

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

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXAMETHASONE VMD 2 mg/mL Solution for injection for cattle, pigs, goats, horses, dogs and cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains :

Active substance :

Dexamethasone 2.0 mg
Equivalent to 2.63 mg dexamethasone sodium phosphate

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)	15.6 mg
Sodium chloride	-
Sodium citrate	-
Sodium hydroxide (for pH adjustment)	-
Citric acid (for pH adjustment)	-
Water for injections	-

Clear, colourless solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, goats, pigs, dogs and cats.

3.2 Indications for use for each target species

Horses, cattle, goats, pigs, dogs and cats:

Treatment of inflammation and allergic reactions.

Horses:

Treatment of arthritis, bursitis or tenosynovitis.

Cattle:

Treatment of primary ketosis (acetonemia).

Induction of parturition.

Goats:

Treatment of primary ketosis (acetonemia).

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.
 See also section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 product is used in animals with a weakened immune system.

Except in cases of ketosis and induction of parturition, the purpose of corticosteroid administration is to induce an improvement in clinical signs rather than a cure. The underlying disease should be further investigated.

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.

Care should be taken not to overdose Channel Island breeds of cattle.

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

This product contains dexamethasone which can cause allergic reactions in some people. Care should be taken 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.

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

Dexamethasone may affect fertility or the unborn child. To avoid the risk from accidental self-injection, pregnant women should not handle this product.

This product is a skin and eye irritant. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash/irrigate the area with clean running water. Seek medical attention if irritation persists. Wash hands after use.

Other precautions:

None.

3.6 Adverse events

Horses, cattle, goats, pigs, dogs and cats:

Frequency undetermined (cannot be estimated from available data):	Iatrogenic hypercorticism (Cushing's disease) ¹ Polyuria ² , polydipsia ² , polyphagia ² Sodium retention ³ , water retention ³ , hypokalaemia ³ , calcinosis of the skin, delayed wound healing, reduced resistance or exacerbation of existing infections ⁴ Gastrointestinal ulceration ⁵ , hepatomegaly ⁶ Changes in blood biochemical and haematological parameters
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	<p>Hyperglycaemia⁷</p> <p>Retained placenta⁸</p> <p>Reduced calf viability⁹</p> <p>Pancreatitis¹⁰</p> <p>Reduced milk production</p> <p>Laminitis</p> <p>Behavioral changes¹¹</p>
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¹ Involving a significant alteration in fat, carbohydrate, protein and mineral metabolism, for example, redistribution of body fat, muscle weakness and wasting and osteoporosis may result.

² After systemic administration and particularly during the early stages of treatment.

³ In the event of long-term use.

⁴ In the presence of bacterial infection, antibacterial drug coverage is generally required when steroids are used. In viral infections, steroids may aggravate or accelerate disease progression.

⁵ May be exacerbated in patients receiving non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

⁶ With increased serum liver enzymes.

⁷ Transient.

⁸ When used for induction of parturition in cattle, with possible subsequent metritis and/or hypofertility.

⁹ When used for induction of parturition in cattle, particularly at early stages.

¹⁰ Increased risk of acute pancreatitis.

¹¹ Steroids may be associated with behavioral changes in dogs and cats (occasional depression in cats and dogs, aggression in dogs).

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 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

Pregnancy and lactation:

Apart from the use of the veterinary medicinal product to induce parturition in cattle, corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.

Use of corticosteroids in lactating cows and goats may cause a temporary reduction in milk yield.

In suckling animals, the veterinary medicinal product should be used only according to the benefit-risk assessment by the responsible veterinarian.

See section 3.6.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent use with non-steroidal anti-inflammatory drugs (NSAIDs) may exacerbate gastrointestinal tract ulceration.

Because corticosteroids can reduce the immune response 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 anticholinesterase 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.

3.9 Administration routes and dosage

Horses

Intravenous, intramuscular, intraarticular and peri-articular use.

