Dormi-Xyl® 2

Injectable Solution

Sedative, analgesic, anesthetic and muscle relaxant

Veterinary Use

petmedica

FORMULATION

Each mL contains:

Xylazine hydrochloride.....	20 mg
Excipients.....q.s.ad.....	1 mL

DESCRIPTION

Dormi-Xyl® 2 is a compound of tranquilizer, analgesic, sedative and relaxing action based on xylazine hydrochloride. Its action is associated with depression of the central nervous system.

Dormi-Xyl® 2 is a compound for tranquilization, analgesia, sedation and muscle relaxation in several animal species.

PHARMACODYNAMICS - MECHANISM OF ACTION

Pharmacodynamic data of the Xylazine Hcl

- T_{max} 1.5 to 2.5 hours
- Beginning of action: 30 to 60 min PO
- Duration of the effect: 8 h. PO

Its muscle relaxant effect is based on inhibition of the transmission of nerve impulses to muscle, stimulating the central α2-adrenergic receptors.

Dormi-Xyl® 2's action, the respiratory frequency diminishes, causing a natural dream state; it also diminishes the cardiac frequency, increasing the temperature frequently during a brief time. After its administration, **Dormi-Xyl® 2** causes a moderate and transitory decrease of the arterial pressure (systolic and diastolic), preceded by a brief increase of the same ones. **Dormi-Xyl® 2** can block the central vasomotor reflexes, without altering the postural reflexes. It decreases slightly the cardiac output, plasma renin activity and catecholamine release; **Dormi-Xyl® 2** does not influence the blood coagulation.

PHARMACOKINETICS

- Bioavailability: 95%
- Mean half-live: 12 h + 7 h.
- Effective concentration: 0.2 to 2 ng/mL
- Absorption: Fast in the GIT. The bioavailability with the chronic administration is 65%.
- Distribution: Widespread. It binds to plasma proteins by 20%.
- Metabolism: Hepatic route 50%.
- Excretion: Renal route 40 - 60%; fecal route 20%. It is also excreted in breast milk.

The **Dormi-Xyl® 2** effect's intensity and duration depends of the doses and the administration route.

Considering these facts, the effect's duration can be:

- Sedative effect 30 minutes to several hours.
- Muscle Relaxation: 20 minutes to an hour and a half.
- Analgesic effect: 10 to 45 minutes.

At the recommended doses, **Dormi-Xyl® 2** can be used along with local anesthetics, based in procaine and lidocaine.

INDICATIONS

Marked sedation and moderate analgesia: for minor procedures (e.g. sedation to incorporate the animal to a strange environment, weighing, bandages's changes, removal of sutures, artificial insemination, x-ray, providing local and regional anesthesia, rumenotomy tranquilization, laparotomy, uterine prolapse and torsion treatment, embryotomy, etc.).

Moderate analgesic and tranquilization: For minor surgical procedures, especially in the nipples (e.g. mammillary channel incision, suture of nipple's superficial wounds, hoof treatment, opening abscess, marking, placement of nose rings, foreskin washes, etc.), to handle unmanageable animals. At this dose is not ensured that the animal remains standing, but generally it is possible to stand up.

Intense sedation, analgesia, anesthesia and muscle relaxation: For very painful procedures it is recommended with infiltration or regional anesthesia (e.g. horn amputation, udder surgeries, suture and amputation, castration, penis examination and treatment, hoof cut, cutaneous cauterization, enucleation, tooth extractions, etc.). At this dose the animal almost never can kept on foot.

ADMINISTRATION ROUTE

In cattle, sheep, goats and camelids the drug is injected by intramuscular route only. In horses by intravenous route only. In small animals is commonly used intramuscularly although can also be used intravenously in dogs.

Action time is 5 minutes after intravenous route and 5 to 15 minutes after intramuscular route. Because the action of the drug may be adversely affected by noise, the animal should be allowed to rest quietly until the full effect has been reached.

DOSAGE

Cattle:

Depending on the kind and degree of desired effect, **Dormi-Xyl® 2** is generally administered at doses of 0.25 to 1.5 mL/100 kg body weight. In extensive raising cattle, not domesticated and with tendency to run, it could be necessary a higher dose than in animals of feed-lots to obtain an identical degree of sedation.

In general, it is recommended to follow the table:

DOSE	mL/50 kg	mL/100 kg	mL/500 kg
I	0.12	0.25	1.2
II	0.25	0.5	2.5
III	0.5	1.0	5.0
IV	0.75	1.5	7.5

In certain occasions, the necessary dose is subject to individual variations. If necessary, **Dormi-Xyl® 2** effects could be prolonged and/or get deeper by a second application, when having determined that the first one has not been enough (10 to 15 minutes later).

