

Medicinal product no longer authorised

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RevitaCAM 5 mg/ml oromucosal spray for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance: Meloxicam 5 mg

Excipients: Ethyl alcohol 150 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oromucosal spray

Yellow colloidal dispersion

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 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 case of hypersensitivity to the active substance or to any of the excipients.

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

This product is for dogs and should not be used in cats as it is not suitable for use in this species.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

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

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

Wash hands after administration of the product.

People with known hypersensitivity to Non Steroidal Anti-inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Avoid direct contact between the product and skin, if accidental exposure occurs wash hands immediately with soap and water.

4.6 Adverse reactions (frequency and seriousness)

Typical adverse drug reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. These side effects occur 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.

In some dogs sneezing, coughing/gagging or drooling may be observed immediately after treatment administration.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 4.3).

4.8 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. RevitaCAM 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 veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

4.9 Amounts to be administered and administration route

Store the vial in an upright position.

Shake gently before use.

To prime the pump depress at least 10 times prior to first use or until a fine spray appears. If RevitaCAM is not used for two days or more, re-prime with one or more sprays or until a fine spray appears.

Immediately after administration of the spray use a moist paper towel or tissue to clean the tip of the pump.

In case of pump failure, wipe nozzle and then re-prime the pump as described above.

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment should be continued once daily by application of the spray to the oral mucosa (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight (see dosing table).

To administer RevitaCAM, the dog's top lip should be grasped and gently pulled away exposing the gums. The mouth should not be opened any wider than necessary to facilitate application. The mist should be directed to the back and towards the gums and/or inner cheek, mucosal surfaces. The pump should be depressed fully, ensuring no mist escapes from the mouth. Allow the pump to fully reflate before administering consecutive sprays.

RevitaCAM is presented in:

10 ml glass vial	containing either 3ml or 6 ml	50 µl pump
20 ml glass vial	containing either 3ml or 11ml	100µl pump
50 ml glass vial	containing either 8 ml or 33 ml	215µl pump

Care should be taken to select the correct size vial depending on the bodyweight of the dog.

Body weight range (kg)	No. of sprays/ treatment	Pump size (µl)	Dose volume (µl)	Total dose meloxicam (mg)*	Maintenance dosage range meloxicam delivered (mg/kg)*
2.1 - 3.5	1	50	50	0.25	0.1 - 0.12
3.6 - 5.0	2	50	100	0.50	0.1 - 0.14
5.1 - 7.5	3	50	150	0.75	0.1 - 0.15
7.6 - 10.0	2	100	200	1.00	0.1 - 0.13
10.1 - 15.0	3	100	300	1.50	0.1 - 0.15
15.1 - 25.0	2	215	430	2.15	0.1 - 0.14
25.1 - 35.0	3	215	645	3.23	0.1 - 0.13
35.1 - 45.0	4	215	860	4.30	0.1 - 0.12
45.1 - 55	5	215	1075	5.38	0.1 - 0.12
55.1 - 70.0	6	215	1290	6.45	0.1 - 0.12

* For the initial treatment of a single dose of 0.2 mg meloxicam/kg body weight, the above maintenance doses should be doubled.

For longer term treatment, once a clinical response has been observed (after ≥ 4 days), the dose of the 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.

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.

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

In the case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids (oxicams)
 ATCvet Code: QM01AC06

5.1 Pharmacodynamic properties

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).

5.2 Pharmacokinetic particulars

Absorption

Meloxicam is completely absorbed following oromucosal administration and maximal plasma concentrations are obtained after approximately 4.5 hours. When the 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethyl alcohol
Polycarbophil
Boric acid
Potassium chloride
Hydrochloric acid
Sodium hydroxide
Water, purified

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months

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

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

10 ml glass vial	containing either 3ml or 6 ml	50 µl pump
20 ml glass vial	containing either 3ml or 11ml	100µl pump
50 ml glass vial	containing either 8 ml or 33 ml	215µl pump

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 products 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/2/12/138/001	6 ml/10 ml vial
EU/2/12/138/002	11 ml/20 ml vial
EU/2/12/138/003	33 ml/50 ml vial
EU/2/12/138/004	3 ml/10 ml vial
EU/2/12/138/005	3 ml/20 ml vial
EU/2/12/138/006	8 ml/50 ml vial

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23/02/2012

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. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE**
- C. STATEMENT OF THE MRLs**
- D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Abbott Logistics B.V.,
Minervum 7201,
Breda 4817 ZJ,
THE NETHERLANDS

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF THE MRLs

Not applicable

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Pharmacovigilance system

The MAH must ensure that the system of pharmacovigilance as described in Part 1 of the marketing authorisation application, is in place and functioning before and whilst the product is on the market.

