloxan 1.5 mg/ml, oral suspension

**2. STATEMENT OF ACTIVE SUBSTANCES**

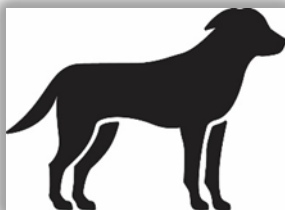
Each ml contains:

Active substance:

Meloxicam 1.5 mg

**3. TARGET SPECIES**

Dogs



*(a pictogram may be used to replace the wording)*

**4. ROUTES OF ADMINISTRATION**

Shake well before use.

To be administered mixed with food or directly into the mouth.

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 6 months

Once opened, use by: .....

**7. SPECIAL STORAGE PRECAUTIONS**

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

aniMedica GmbH

*{Name or company name or logo name of the marketing authorisation holder}*

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

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS  
(10 ml, 25 ml, 50ml)**

**VIA ADHESIVE LABEL ON BOTTLE**

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

Animeloxan

Dogs



*(a pictogram may be used to replace the wording)*

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

Meloxicam 1.5 mg/ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 6 months

Once opened, use by: .....

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### **1. Name of the veterinary medicinal product**

Animeloxan 1.5 mg/ml oral suspension for dogs

### **2. Composition**

Each ml contains:

Active substance:

Meloxicam 1.5 mg

Excipient:

Sodium benzoate 1.5 mg

Pale yellow viscous suspension.

### **3. Target species**

Dogs

### **4. Indications for use**

Meloxicam is a Non Steroidal Anti-Inflammatory Drug (NSAID) that alleviates inflammation and pain in both acute and chronic musculo-skeletal disorders.

### **5. Contraindications**

- Do not use in pregnant or lactating animals.
- Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
- Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
- Do not use in dogs less than 6 weeks of age.

### **6. Special warnings**

Special warnings:

None.

Special precautions for safe use in the target species:

If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

In case of prolonged use, monitoring during treatment should be carried out.



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

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

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

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy:

Do not use during pregnancy.

Lactation:

Do not use for nursing bitches.

Interaction with other medicinal products and or other form of interaction:

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Meloxicam must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the veterinary medicinal products used previously.

Meloxicam may antagonise the antihypertensive effects of ACE inhibitors.

Overdose:

In the case of overdosage symptomatic treatment should be initiated.

Major incompatibilities:

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

## **7. Adverse events**

Dog:

Undetermined frequency (cannot be estimated from the available data):  
Appetite loss<sup>1</sup>, vomiting<sup>1</sup>, diarrhoea<sup>1</sup>, blood in faeces<sup>1,2</sup>, apathy<sup>1</sup>

<sup>1</sup>These typical adverse drug reactions of NSAIDs occur occasionally and generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

<sup>2</sup>occult

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**

### **Dosage**

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight (equivalent to 0,07 ml/kg).

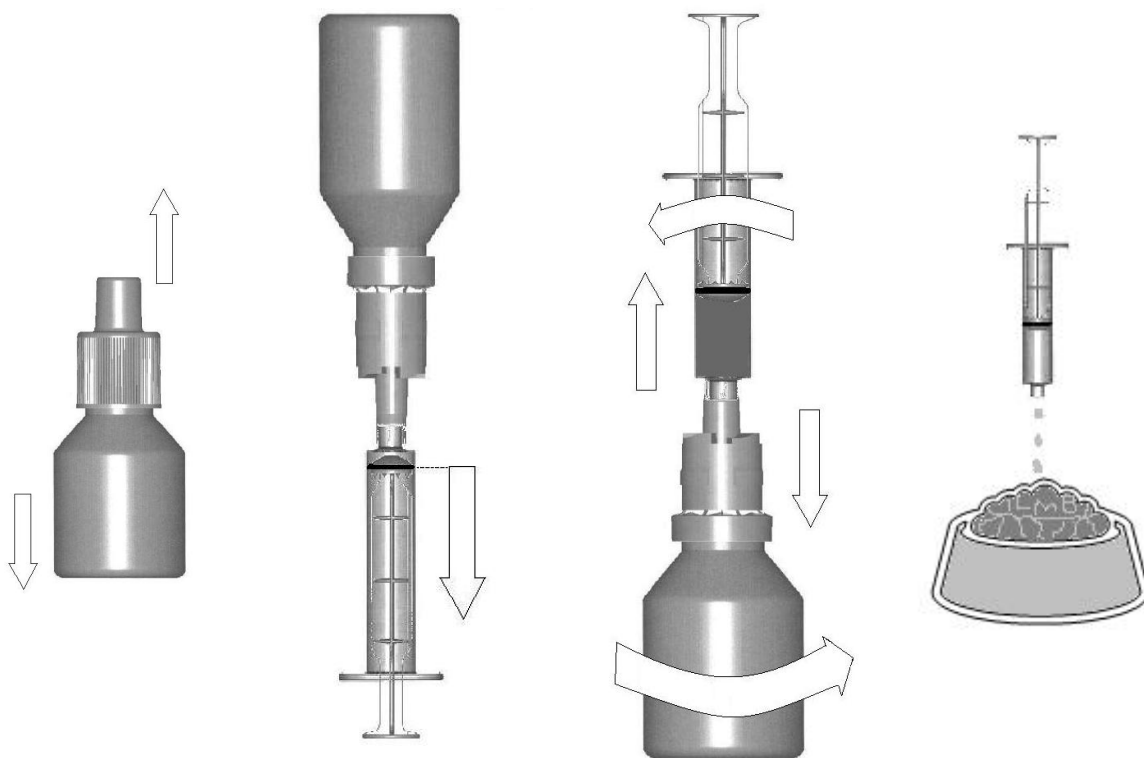
### **Method and route of administration**

Shake well before use. To be administered mixed with food or directly into the mouth.

The suspension can be given using the measuring syringe provided in the package (see below).

The syringe provided allows dosing for dogs with a body weight of 2.5 – 45 kg. For dosing for dogs with a body weight of less than 2.5 kg, a syringe with a smaller volume (0.5 ml, 1 ml) must be used.

The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg body weight corresponds to 0,07 ml/kg bodyweight). Thus for the first day, twice the maintenance volume will be required.



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle.

Turn the bottle/syringe upside down. Pull the plunger out until the line on the plunger corresponds to your dog's bodyweight in kilograms

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle

Empty the contents of the syringe onto the food or directly into the mouth by pushing the plunger in.

A clinical response is normally seen within 3 - 4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

For longer term treatment, once clinical response has been observed (after  $\geq 4$  days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Avoid introduction of contamination during use.

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

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

The date of first use (on first opening of the bottle) should be recorded on the space provided on the label or carton, along with the expiry date of the opened bottle (six months from the date of opening). Any unused veterinary medicinal product should be discarded after this date.

## **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.

After each dose, the tip of the syringe should be wiped and the bottle cap screwed back on tightly. The syringe should be stored in the carton box in between uses.

Shelf-life after first opening the immediate packaging: 6 months.

Do not use after the expiry date stated on the carton and the bottle.

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.

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**

XXXXXXXXXXXX

10 ml, 25 ml, 50 ml, 100 ml or 125 ml bottle.

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:

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Tel: +49-2536-3302-0

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.

**17. Other information**