[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rapidexon 2 mg/ml solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 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 (E1519)	15.0 mg
Sodium chloride	
Sodium citrate dihydrate	
Citric acid monohydrate	
Sodium hydroxide	
Water for injections	

A clear colourless solution practically free from particles.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs, cats and dogs.

3.2 Indications for use for each target species

In horses, cattle, pigs, dogs and cats:
Treatment of inflammatory or allergic conditions.

In cattle:
Treatment of primary ketosis (acetonaemia).
Induction of parturition

In horses:
Treatment of arthritis, bursitis or tenosynovitis.

3.3 Contraindications

Except in emergency situations, do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency, hyperadrenocorticism, or osteoporosis.
Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections.
Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis.
Do not administer intra-articularly where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis.

Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
Refer to section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
If the veterinary medicinal product is used for induction of parturition in cattle, then a high incidence of retained placentae may be experienced and possible subsequent metritis and/or subfertility.
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.
Use of corticosteroids in horses has been reported to induce laminitis. Therefore horses treated with such preparations should be monitored frequently during the treatment period.
Because of the pharmacological properties of the active ingredient, special care should be taken when the veterinary medicinal product is used in animals with a weakened immune system.
Except in cases of acetonaemia and induction of the parturition, corticoid administration is to induce an improvement in clinical signs rather than a cure. The underlying disease should be further investigated. When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper.
Following intra-articular administration, use of the joint should be minimized for one month and surgery on the joint should not be performed within eight weeks of use of this route of administration.
Only the 25 ml vial should be used to treat cats, dogs and small piglets to prevent excessive puncturing of the closure.
See section 3.6.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.
The veterinary medicinal product should not be administered by pregnant women.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses, cattle, pigs, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polydipsia[1], polyphagia[1] Polyuria[1] Hypokalaemia[2], changes in blood biochemical and haematological parameters, hyperglycaemia[3] Hepatomegaly[4] Pancreatitis[5] Laminitis
Undetermined frequency (cannot be estimated from the available data)	Iatrogenic hyperadrenocorticism (Cushing's disease)[6] Sodium retention[2], water retention[2] Cutaneous calcinosis Delayed wound healing, weakened resistance to or exacerbation of existing infections[7] Gastrointestinal ulceration[8] Retained placenta, metritis, subfertility

	Milk production decrease

[1] After systemic administration and particularly during early stages of therapy.
[2] Upon long-term use.
[3] Transient.
[4] With increased serum hepatic enzymes.
[5] Increased risk of acute pancreatitis.
[6] Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g., redistribution of body fat, muscle weakness and wastage and osteoporosis may result.
[7] In the presence of bacterial infection, antibacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.
[8] May be exacerbated in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

Corticosteroids are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe adverse reactions with long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control clinical signs.

During therapy effective doses suppress the hypothalamo-pituitreal adrenal axis. Following cessation of treatment, signs of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment (for further information see standard texts).

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

Pregnancy and lactation:
Do not administer the veterinary medicinal product in pregnant females, except where the intention is to induce parturition. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy is likely to cause abortion or early parturition in ruminants and may have a similar effect in other species.
Use of the veterinary medicinal product in lactating cows may cause a reduction in milk yield.
Refer to section 3.5.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.
Because corticosteroids can reduce the immunoresponse to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.
Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.
Concurrent use with anticholinestaerase may lead to increased muscle weakness in patients with myasthenia gravis.
Glucocorticoids antagonise the effects of insulin.
Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethason.

3.9 Administration routes and dosage

Horses: Intravenous, intramuscular, intraarticular, intrabursal or local use.
Cattle, pigs, dogs and cats: Intramuscular use.

For the treatment of inflammatory or allergic conditions the following average doses are advised. However the actual dose used should be determined by the severity of the signs and the length of time for which they have been present.

