PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX CONTAINING 1 vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tildren 500 mg lyophilisate for solution for infusion for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 vial contains 500 mg of Tiludronic acid (as disodium salt).

3. PACKAGE SIZE

1 vial

4. TARGET SPECIES

Horses over 3 years of age.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intravenous infusion after reconstitution and dilution.

7. WITHDRAWAL PERIODS

Meat and offal: zero days

Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted and diluted, store at 2°-8°C for no longer than 24 hours.
Any remaining solution should be discarded.

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

AUDEVARD

14. MARKETING AUTHORISATION NUMBER

Vm 44684/5003

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

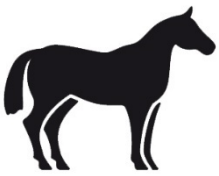
17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {1 VIAL LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tildren 500 mg lyophilisate for solution for infusion for horses



2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

500 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted and diluted, store at 2°-8°C for no longer than 24 hours.
Any remaining solution should be discarded.

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tildren 500 mg lyophilisate for solution for infusion for horses

2. COMPOSITION

Each vial contains:

Active substance:

Tiludronic acid (as disodium salt) 500 mg

After reconstitution: 1 ml solution contains 20 mg tiludronic acid.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Mannitol (E421)	/

Lyophilisate for solution for infusion.
Compact freeze-dried white powder.

3. TARGET SPECIES

Horses over 3 years of age.

4. INDICATIONS FOR USE

As an aid in the treatment of clinical signs of lameness associated with bone spavin in combination with a controlled exercise regime.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
In the absence of any data relating to the adverse effects of tiludronic acid on the skeleton of young animals, do not administer to a horse less than 3 years old.
Do not administer to horses with impaired renal function. Renal function should ideally be evaluated prior to treatment.
Do not use in pregnant or lactating mares (see “Pregnancy and lactation”).

Do not use in horses producing milk for human consumption (see also “Withdrawal periods”).

6. SPECIAL WARNING

Special precautions for safe use in the target species:

The clinical effect of the veterinary medicinal product depends on the presence of osteolytic processes causing pain and leading to lameness. The product should be used only after a proper diagnosis combining a complete orthopaedic clinical examination including local analgesia and appropriate imaging techniques in order to identify the cause of pain and the nature of bone lesions.

It is recommended to respect the recommended 30 minute duration of infusion as the duration of infusion has an effect on the occurrence or severity of the adverse reactions.

It is advisable for an experienced horse person to observe the horse for the first four hours following the infusion due to the possible onset of side effects.

The product should be administered with caution in a hypocalcemic horse. In this case, it is advised to slow down the speed of the infusion. As the risk of side effects might be increased under these circumstances, these animals should be the subject of particularly close surveillance.

Because of its mild hypocalcemic effect, the product should be administered with caution in horses with disorders of heart function. In this case, it is advisable to slow down the speed of infusion.

Adequate access to drinking water should be provided when using the product. If uncertainty exists about renal function, renal parameters should be assessed before administration of the product. Water consumption and urine output should be monitored after administration.

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

Avoid contact with skin and eyes.
Avoid accidental self-injection: it is recommended to insert the intravenous infusion needle into the vein before the reservoir containing the product is connected.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wear impervious gloves when preparing the solution for injection.
Wash hands after use.

Pregnancy and lactation:

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

Studies conducted on laboratory animals (mice, rats, rabbits) did not reveal any embryotoxic, foetotoxic or teratogenic effects nor effects on peri- or post-natal development. Particularly, no adverse effects have been observed on the skeleton.

Interaction with other medicinal products and other forms of interaction:

Do not mix or concomitantly administer intravenously the reconstituted solution with solutions containing divalent metal ions (Ca2+ or Mg2+) such as Lactated Ringers. A solution of tiludronic acid may form complexes with these ions.
Avoid concomitant intravenous administration with drugs that can reduce serum calcium (such as tetracyclines) or whose toxicity can be exacerbated by a reduction in serum calcium (such as aminoglycosides).

Concurrent administration of potentially nephrotoxic substances, such as NSAIDs,

should be approached with caution and renal function should be monitored.