Cattle, goats and pigs

Intravenous and intramuscular use.

Dogs and cats

Intravenous, intramuscular and subcutaneous use.

For the treatment of inflammatory or allergic conditions the following 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, goats, pigs	0.06 mg of dexamethasone/kg bw (1.5 ml of product/50 kg bw)
Dog, cat	0.1 mg of dexamethasone/ kg bw (0.5 ml of product/10 kg bw)

To ensure a correct dosage, body weight should be determined as accurately as possible.

For the treatment of primary ketosis in cattle and goats (acetoaemia): a dose of 0.02-0.04 mg of dexamethasone/kg bw (cattle: 5-10 ml of product per 500 kg bw; goats: 0.65-1.3 ml of product per 65 kg bw) given by single intramuscular injection is advocated dependent on the size of the animal and the duration of the signs. Larger doses (i.e. 0.04 mg/kg) will be required if the signs have been present for some time or if relapsed animals are being treated.

For the induction of parturition in cattle - to avoid foetal oversize and mammary oedema. A single intramuscular injection of 0.04 mg of dexamethasone/kg bw (corresponding to 10 ml of product for a cow weighing 500kg) after day 260 of pregnancy. Parturition will normally occur within 48-72 hours.

For the treatment of arthritis, bursitis or tenosynovitis by intra-articular or periarticular injection in the horse.

Dose: 0.125 - 5 ml of product per treatment

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. In horses producing food intended for human consumption a total dose of 0.06 mg dexamethasone/kg bw should not be exceeded. Strict asepsis is essential.

The stopper of the 25, 50 and 100 mL vials may be punctured up to 20 times.

When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper. The draw-off needle should be removed after treatment.

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

High doses of corticosteroids can cause sleepiness and lethargy in horses.

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 and goats:

Meat and offal: 8 days.

Milk: 3 days.

Horses:

Meat and offal: 8 days.

Milk: Not authorised for use in mares producing milk for human consumption.

Pigs:

i.m. injection

Meat and offal: 2 days.

i.v. injection

Meat and offal: 6 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QH02AB02

4.2 Pharmacodynamics

Dexamethasone is a potent synthetic glucocorticoid with low mineralocorticoid activity. Dexamethasone has ten to twenty times the anti-inflammatory activity of prednisolone at an equivalent molar dose. Corticosteroids can reduce the immune response by inhibiting capillary dilation, leukocytes migration and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis. Administration of dexamethasone mimics the effects of cortisol and therefore produces a signal that initiates induction of parturition in ruminants if the foetus is alive.

4.3 Pharmacokinetics

After intramuscular administration, dexamethasone sodium phosphate is quickly absorbed and hydrolysed to dexamethasone (base), giving a quick response of short duration (approximately 48 hours). The T_{max} in cattle, goats, horses, pigs, dogs and cats is reached in the first 30 minutes after intramuscular administration. The $T_{1/2}$ (half-life) varies between 5 and 20 hours depending on the species. Bioavailability after intramuscular administration is approximately 100%.

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: 30 months.

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

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Type I colourless glass vials: 25 mL, 50 mL, 100 mL

Chlorobutyl rubber stoppers with aluminium cap.

Each vial is packaged in a cardboard box.

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

V.M.D. n.v.

7. MARKETING AUTHORISATION NUMBER(S)

XXXX

Box of 1 vial of 25 mL

Box of 1 vial of 50 mL

Box of 1 vial of 100 mL

8. DATE OF FIRST AUTHORISATION

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

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

{DD/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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 25 mL
Box of 50 mL
Box of 100 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXAMETHASONE VMD 2 mg/mL Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Dexamethasone 2.0 mg/mL
Equivalent to 2.63 mg/mL dexamethasone sodium phosphate

3. PACKAGE SIZE

25 mL
50 mL
100 mL

4. TARGET SPECIES



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Horses: i.m., i.v., intraarticular, periarticular
Cattle, goats and pigs: i.m., i.v.
Dogs and cats: s.c., i.m., i.v.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle and goats:

Meat and offal: 8 days

Milk: 3 days

Horses:

Meat and offal: 8 days

Milk: Not authorised for use in mares producing milk for human consumption.

