

[Version 9.1,11/2024]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfenil 40 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Tolfenamic acid..... 40.0 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 (E-1519)	10.4 mg
Sodium formaldehyde sulfoxylate	5.0 mg
Ethanolamine	
Diethylene glycol monoethyl ether	
Water for injections	

Clear, yellowish solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, dogs, and cats.

3.2 Indications for use for each target species

Cattle:

- As an adjunct in the reduction of acute inflammation associated with respiratory diseases.
- As an adjunct in the treatment of acute mastitis.

Pigs:

- As an adjunct in the treatment of metritis, mastitis and agalactia syndrome.

Dogs:

- For the treatment of inflammatory and painful postoperative syndromes.
- For the reduction of postoperative pain.

Cats:

- As an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with cardiac disease, impaired hepatic function, or acute renal insufficiency.
Do not use in case of ulceration or digestive bleeding or in case of blood dyscrasia.
Do not inject intramuscularly in cats.

Avoid its use in dehydrated, hypovolemic, or hypotensive animals, due to its potential risk of increasing renal toxicity.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Concurrent administration of potential nephrotoxic drugs should be avoided. It is preferable that the product is not administered to animals undergoing general anaesthesia until fully recovered.

The scale of pain relief after pre-operative administration in dogs may be influenced by the severity and duration of the operation.

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

To avoid renal insufficiency, an adequate drinking water supply for the animals has to be ensured during treatment.

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

The veterinary medicinal product may cause skin sensitisation. People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) or to benzyl alcohol should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin or eyes.

In case of accidental contact, wash immediately exposed area with plenty of clean water.

Wash hands after use.

Administer the veterinary medicinal product with caution to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

If there is suspicion of a hypersensitivity reaction following accidental exposure, appropriate treatment should be administered. 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

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	- Collapse ¹
Undetermined frequency (cannot be estimated from the available data):	- Injection site reaction

¹ After rapid intravenous injection. When administered intravenously, the product should be injected slowly. After the first signs of intolerance appear, stop the injection.

Dogs and cats:

Undetermined frequency (cannot be estimated from the available data):	- Anorexia ¹ , polydipsia ¹ - Vomiting ¹ , diarrhoea ¹ , blood in faeces ¹ - Polyuria ¹ - Injection site reaction ¹
---	---

¹ Usually disappear spontaneously upon suppression of treatment

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

Cattle and pigs:

The results of the studies carried out in the rat and in the rabbit showed no teratogenic effect. Peri and postnatal studies performed in the rat showed that tolfenamic acid has no influence on the evolution of viability, the gestation index, or the appearance of malformations. Use only according to the benefit-risk assessment by the responsible veterinarian.

Dogs and cats:

The safety of the veterinary medicinal product has not been established in dogs and cats during pregnancy and lactation. The use is not recommended during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

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

Do not administer in conjunction with anticoagulants.

Avoid simultaneous administration of potentially nephrotoxic drugs.

Do not administer in conjunction with glucocorticoids.

3.9 Administration routes and dosage

Cattle: Intramuscular (i.m.) and intravenous (i.v.) use.

Pigs: Intramuscular use.

Dogs: Intramuscular and subcutaneous use.

Cats: Subcutaneous (s.c.) use.

Cattle:

- As an adjunct in the reduction of acute inflammation associated with respiratory diseases: 2 injections of 2 mg of tolfenamic acid /kg b.w. (equivalent to 1 ml of the veterinary medicinal product/20 kg b.w. each one), by i.m. route in the neck muscles, separate by 48 hours. Do not exceed 20 ml per injection site.

- As an adjunct in the treatment of acute mastitis: 4 mg of tolafenamic acid/kg b.w. (equivalent to 1 ml of the veterinary medicinal product/10 kg b.w.) by i.v. route, in a single dose.

Pigs:

- As an adjunct in the treatment of Metritis Mastitis Agalactia syndrome: 2 mg of tolafenamic acid/kg b.w. (equivalent to 1 ml of the veterinary medicinal product/20 kg b.w.) by i.m. route in the neck muscles, in a single dose. Do not exceed 20 ml per injection site.