No information is available on the safety and efficacy of this veterinary medicinal product when used with any other veterinary medicinal product.

Overdose:

At 2, 3 or 5 times the recommended dosage, an increase in frequency of the side effects, in particular restlessness, signs of discomfort or signs of colic, is observed.

These signs may appear during or after the infusion, are usually mild and transient and generally resolve spontaneously at the end of the infusion without requiring any specific treatment. In cases where signs persist, conventional treatments should be administered.

Major incompatibilities:

Do not mix or concomitantly administer intravenously the reconstituted solution with solutions containing divalent metal ions (Ca2+ or Mg2+) such as Lactated Ringers. A solution of tiludronic acid may form complexes with these ions. In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal product.

7. ADVERSE EVENTS

Horse:

Common (1 to 10 animals / 100 animals treated):	Colic[1] Discomfort[2] (belly watching, yawning, pawing or kicking, stretching, light bruxism) Restlessness[2] Increased sweating Soft stool
Rare (1 to 10 animals / 10,000 animals treated):	Acute renal failure[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[4] Anaphylaxis[4]
Undetermined frequency (cannot be estimated from the available data):	Recumbency[5]

[1] Signs of colic appear within a few hours following treatment, are mild and generally resolve without any specific treatment. In case signs persist, conventional treatments should be administered. The administration of an alpha 2 adrenergic agonist prior infusion may reduce the occurrence of signs of colic.
[2] An increase in frequency of signs of discomfort and restlessness is observed when the infusion duration is less than 15 minutes.
[3] may occur within 1 week after administration. Renal parameters should be monitored before administration and water consumption and urine output should be monitored where possible after administration. Renal insufficiency is more frequently observed in animals concurrently exposed to NSAIDs. In these cases, appropriate fluid therapy should be instituted, and renal parameters monitored.
[4] signs of reaction ranged from urticaria to anaphylactic shock, which can be fatal. Appropriate treatment should be sought immediately.

^{5} may occur after the infusion. Care should be taken to ensure that the horse can lie down in a comfortable, unrestricted area.

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 the package leaflet for respective contact details.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intravenous infusion after reconstitution and dilution.

1 mg of tiludronic acid per kg of body weight, corresponding to 5 ml of reconstituted solution per 100 kg.

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

Preparation of the ready-to-use solution for infusion:

- Using a sterile needle and a suitable sterile disposable syringe, remove 25 ml of 0.9% Sodium Chloride solution or 5% Glucose solution from a 1 l to 3 l infusion container.
- Add the 25 ml of isotonic Sodium Chloride or Glucose solution to the vial of powder.
- Shake until the powder is completely dissolved. The concentrate appears as a clear, particle free and colourless solution.
- Adhering to strict aseptic technique, inject the reconstituted solution immediately into the infusion container
- Gently invert the container several times.
- Administer through a suitable needle or catheter inserted into the jugular vein and connected to the infusion container with sterile disposable infusion tubing.
- Each vial is for single use only. Cloudy solutions or solutions containing visible solid particles should not be administered.

9. ADVICE ON CORRECT ADMINISTRATION

The product should be infused over 30 minutes at an even rate. Fluctuations in the infusion rate could increase the risk of the horse showing signs of colic during or after the infusion.

Do not exceed the infusion rate as this could increase the risk of the horse showing signs of colic during or after infusion.

Do not exceed the recommended dosage.

10. WITHDRAWAL PERIODS

Meat and offal: zero days

Not authorised for use in animals producing milk for human consumption.

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.
After reconstitution and dilution according to directions, the product may be stored at 2 to 8°C for no longer than 24 hours.

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

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

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.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 44684/5003

A clear glass (type II) vial with chlorobutyl rubber closure secured by aluminium overseal with plastic flip-off cap within cardboard carton.

Pack size: 1 vial

1 vial:

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder, Local representatives and contact details to report suspected adverse reactions:

AUDEVARD
37-39 rue de Neuilly
92110 Clichy
France
pvrc@audevard.com
+33 1 47 56 38 26

17. OTHER INFORMATION

Gavin Hall

Approved 22 June 2024