Pigs:

i.m. injection

Meat and offal: 2 days

i.v. injection

Meat and offal: 6 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

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

V.M.D. n.v.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 100 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXAMETHASONE VMD 2 mg/mL Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Dexamethasone 2.0 mg/mL
Equivalent to 2.63 mg/mL dexamethasone sodium phosphate

3. TARGET SPECIES



4. ROUTES OF ADMINISTRATION

Horses: i.m., i.v., intraarticular, periarticular
Cattle, goats and pigs: i.m., i.v.
Dogs and cats: s.c., i.m., i.v.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle and goats:

Meat and offal: 8 days

Milk: 3 days

Horses:

Meat and offal: 8 days

Milk: Not authorised for use in mares producing milk for human consumption.

Pigs:

i.m. injection

Meat and offal: 2 days

i.v. injection

Meat and offal: 6 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

V.M.D. n.v.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials of 25 and 50 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXAMETHASONE VMD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Dexamethasone 2.0 mg/mL
Equivalent to 2.63 mg/mL dexamethasone sodium phosphate

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

DEXAMETHASONE VMD 2 mg/mL Solution for injection for cattle, pigs, goats, horses, dogs and cats.

2. Composition

Each mL contains:

Active substance:

Dexamethasone: 2.0 mg

Equivalent to 2.63 mg dexamethasone sodium phosphate

Excipients:

Benzyl alcohol (E1519): 15.6 mg

Clear, colourless solution, free from visible particles.

3. Target species



Horses,



cattle,



goats,



pigs,



dogs and



cats.

4. Indications for use

Horses, cattle, goats, pigs, dogs and cats:

Treatment of inflammation and allergic reactions.

Horses:

Treatment of arthritis, bursitis or tenosynovitis.

Cattle:

Treatment of primary ketosis (acetonemia).

Induction of parturition.

Goats:

Treatment of primary ketosis (acetonemia).

5. 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.

See also section Pregnancy and lactation.

6. Special warnings

Special precautions for safe use in the target species:

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 product is used in animals with a weakened immune system.

Except in cases of ketosis and induction of parturition, the purpose of corticosteroid administration is to induce an improvement in clinical signs rather than a cure. The underlying disease should be further investigated.

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.

Care should be taken not to overdose Channel Island breeds of cattle.

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

This product contains dexamethasone which can cause allergic reactions in some people. Care should be taken 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.

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

Dexamethasone may affect fertility or the unborn child. To avoid the risk from accidental self-injection, pregnant women should not handle this product.

This product is a skin and eye irritant. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash/irrigate the area with clean running water. Seek medical attention if irritation persists. Wash hands after use.

Pregnancy and lactation:

Apart from the use of the veterinary medicinal product to induce parturition in cattle, corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.

Use of corticosteroids in lactating cows and goats may cause a temporary reduction in milk yield.

In suckling animals, the veterinary medicinal product should be used only according to the benefit-risk assessment by the responsible veterinarian.

See section Adverse events.

Interaction with other medicinal products and other forms of interaction:

Concurrent use with non-steroidal anti-inflammatory drugs (NSAIDs) may exacerbate gastrointestinal tract ulceration.

Because corticosteroids can reduce the immune response 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 anticholinesterase 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:

High doses of corticosteroids can cause sleepiness and lethargy in horses.