Species	**Dosage**
Horses, cattle, pigs	0.06 mg/kg body weight corresponding to 1.5 ml/50 kg
Dogs, cats	0.1 mg/kg body weight corresponding to 0.5 ml/10 kg

For the treatment of primary ketosis in cattle (acetonaemia)
0.02 to 0.04 mg/kg body weight corresponding to 5-10 ml per cow given by intramuscular injection is advocated dependent on the size of the cow and the duration of the signs. Care should be taken not to overdose Channel Island breeds. Larger doses will be required if the signs have been present for some time or if relapsed animals are being treated.

For the induction of parturition
0.04 mg/kg body weight corresponding to 10 ml per cow as a single intramuscular injection after day 270 of pregnancy.
Parturition will normally occur within 48-72 hours.

For the treatment of arthritis, bursitis or tenosynovitis by single intra-articular, intrabursal or local injection in the horse
Dosage 1-5 ml
These quantities are not specific and are quoted purely as a guide. Injections into joint spaces or bursae should be preceded by the removal of an equivalent volume of synovial fluid. Strict asepsis is essential.
To measure small volumes of less than 1 ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

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

An overdose can induce drowsiness and lethargy in horses. Refer to section 3.6.

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	Meat and offal: 8 days
	Milk: 72 hours
Pigs	Meat and offal: 2 days
Horses	Meat and offal: 8 days.
	Not authorised for use in horses producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB02

4.2 Pharmacodynamics

This preparation contains the sodium phosphate ester of dexamethasone, a fluoro-methyl derivative of prednisolone, which is a potent glucocorticoid with minimal mineralocorticoid activity. Dexamethasone has ten to twenty times the anti-inflammatory activity of prednisolone. Corticosteroids suppress the immunologic response by inhibition of dilatation of capillaries, migration and function of leucocytes and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis.

4.3 Pharmacokinetics

Following intramuscular injection this soluble ester of dexamethasone is readily absorbed and hydrolysed to the parent alcohol giving a prompt response which is maintained for approximately 48 hours. T_{max} in cattle, horses, pigs and dogs is reached within 20 minutes following intramuscular administration. $T_{½}$ varies per species between 5 and 20 hours. Bioavailability after intramuscular administration is almost 100%. Dexamethasone has a medium duration of activity.

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 in 50 ml and 100 ml vials: 2 years.
Shelf life of the veterinary medicinal product as packaged for sale in 25 ml vials: 18 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C. Do not freeze. Keep the vial in the outer carton.

5.4 Nature and composition of immediate packaging

- Vial
    * volume 25 ml (filled in 30 ml vial), 50 ml and 100 ml;
    * glass type I; quality Ph.Eur.
    * uncoloured;

- Stopper
    * bromobutyl rubber stopper type I
    * secured with aluminium cap

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

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

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

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rapidexon 2 mg/ml solution for injection
[Pharmaceutical form pictogram]

2. STATEMENT OF ACTIVE SUBSTANCES

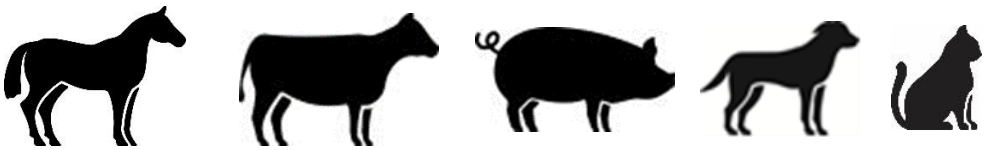
Each ml contains:
Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg

3. PACKAGE SIZE

25 ml
50 ml
100 ml

4. TARGET SPECIES

Horses, cattle, pigs, dogs and cats.



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Horses: Intravenous, intramuscular, intraarticular, intrabursal or local use.
Cattle, pigs, dogs and cats: Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle	Meat and offal: 8 days
	Milk: 72 hours
Pigs	Meat and offal: 2 days
Horses	Meat and offal: 8 days
	Not authorised for use in horses producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the container: 28 days.
Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Do not freeze.
Keep the vial in the outer carton.