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ANNEX III

LABELLING AND PACKAGE LEAFLET

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A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RevitaCAM 5 mg/ml oromucosal spray for Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 5 mg/ml

3. PHARMACEUTICAL FORM

Oromucosal Spray

4. PACKAGE SIZE

3 ml
6 ml
3 ml
11 ml
8 ml
33 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake gently before use.
Oromucosal use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP {month/year}

Shelf-life of opened vial: 6 months

11. SPECIAL STORAGE CONDITIONS

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/2/12/138/001 6 ml/10ml vial
EU/2/12/138/002 11 ml/20 ml vial
EU/2/12/138/003 33 ml/50 ml vial
EU/2/12/138/004 3 ml/10 ml vial
EU/2/12/138/005 3 ml/20 ml vial
EU/2/12/138/006 8 ml/50 ml vial

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RevitaCAM 5 mg/ml oromucosal spray for Dogs
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5mg/ml

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

3 ml
6ml
3 ml
11 ml
8 ml
33 ml

4. ROUTE(S) OF ADMINISTRATION

Shake gently before use.
Oromucosal use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}>
Shelf-life of opened vial: 6 months
Once broached, use by ...

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Medicinal product no longer authorised

B. PACKAGE LEAFLET

**PACKAGE LEAFLET FOR:
RevitaCAM 5mg/ml oromucosal spray for Dogs**

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 for the batch release:

Abbott Logistics B.V., Minervum 7201, Breda 4817 ZJ, THE NETHERLANDS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RevitaCAM 5 mg/ml oromucosal spray for Dogs
Meloxicam

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

Meloxicam 5 mg/ml

4. INDICATION(S)

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

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 case of hypersensitivity to the active substance or to any of the excipients.

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

This product is for dogs and should not be used in cats as it is not suitable for use in this species.

6. ADVERSE REACTIONS

Typical adverse drug reactions of Non Sterioidal Anit-Inflammatory Drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. These side effects occur 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. In some dogs sneezing, coughing/gagging or drooling may be observed immediately after treatment administration.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)

- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

Store the vial in an upright position.

Shake gently before use.

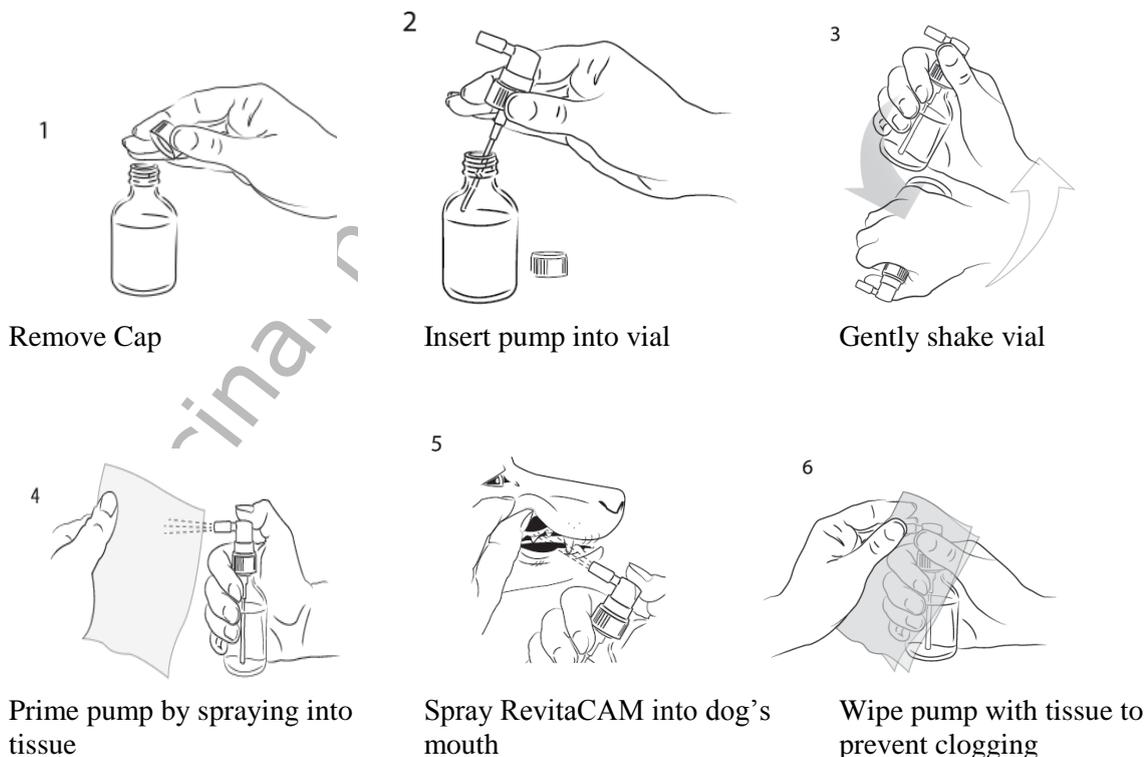
To prime the pump depress at least 10 times prior to first use or until a fine spray appears. If RevitaCAM is not used for two days or more, re-prime with one or more sprays or until a fine spray appears.