The IV dose, after deletion of food for several hours, is given only for special cases, in case of very painful or long procedures, or in order to obtain a more persistent and especially intense muscle relaxation.

In these kind of procedures it is convenient the combination of **Dormi-Xyl® 2** with a local or regional anesthesia. The latter can be applied more easily, precise and free of danger.

Given the possibility that in the doses III and IV the animals remain asleep for several hours, it would be necessary to leave them under shadow after the procedure. In an eventual case of overdosage, with respiratory failure, apply cold-water showers and artificial respiration.

* In this specie is able to associate with ketamine.

Horses:

The dose is 3 – 5 mL/100 kg, being usually enough 4 mL/100 kg by IV route.

The dosage is being established depending of the desired sedation grade. The analgesic or the anesthetic effect changes individually and it is lower in horses than in cattle. Nervous and very excited animals need general a higher doses.

Older horses, and the animals that are being treated with **Dormi-Xyl® 2** after physical efforts, respond intensively.

* In this specie, it is able to associate with lidocaine, chloral hydrate , barbiturates (with precaution), halothane or fluothane and ketamine.

Goats, sheep and camelids:

The dose is 0.15 mL/10 kg.

* In these species, it is able to associate with ketamine.

Dogs and cats:

The dose is 0.15 mL/kg of body weight.

*In dogs, it is able to associate with lidocaine, chloral hydrate, barbiturates (with precaution), ether, halothane or fluothane, atropine, acepromazine and ketamine.

WARNINGS

Due to the depressor effect over the CNS, there should be extreme precautions in the case of the use of this product in animals with a severe respiratory depression, cardiac failure or deep shock. In large animals, do not administer by intra-carotid route and, when the endovenous route is used cautions should be taken for jugular route application.

Additional depressive effects can occur with the use of xylazine and barbiturates; barbiturates for anesthesia must be applied in reduced doses and administered slowly by IV route.

PRECAUTIONS

- Precaution in case of pulmonary diseases.
- Leave the animal fasting before prolonged operations.
- Avoid noises and movements in the room until the full effect has been reached.
- Tympany can occur in recumbent ruminants, which disappears raising the animal to sternal recumbency.
- Agrovet Market S.A. is not responsible for the consequences of a different use (of the product) to the one indicated in this leaflet.

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS

- Do not handle this product if you know you are sensitized or if you have been advised not to work with such preparations.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

ADVERSE EFFECTS

At recommended doses slight muscle tremors, cardiac arrhythmia, bradycardia with partial atrioventricular block and decreased respiratory rate can be observed. All these effects reverse spontaneously after the effect of sedation goes away.

Occasionally, it may appear some mild cases of diarrheas, psychomotor disorders and decreased milk production.

Similarly, in some cases, vomiting and polyuria are observed in dogs and cats. It can manifest infrequently hypersensitivity reactions, if they occur, discontinue treatment.

Local reaction (swelling) may occur at the injection site in animals for up to a week after administration

During intravenous administration, shock may occur. In this case the medication be discontinued and appropriate measures will be taken.

CONTRAINDICATIONS

- Because xylazine may induce premature parturition or abortion, it should generally not be used in the last trimester of pregnancy. In this period, it may induce retention of the fetal membranes.
- Concurrent administration of adrenoceptor stimulants is not recommended.
- Do not use in a mechanical obstruction of the GIT, stomach torsions, hernias and other similar situations in dogs and cats.
- It should not be used in animals with preexisting cardiac or respiratory dysfunction.
- Xylazine should not be used in combination with neuroleptics or tranquillizers.
- The use of xylazine should be avoided in ruminants with marked signs of weakening by disease, more specifically, do not administer to animals with hypovolemia or urinary tract obstruction.

WITHDRAWAL PERIOD

In dairy cows, intramuscular doses (0.2 – 0.4 mg/kg) of xylazine are not detected in milk after 5 to 21 hours after the application. Dairy cattle do not excrete xylazine in significant quantities in milk.

- Meat: None.
- Milk: None.

STORAGE

Keep in a cool and dry place, protected from light. Store among 15° to 30° C. Keep out of reach of children and domestic animals.

COMMERCIAL PRESENTATION

10 mL, 20 mL and 100 mL vials.

Reg. SENASA Peru: F.23.01.N.0053; BOLIVIA SENASAG Reg. PUV- Nº 005305/13; Costa Rica: Reg. MAG MV-4169; Reg. Ecuador: 8A1-9550-AGROCALIDAD; Reg. EAU: AUD-APH-10-3021961; Reg. Guatemala: MV-5094; Mexico: REGISTRO Q-0616-047; Reg. Panama: MV-3299; Reg. Rep. Dominicana: 5636.

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Strengthening bonds

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