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

[Company logo]

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

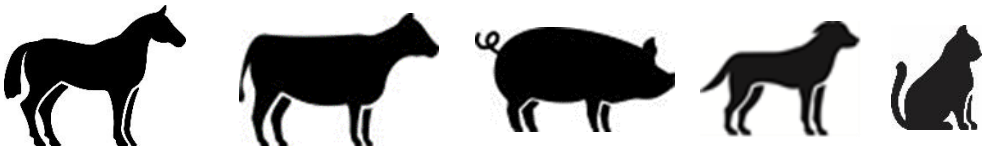
Rapidexon 2 mg/ml solution for injection
[Pharmaceutical form pictogram]

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg

3. TARGET SPECIES

Horses, cattle, pigs, dogs and cats.



4. ROUTES OF ADMINISTRATION

Horses: Intravenous, intramuscular, intraarticular, intrabursal or local use.
Cattle, pigs, dogs and cats: Intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle	Meat and offal: 8 days
	Milk: 72 hours
Pigs	Meat and offal: 2 days
Horses	Meat and offal: 8 days
	Not authorised for use in horses producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the container: 28 days.
Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Do not freeze.
Keep the vial in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

[Company logo]

9. BATCH NUMBER

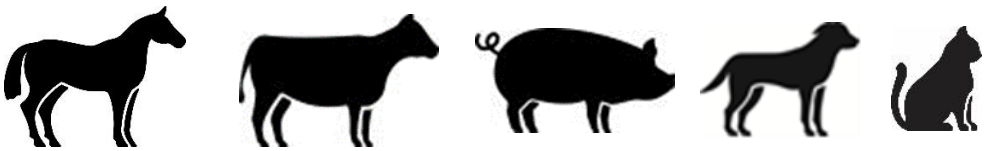
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

25 / 50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rapidexon



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the container: 28 days.
Once broached use by …

[Company logo]

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Rapidexon 2 mg/ml, solution for injection

2. Composition

Each ml contains:
Active substance:
Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg

Excipient:
Benzyl alcohol, (E1519) 15.0 mg

A clear colourless solution practically free from particles.

3. Target species

Horses, cattle, pigs, cats and dogs.

4. Indications for use

In horses, cattle, pigs, dogs and cats:
Treatment of inflammatory and allergic conditions.

In cattle:
Treatment of primary ketosis.
Induction of calving.

In horses:
Treatment of inflammation of joints, bursas or tendon(sheath)s.

5. Contraindications

Except in emergency situations, do not use in animals suffering from diabetes, kidney insufficiency, heart insufficiency, Cushing's syndrome or osteoporosis.
Do not use in viral infections during the viraemic stage or in cases of systemic fungal infections.
Do not use in animals suffering from gastrointestinal ulcers or ulcers of the cornea, or demodicosis.
Do not administer intra-articulary where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis (cell death).
Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
Refer to section 'Special warnings'.

6. Special warnings

Special precautions for safe use in the target species:
If the veterinary medicinal product is used for induction of parturition in cattle, then a high incidence of retained placentae may be experienced and possible subsequent metritis and/or subfertility.
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Use of corticosteroids in horses has been reported to induce laminitis. Therefore horses treated with such preparations should be monitored frequently during the treatment period.
Because of the pharmacological properties of the active ingredient, special care should be taken when the veterinary medicinal product is used in animals with a weakened immune system.
When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper.
Except in cases of acetonemia and induction of the parturition, corticoid administration is to induce an improvement in clinical signs rather than a cure.
Following intra-articular administration, use of the joint should be minimized for one month and surgery on the joint should not be performed within eight weeks of use of this route of administration.
Only the 25 ml vial should be used to treat cats, dogs and small piglets to prevent excessive puncturing of the closure.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.
The veterinary medicinal product should not be administered by pregnant women.