Dogs:

- For the treatment of inflammatory and painful postoperative syndromes: 4 mg of tolafenamic acid/kg b.w. (equivalent to 1 ml of the veterinary medicinal product/10 kg b.w.) by i.m. or s.c. route. This dose can be repeated after 24 hours.
- For the reduction of postoperative pain: 4 mg of tolafenamic acid/kg b.w. (equivalent to 1 ml of the veterinary medicinal product/10 kg b.w.), by i.m. route, in a single dose, one hour before induction to anaesthesia.

Cats:

- As an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate: 4 mg of tolafenamic acid/kg b.w. (equivalent to 1 ml of the veterinary medicinal product /10 kg b.w.), by s.c. route. This dose can be repeated after 24 hours.
Do not use i.m. route in cats.

In animals of reduced weight, it is advisable to use insulin-type syringes to ensure a correct dosage.

The stopper should not be punctured more than 50 times in 250 ml vials and 25 times in 20 ml and 100 ml vials. The user should choose the most appropriate vial size according to the target species to treat.

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

Cattle:

Tolerance studies in cattle allowed to define that a dose 4 times higher than the therapeutic one (16 mg/kg b.w.) could constitute the margin of safety for administration of the veterinary medicinal product.

At doses of 18 and 20 mg/kg b.w. (4.5 and 5 times the therapeutic dose), signs of central toxicity in the form of agitation, balance disorders and motor incoordination were transiently recorded.

Significant variations were recorded in haematological and biochemical parameters that corresponded to transient modifications of digestive and liver functions.

Pigs:

Tolafenamic acid is well tolerated (doses up to 5 times higher than the therapeutic dose), although there may be reactions at the injection site that are intense and spontaneously recover in 7-14 days.

Dogs and cats:

The symptoms described in the section 3.6 Adverse events may appear exacerbated. In this case, it is recommended to suspend the treatment and initiate a symptomatic treatment.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal period

Cattle:

Intramuscular injection:

Meat and offal: 12 days.

Milk: Zero hours.

Intravenous injection:

Meat and offal: 4 days.

Milk: 24 hours.

Pigs:

Meat and offal: 16 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AG02

4.2 Pharmacodynamics

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

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

4.3 Pharmacokinetics

In cattle and pigs, tolfenamic acid, administered by IM route at a dose of 2 mg/kg b.w., is rapidly absorbed from the injection site, reaching maximum mean plasma concentrations of around 1.4 µg/ml in cattle and 2.3 µg/ml in pigs in approximately 1 hour, with a volume of distribution of about 1.3 l/kg in both species and a plasma albumin binding > 97%.

In dogs, tolfenamic acid is easily absorbed. After parenteral administration of a dose of 4 mg/kg b.w., a maximum plasma concentration of about 4 µg/ml (s.c) and 3 µg/ml (i.m.) is obtained after two hours.

In cats, absorption is rapid. After one hour of parenteral administration of 4 mg/kg b.w., a peak of 3.9 µg/ml is recorded.

Tolfenamic acid is distributed in all organs with a higher concentration in plasma, digestive tract, liver, lungs, and kidneys, being on the contrary very weak in brain. Tolfenamic acid and its metabolites cross the placenta in a small proportion.

In extracellular fluids, concentrations are similar to those of plasma in both healthy and inflamed peripheral tissues.

It also appears in milk in active form, mainly associated with the curds.

Tolfenamic acid follows an enterohepatic cycle that ensures a longer duration of therapeutic concentrations in plasma.

The elimination half-life of tolfenamic acid varies between 3-5 hours in pigs and 8-15 hours in bovines.

It is excreted fundamentally unaltered by urinary (~ 70%), biliary and fecal (~ 30%) in both species. The milk excretion is negligible.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening of the immediate packaging: 28 days.

5.3. Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type II amber glass vials closed with type I bromobutyl rubber stoppers and flip-off caps.

Pack sizes:

Cardboard box with 1 vial of 20 ml
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 ml

Cardboard box with 5 vials of 20 ml
Cardboard box with 10 vials of 100 ml
Cardboard box with 15 vials of 250 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

MEVET S.A.U.