Immediately after administration of the spray use a moist paper towel or tissue to clean the tip of the pump.

In case of pump failure, wipe nozzle and then re-prime the pump as described above.

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 oromucosal administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight (see dosing table).

To administer RevitaCAM, the dog's top lip should be grasped and gently pulled away exposing the gums. The mouth should not be opened any wider than necessary to facilitate application. The mist should be directed to the back and towards the gums and/or inner cheek, mucosal surfaces. The pump should be depressed fully, ensuring no mist escapes from the mouth. Allow the pump to fully reflate before administering consecutive sprays.



RevitaCAM is presented in:

10 ml glass vial	containing either 3ml or 6 ml	50 µl pump
20 ml glass vial	containing either 3ml or 11ml	100µl pump
50 ml glass vial	containing either 8 ml or 33 ml	215µl pump

Care should be taken to select the correct size vial depending on the weight of the dog.

Body weight range (kg)	No. of sprays/ treatment	Pump size (µl)	Dose volume (µl)	Total dose meloxicam (mg)*	Maintenance dosage range meloxicam delivered (mg/kg)*
2.1 - 3.5	1	50	50	0.25	0.1 - 0.12
3.6 - 5.0	2	50	100	0.50	0.1 - 0.14
5.1 - 7.5	3	50	150	0.75	0.1 - 0.15
7.6 - 10.0	2	100	200	1.00	0.1 - 0.13
10.1 - 15.0	3	100	300	1.50	0.1 - 0.15
15.1 - 25.0	2	215	430	2.15	0.1 - 0.14
25.1 - 35.0	3	215	645	3.23	0.1 - 0.13
35.1 - 45.0	4	215	860	4.30	0.1 - 0.12
45.1 - 55.0	5	215	1075	5.38	0.1 - 0.12
55.1 - 70.0	6	215	1290	6.45	0.1 - 0.12

* For the initial treatment of a single dose of 0.2 mg meloxicam/kg body weight, the above maintenance doses should be doubled.

For longer term treatment, once a clinical response has been observed (after ≥ 4 days), the dose of the 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.

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.

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.

10. WITHDRAWAL PERIOD

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.

Shelf-life after first opening the container: 6 months.

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

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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

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

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

Wash hands after administration of the product.

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

Avoid direct contact between the product and skin, if accidental exposure occurs wash hands immediately with soap and water.

Use during pregnancy and lactation:

See section "Contraindications".

Interactions 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. RevitaCAM 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 veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose symptomatic treatment should be initiated.

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

Medicines should not be disposed of via wastewater or household waste but in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

10 ml glass vial	containing either 3ml or 6 ml	50 µl pump
20 ml glass vial	containing either 3ml or 11ml	100µl pump
50 ml glass vial	containing either 8 ml or 33 ml	215µl pump

Not all pack sizes may be marketed.

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

België/Belgique/Belgien

Ecuphar nv/sa
Tél/Tel: +32 (0) 50 31 42 69

Република България

Zoetis Luxembourg Holding Sarl
Тел: +359 2 8021933

Česká republika

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Ísland

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Slovenija

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Slovenská republika

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Sverige

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United Kingdom
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Tel: +44 (0) 845 300 8034

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