Pregnancy and lactation:
Do not administer the veterinary medicinal product in pregnant females, except where the intention is to induce parturition. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy is likely to cause abortion or early calving in ruminants and may have a similar effect in other species.
Use of the veterinary medicinal product in lactating cows may cause a reduction in milk yield.

Interaction with other medicinal products and other forms of interaction:
Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.
Because corticosteroids can reduce the immunoresponse to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.
Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from heart glycosides. The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.
Concurrent use with anticholinestaerase may lead to increased muscle weakness in patients with myasthenia gravis.
Glucocorticoids antagonise the effects of insulin.
Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethasone.

Overdose:
An overdose can induce drowsiness and lethargy in horses. Refer to section ‘Adverse events’.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

Horses, cattle, pigs, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polydipsia[1], polyphagia[1] Polyuria[1] Hypokalaemia[2], changes in blood biochemical and haematological parameters, hyperglycaemia[3] Hepatomegaly[4] Pancreatitis[5] Laminitis
Undetermined frequency (cannot be estimated from the available data)	Iatrogenic hyperadrenocorticism (Cushing's disease)[6] Sodium retention[2], water retention[2] Cutaneous calcinosis Delayed wound healing, weakened resistance to or exacerbation of existing infections[7] Gastrointestinal ulceration[8] Retained placenta, metritis, subfertility Milk production decrease

[1] After systemic administration and particularly during early stages of therapy.
[2] Upon long-term use.
[3] Transient.
[4] With increased serum hepatic enzymes.
[5] Increased risk of acute pancreatitis.
[6] Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g., redistribution of body fat, muscle weakness and wastage and osteoporosis may result.
[7] In the presence of bacterial infection, antibacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.
[8] May be exacerbated in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

Corticosteroids are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe adverse reactions with long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control clinical signs.

During therapy effective doses suppress the hypothalamo-pituitreal adrenal axis. Following cessation of treatment, signs of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment (for further information see standard texts).

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

Horses: Intravenous, intramuscular, intraarticular, intrabursal or local use.
Cattle, pigs, dogs and cats: Intramuscular use.

For the treatment of inflammatory or allergic conditions the following average doses are advised. However the actual dose used should be determined by the severity of the signs and the length of time for which they have been present.

Species **Dosage**

Horses, cattle, pigs	0.06 mg/kg body weight corresponding to 1.5 ml/50 kg
Dogs, cats	0.1 mg/kg body weight corresponding to 0.5 ml/10 kg

For the treatment of primary ketosis in cattle
0.02 to 0.04 mg/kg body weight corresponding to 5-10 ml per cow given by intramuscular injection is recommended dependent on the size of the cow and the duration of the signs. Care should be taken not to overdose Channel Island breeds. Larger doses will be required if the signs have been present for some time or if relapsed animals are being treated.

For the induction of calving
0.04 mg/kg body weight corresponding to 10 ml per cow as a single intramuscular injection of after day 270 of pregnancy.
Calving will normally occur within 48-72 hours.

For the treatment of inflammation of joints, bursas or tendon(sheath)s by single intra-articular, intrabursal or local injection in the horse

Dosage 1-5 ml

These quantities are not specific and are quoted purely as a guide. Injections into joint spaces or bursae should be preceded by the removal of an equivalent volume of synovial fluid. Strict asepsis is essential.

9. Advice on correct administration

To measure small volumes of less than 1 ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

10. Withdrawal periods

Cattle	Meat and offal: 8 days
	Milk: 72 hours
Pigs	Meat and offal: 2 days
Horses	Meat and offal: 8 days
	Not authorised for use in horses producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C. Do not freeze. Keep the vial in the outer carton.

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

Cardboard box with 1 x 25 ml, 50 ml or 100 ml vial.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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:

Manufacturer responsible for batch release:
Eurovet Animal Health B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands

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