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, goats, pigs, dogs and cats:

Frequency undetermined (cannot be estimated from available data):	Iatrogenic hypercorticism (Cushing's disease) ¹ Polyuria ² , polydipsia ² , polyphagia ² Sodium retention ³ , water retention ³ , hypokalaemia ³ , calcinosis of the skin, delayed wound healing, reduced resistance or exacerbation of existing infections ⁴ Gastrointestinal ulceration ⁵ , hepatomegaly ⁶ Changes in blood biochemical and haematological parameters Hyperglycaemia ⁷ Retained placenta ⁸ Reduced calf viability ⁹ Pancreatitis ¹⁰ Reduced milk production Laminitis Behavioral changes ¹¹
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¹ Involving a significant alteration in fat, carbohydrate, protein and mineral metabolism, for example, redistribution of body fat, muscle weakness and wasting and osteoporosis may result.

² After systemic administration and particularly during the early stages of treatment.

³ In the event of long-term use.

⁴ In the presence of bacterial infection, antibacterial drug coverage is generally required when steroids are used. In viral infections, steroids may aggravate or accelerate disease progression.

⁵ May be exacerbated in patients receiving non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

⁶ With increased serum liver enzymes.

⁷ Transient.

⁸ When used for induction of parturition in cattle, with possible subsequent metritis and/or hypofertility.

⁹ When used for induction of parturition in cattle, particularly at early stages.

¹⁰ Increased risk of acute pancreatitis.

¹¹ Steroids may be associated with behavioral changes in dogs and cats (occasional depression in cats and dogs, aggression in dogs).

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 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 (i.v.), intramuscular (i.m.), intraarticular and peri-articular use.

Cattle, goats and pigs

Intravenous and intramuscular use.

Dogs and cats

Intravenous, intramuscular and subcutaneous (s.c.) use.

For the treatment of inflammatory or allergic conditions the following 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, goats, pigs	0.06 mg of dexamethasone/kg bw (1.5 ml of product/50 kg bw)
Dog, cat	0.1 mg of dexamethasone/ kg bw (0.5 ml of product/10 kg bw)

To ensure a correct dosage, body weight should be determined as accurately as possible.

For the treatment of primary ketosis in cattle and goats (acetoaemia): a dose of 0.02-0.04 mg of dexamethasone/kg bw (cattle: 5-10 ml of product per 500 kg bw; goats: 0.65-1.3 ml of product per 65 kg bw) given by single intramuscular injection is advocated dependent on the size of the animal and the duration of the signs. Larger doses (i.e. 0.04 mg/kg) will be required if the signs have been present for some time or if relapsed animals are being treated.

For the induction of parturition in cattle - to avoid foetal oversize and mammary oedema. A single intramuscular injection of 0.04 mg of dexamethasone/kg bw (corresponding to 10 ml of product for a cow weighing 500kg) after day 260 of pregnancy. Parturition will normally occur within 48-72 hours.

For the treatment of arthritis, bursitis or tenosynovitis by intra-articular or periarticular injection in the horse.

Dose: 0.125 - 5 ml of product per treatment

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. In horses producing food intended for human consumption a total dose of 0.06 mg dexamethasone/kg bw should not be exceeded. Strict asepsis is essential.

9. Advice on correct administration

The stopper of the 25, 50 and 100 mL vials may be punctured up to 20 times.

When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper. The draw-off needle should be removed after treatment.

10. Withdrawal periods

Cattle and goats:

Meat and offal: 8 days.

Milk: 3 days.

Horses:

Meat and offal: 8 days.

Milk: Not authorised for use in mares producing milk for human consumption.

Pigs:

i.m. injection

Meat and offal: 2 days

i.v. injection

Meat and offal: 6 days

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and the 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 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 vial of 25 mL

Cardboard box with 1 vial of 50 mL

Cardboard box with 1 vial of 100 mL

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

V.M.D. n.v.
HOGE MAUW 900
2370 ARENDONK
BELGIUM
+32 (0) 14 67 20 51
pv@inovet.eu

Manufacturer responsible for batch release:

LABORATOIRES BIOVE
3 RUE DE LORRAINE
62510 ARQUES
FRANCE
+33 (0)3 21 98 21 21