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

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 1 vial of 20 ml
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 ml
Cardboard box with 5 vials of 20 ml
Cardboard box with 10 vials of 100 ml
Cardboard box with 15 vials of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfenil 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tolfenamic acid..... 40.0 mg

3. PACKAGE SIZE

20 ml
100 ml
250 ml
5 x 20 ml
10 x 100 ml
15 x 250 ml

4. TARGET SPECIES

Cattle, pigs, dogs, and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: For intramuscular and intravenous use.
Pigs: For intramuscular use.
Dogs: For intramuscular and subcutaneous use.
Cats: For subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal: Intramuscular route: 12 days. Intravenous route: 4 days.

Milk: Intramuscular route: zero hours. Intravenous route: 24 hours.

Pigs:

Meat and offal: 16 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

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

MEVET S.A.U.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial (20 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfenil

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Tolfenamic acid..... 40.0 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

Once opened, use by:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial (100 ml / 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfenil 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Tolfenamic acid.....40.0 mg

3. TARGET SPECIES

Cattle, pigs, dogs, and cats.

4. ROUTES OF ADMINISTRATION

Cattle: for intramuscular and intravenous use.

Pigs: for intramuscular use.

Dogs: for intramuscular and subcutaneous use.

Cats: for subcutaneous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal: Intramuscular route: 12 days. Intravenous route: 4 days.

Milk: Intramuscular route: zero hours. Intravenous route: 24 hours.

Pigs:

Meat and offal: 16 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

Once opened use by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MEVET S.A.U.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Tolfenil 40 mg/ml solution for injection

2. Composition

Each ml contains:

Active substance:

Tolfenamic acid..... 40.0 mg

Excipients:

Benzyl alcohol (E 1519) 10.4 mg

Sodium formaldehyde sulfoxylate..... 5.0 mg

Clear, yellowish solution, free from visible particles.

3. Target species

Cattle, pigs, dogs, and cats.

4. Indications for use

Cattle:

- As an adjunct in the reduction of acute inflammation associated with respiratory diseases.
- As an adjunct in the treatment of acute mastitis.

Pigs:

- As an adjunct in the treatment of metritis, mastitis and agalactia syndrome.

Dogs:

- For the treatment of inflammatory and painful postoperative syndromes.
- For the reduction of postoperative pain.

Cats:

- As an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate.

5. Contraindications

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

Do not use in animals with cardiac, impaired hepatic function or acute renal insufficiency.

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

Do not inject intramuscularly in cats.

Avoid its use in dehydrated, hypovolemic, or hypotensive animals, due to its potential risk of increasing renal toxicity.

6. Special warnings

Special warnings for safe use in the target species:

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

Concurrent administration of potential nephrotoxic drugs should be avoided. It is preferable that the product is not administered to animals undergoing general anaesthesia until fully recovered.

The scale of pain relief after pre-operative administration in dogs may be influenced by the severity and duration of the operation.

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

To avoid renal insufficiency, an adequate drinking water supply for the animals has to be ensured during treatment.

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

The veterinary medicinal product may cause skin sensitisation. People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) or to benzyl alcohol should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin or eyes.

In case of accidental contact, wash immediately exposed area with plenty of clean water.

Wash hands after use.

Administer the veterinary medicinal product with caution to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

If there is suspicion of a hypersensitivity reaction following accidental exposure, appropriate treatment should be administered. Seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

Cattle and pigs:

The results of the studies carried out in the rat and in the rabbit showed no teratogenic effect. Peri and postnatal studies performed in the rat showed that tolfenamic acid has no influence on the evolution of viability, the gestation index, or the appearance of malformations.

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

Dogs and cats:

The safety of the veterinary medicinal product has not been established in cats and dogs during pregnancy and lactation.

The use is not recommended during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:

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

Do not administer in conjunction with anticoagulants.

Avoid simultaneous administration of potentially nephrotoxic drugs.

Do not administer in conjunction with glucocorticoids.

Overdose:

Cattle:

Tolerance studies in cattle allowed to define that a dose 4 times higher than the therapeutic one (16 mg/kg b.w.) could constitute the margin of safety for administration of the veterinary medicinal product.

