

XYLASED 100 mg/ml solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Bioveta, a.s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

XYLASED 100 mg/ml solution for injection
Xylazine (as xylazine hydrochloride)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S) 1 ml of the solution for injection contains:

Active substance: Xylazine (as xylazine hydrochloride) 100.0 mg

Excipients: Methylparaben (E218) 1.0 mg
Clear, colourless solution, free of visible particles.

4. INDICATIONS

Cattle:
Sedation, myorelaxation and analgesia for small surgeries.

Horse:
Sedation and myorelaxation.

5. CONTRAINDICATIONS

In general:

Do not administer to animals with cardiovascular insufficiencies and disorders.

Do not administer to animals with signs of arterial hypotension and to animals in shock.

Do not administer to animals with renal insufficiency and urinary tract obstruction.

Do not administer to animals with hepatic insufficiency.

Do not administer to animals with respiratory insufficiency.

Do not administer to debilitated and dehydrated animals.

Do not administer to animals with diabetes mellitus.

Cattle:
Do not administer to animals with rumen dysfunction, gastrointestinal motility disorder and with metabolic acidosis.

Horses:
Do not administer to animals with laminitis

in vasoconstrictive phase.

6. ADVERSE REACTIONS

Cattle:

Bradycardia, hypotension.
Bradypnea to respiratory arrest.

Reversible local irritation when administered intramuscularly.

Increased salivation, inhibited motility of forestomachs, tympanites, inability to move the tongue, regurgitation.

Uterus contractions.

Paradoxical excitation (at higher doses).

Hyperglycemia.

Polyuria with glycosuria.

Transient inhibition of body temperature regulation.

Reversible changes in the blood count (erythropenia, lower hematocrit, leukopenia with lymphopenia and neutrophilia).

Alteration of biochemical parameters in plasma (mild decrease in total protein, higher concentration of urea).

Horse

Bradycardia, reversible arrhythmia and hypotension.

Bradypnea to respiratory arrest.

Paradoxical excitation (at higher doses).

Hyperglycemia.

Polyuria without glycosuria.

Reversible changes in the blood count (reduced hematocrit).

7. TARGET SPECIES

Cattle, horses.

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

Cattle

Method of administration: Single slow intravenous or intramuscular administration.

When administered intramuscularly, the product may be applied by injection or tranquiliser shot.

Recommended doses for individual routes of administration:

i) Intravenous administration: 0.03-0.1 ml of the product/100 kg bw, which is equivalent to a xylazine dose of 0.03-0.1 mg/kg bw

ii) Intramuscular administration: 0.05-0.3 ml of the product/100 kg bw, which is equivalent to a xylazine dose of 0.05-0.3 mg/kg bw

Horse

Method of administration: Single slow

intravenous administration.

Recommended dose: 0.6-1 ml of the product/100 kg bw, which is equivalent to a xylazine dose of 0.6-1.0 mg/kg bw

9. ADVICE ON CORRECT ADMINISTRATION

The product dose is intended for a single administration. The stopper can be punctured up to 50 times.

10. WITHDRAWAL PERIOD

Cattle:

Meat: 3 days.

Milk: 36 hours.

Horse:

Do not use in horses the meat of which

is intended for human consumption.

Do not use in horses the milk of which

is intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach of children.

Protect from frost.

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

Do not use after the expiry date which is stated on the packaging.

Shelf life after first opening the immediate

packaging: 28 days.

12. SPECIAL WARNING(S)

Special warnings for use in animals

The animals sedated using xylazine should be handled carefully. They can be awakened

by external stimuli and make sudden targeted protective movements.

When handling horses, be aware of the hazard of protective movements of the animal's rear legs during sedation.

At intravascular administration, intravenous

administration is preferred. Intraarterial

administration may lead to a collapse.

Special warnings for each target species:

Cattle:

To prevent aspiration of food and saliva, the head and the neck of lying ruminants should be laid down. To minimise the risk of regurgitation, the animals should be fasted and should have a reasonably limited access to water 24 hours prior to administration.

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

Avoid accidental self-administration of injection or tranquiliser shot. Protect the needle until

administration of the product. In case

of accidental ingestion or self-injection seek

medical advice immediately and show the

package leaflet or label to a practitioner. DO

NOT DRIVE A CAR as you may be sedated and

your blood pressure may be changed.

Avoid contact with skin, eyes and mucous membranes. Wash the affected skin immediately with plenty of clean water. Remove contaminated clothing which is in direct contact with the skin.

In case of accidental contact with eyes, rinse immediately with plenty of water. If symptoms appear, seek medical attention.

If the product is handled by a pregnant woman, increased caution is necessary to prevent self-injection. Uterine contraction and decrease in

the blood pressure of the foetus may occur after accidental systemic exposure.

Do not eat, drink or smoke while handling the product.

To the physician:

Xylazine is an alpha-2 adrenoceptor agonist.

Following absorption, the clinical signs may include dose-dependent sedation, respiratory

depression, bradycardia, hypotension, dry mouth and hyperglycemia. Cases of ventricular

arrhythmia have also been reported. Respiratory and hemodynamic signs should be treated

symptomatically.

Incompatibilities

Compatibility studies are not available, therefore

this veterinary medicinal product must not be

mixed with other veterinary medicinal products.

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

Medicines should not be disposed of via

wastewater or household waste.

Any unused veterinary medicinal product or waste materials derived from such veterinary

medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

For animal treatment only.

Veterinary medicinal product subject to

prescription.

For use by veterinary surgeons only.

Pack size:

1 × 10 ml

1 × 50 ml

Not all pack sizes may be marketed.

bioveta



Dimensions (mm):

Colours:

Prepared by:

Date:

A6 (105 × 148 mm) duplex printing

black

Hanáková

17. 5. 2021

Šárka

Approved by: Svobodová

Date: 17. 5. 2021

Digitálně podepsal

Šárka Svobodová

Datum: 2021.05.17

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