At doses of 18 and 20 mg / kg b.w. (4.5 and 5 times the therapeutic dose), signs of central toxicity, in the form of agitation, balance disorders and motor incoordination were transiently recorded.

Significant variations were recorded in haematological and biochemical parameters that corresponded to transient modifications of digestive and liver functions.

Pigs:

Tolfenamic acid is well tolerated (doses up to 5 times higher than the therapeutic dose), although there may be reactions at the injection site that are intense and spontaneously recover in 7-14 days.

Dogs and cats:

The symptoms described in the section *Adverse events* may appear exacerbated. In this case, it is recommended to suspend the treatment and initiate a symptomatic treatment.

Special restrictions for use and special conditions for use:

Major incompatibilities:

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

7. Adverse events

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	- Collapse ¹
Undetermined frequency (cannot be estimated from the available data):	- Injection site reaction

¹ After rapid intravenous injection. When administered intravenously, the product should be injected slowly. After the first signs of intolerance appear, stop the injection.

Dogs and cats:

Undetermined frequency (cannot be estimated from the available data):	- Anorexia ¹ , polydipsia ¹ - Vomiting ¹ , diarrhoea ¹ , blood in faeces ¹ - Polyuria ¹ - Injection site reaction ¹
---	---

¹ Usually disappear spontaneously upon suppression of treatment

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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

Cattle: Intramuscular (i.m.) and intravenous (i.v.) use.

Pigs: Intramuscular use.

Dogs: Intramuscular and subcutaneous use.

Cats: Subcutaneous (s.c.) use.

Cattle:

- As an adjunct in the reduction of acute inflammation associated with respiratory diseases: 2 injections of 2 mg of tolfenamic acid/kg b.w. (equivalent to 1 ml of the veterinary medicinal product/20 kg b.w. each one), by i.m. route in the neck muscles, separate by 48 hours. Do not exceed 20 ml per injection site.
- As an adjunct in the treatment of acute mastitis: 4 mg of tolfenamic acid/kg bodyweight (equivalent to 1 ml of the veterinary medicinal product/10 kg b.w.) by i.v. route, in a single dose.

Pigs:

- As an adjunct in the treatment of Metritis Mastitis Agalactia syndrome: 2 mg of tolfenamic acid/kg b.w. (equivalent to 1 ml of the veterinary medicinal product/20 kg b.w.) by i.m. route in the neck muscles, in a single dose. Do not exceed 20 ml per injection site.

Dogs:

- For the treatment of inflammatory and painful postoperative syndromes: 4 mg of tolfenamic acid/kg b.w. (equivalent to 1 ml of the veterinary medicinal product/10 kg b.w.) by i.m. or s.c. route. This dose can be repeated after 24 hours.
- For the reduction of postoperative pain: 4 mg of tolfenamic acid/kg bw (equivalent to 1 ml of the veterinary medicinal product/10 kg b.w.), by i.m. route, in a single dose, one hour before induction to anaesthesia.

Cats:

- As an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate: 4 mg of tolfenamic acid/kg bw (equivalent to 1 ml of the veterinary medicinal product/10 kg b.w.) by s.c. route. This dose can be repeated after 24 hours. Do not use i.m. route in cats.

The stopper should not be punctured more than 50 times in 250 ml vials and 25 times in 20 ml and 100 ml vials.

9. Advice on correct administration

The user should choose the most appropriate vial size according to the target specie to treat. In animals of reduced weight, it is advisable to use insulin-type syringes to ensure a correct dosage.

10. Withdrawal periods

Cattle:

Intramuscular injection:

Meat and offal: 12 days.

Milk: Zero hours.

Intravenous injection:

Meat and offal: 4 days.

Milk: 24 hours.

Pigs:

Meat and offal: 16 days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening of 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

Pack sizes:

Cardboard box with 1 vial of 20 ml

Cardboard box with 1 vial of 100 ml

Cardboard box with 1 vial of 250 ml

Cardboard box with 5 vials of 20 ml

Cardboard box with 10 vials of 100 ml

Cardboard box with 15 vials of 250 ml

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

MEVET S.A.U.

Polígono Industrial El Segre, p. 409-410, 25191 Lleida (Spain).

Tel.: +34 973210269

regulatorymevet@mevet.es