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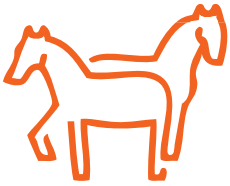
TECHNICAL BULLETIN



The Cost of Re-sedation ("Topping Up") in Equine Power Dentistry

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KEY POINTS

- A study was conducted to determine the sedation protocols and re-sedation (i.e., inadequate primary sedation) rates reported by 10 equine veterinarians in the performance of 363 power-floating procedures.
- The study revealed that the power dentistry test procedure was most profitable when re-sedation did not occur, and that inadequate primary sedation was the key factor contributing to incidence of re-sedation.
- Lack of a standard of care for the equine dentistry procedure resulted in widely varying re-sedation rates ranging from 2.5% to 73.5%, with an overall rate of 27.8%.
- DORMOSEDAN® (detomidine hydrochloride) was used as an alpha-2 agonist sedative in 92.1% of the cases, but usually in combination protocols and, in 67% of the cases, at suboptimal (less than the lowest approved) dose.
- The study revealed five consequences of re-sedation compared to cases where re-sedation was not required: longer procedure time, lower quality of sedation, higher sedation fees to the client, higher sedation costs to the veterinarian, and a decreased effective hourly billing rate (EHBR) for nonsedation charges.
- The three veterinarians with the lowest re-sedation rates (representing 96 cases) had a superior quality-of-sedation score (4.22 vs. 3.15 on a five-point scale from lowest to highest) and a $40.24 better EHBR ($330.32 vs. $290.08) for nonsedation charges when compared with the three veterinarians with highest re-sedation rates (representing 113 cases).
- The two most common causes of re-sedation were a sub-optimal initial sedative dose and failure to allow adequate time (at least 5 minutes) to elapse between administration of the sedative and initiation of the power floating procedure.
- Results indicate that a re-sedation rate of ≤ 10% is an achievable goal and associated with superior case outcomes in terms of quality, time, and compensation.
- Practitioners can establish an effective sedation protocol by using an equine-approved sedative such as DORMOSEDAN at an appropriate primary dose that provides an adequate response, tracking the resedation rate, and adjusting the protocol accordingly.
- An effective sedation protocol may be applied not only to power floating but to any repetitive procedure (eg, diagnostic procedures, examinations, wound treatment) in equine practice.

Sedation plays a vital role in equine practice, helping ensure safety of the veterinarian and other handlers, compassionate care of the horse, and precise and efficient completion of the procedure being performed. As practiced today, equine sedation for standing procedures typically involves administering a combination of any of several sedatives, tranquilizers, or opioid analgesics. Alpha-2 agonists are widely used in these combination protocols because they provide rapid and reversible, dose-dependent sedation, are nonnarcotic (nonscheduled), and produce clinically significant analgesia as well as profound sedation.

Although Zoetis does not endorse extra-label use of products, the practice of multidrug sedation remains the norm in equine medicine. This is partly due to the limitations of xylazine, the original veterinary alpha-2 agonist. Xylazine is short acting, delivers comparatively poor analgesia, and has a lower alpha-2 receptor specificity and potency compared to detomidine hydrochloride (DORMOSEDAN, Zoetis),[1-4] a more potent and selective alpha-2 agonist developed after the introduction of xylazine. This has given rise to the use of various off-label drug combinations for equine sedation, an approach intended to provide a synergistic or supplementary effect to compensate for the limitations of xylazine. Examples include use of DORMOSEDAN and xylazine (two alpha-2 agonists) and DORMOSEDAN or xylazine and butorphanol (an alpha-2 agonist and opioid). When combination protocols are used, each drug is usually given at lower than recommended dosages, often for purposes of reducing drug costs. An important disadvantage of this deliberate underdosing is suboptimal depth and duration of sedation. When that occurs, the horse resumes vigilance, lifts its head, moves about, and needs to be re-sedated or "topped up." This interrupts and prolongs the procedure and adds to drug costs.

The study described in this report evaluated the frequency of re-sedation reported by 10 equine veterinarians and the effect of re-sedation on procedure duration, quality of sedation, and economic return to the veterinarian. Power floating using a motorized grinding tool was used as the test procedure in all cases. This provided a relatively uniform procedure, billable on a cost-plus-fee basis, with minimal variation in time and technique for evaluating outcomes. A large number of cases (n = 363) gave statistical validity to the study.

Study Design

Ten equine practitioners were selected for the study. All 10 participants used DORMOSEDAN as a component of their sedation protocol, either as monotherapy at relatively high doses or combined with other agents at lower than approved doses. Veterinarians administered DORMOSEDAN by the approved intramuscular (IM) or intravenous (IV) routes according to individual preference. A diary study format was used whereby participants provided on-site data in response to a standard set of questions for each case. Each veterinarian documented up to 40 power dentistry cases requiring standing sedation. For each equine patient, the veterinarian recorded the sedation protocol used, whether re-sedation was required, overall duration of the procedure, and quality of sedation achieved as scored on a 1 to 5 scale from lowest to highest quality. If multidrug protocols were used, each drug was identified and the dosage volume and time of administration were indicated.

Participating veterinarians also noted the fee charged for each case, itemized by sedation and nonsedation charges. An average effective hourly rate (EHBR) was calculated for nonsedation fees, the component of the total fee not affected by additional drug costs that can be passed on to the client. The EHBR was prorated by the average time to completion of the procedure, using the following formula:

$$EHBR = Fp \div (Tp \text{ mins} \div 60 \text{ mins}),$$

where EHBR is in dollars, Fp is the fee for the procedure, and Tp is the time for completion of the procedure. Average EHBRs were calculated for cases requiring re-sedation and those requiring primary sedation only.

Results

Sedation Regimens

The 10 participating veterinarians used the sedation regimens shown in Table 1. Four different protocols were used for primary sedation and seven different protocols for re-sedation, usually involving multidrug combinations given at partial dosages of the individual agents used. Five of the 10 veterinarians used DORMOSEDAN in combination with other sedative or analgesic agents as a primary sedation regimen, while four veterinarians used DORMOSEDAN as primary monotherapy. One veterinarian used xylazine and butorphanol as primary cotherapy.

For re-sedation, five veterinarians used regimens that differed from their primary regimen. The remaining five veterinarians used their primary regimens for re-sedation. Two veterinarians used DORMOSEDAN exclusively for primary sedation and re-sedation. DORMOSEDAN was used in 92.1% of the cases in the study, either for primary or secondary sedation or both.

Sedation Dosing Patterns

Table 1 – Sedation Regimens by Veterinarians for Equine Dentistry Cases[5]

Veterinarian	Primary regimen	Re-sedation regimen
1	xylazine/butorphanol	DORMOSEDAN/xylazine
1	DORMOSEDAN/xylazine	xylazine
1	DORMOSEDAN	DORMOSEDAN/diazepam
1	DORMOSEDAN/butorphanol	DORMOSEDAN/butorphanol
1	DORMOSEDAN	DORMOSEDAN/xylazine/acepromazine
1	DORMOSEDAN/butorphanol	xylazine/butorphanol
2	DORMOSEDAN/xylazine	DORMOSEDAN/xylazine
2	DORMOSEDAN	DORMOSEDAN/xylazine

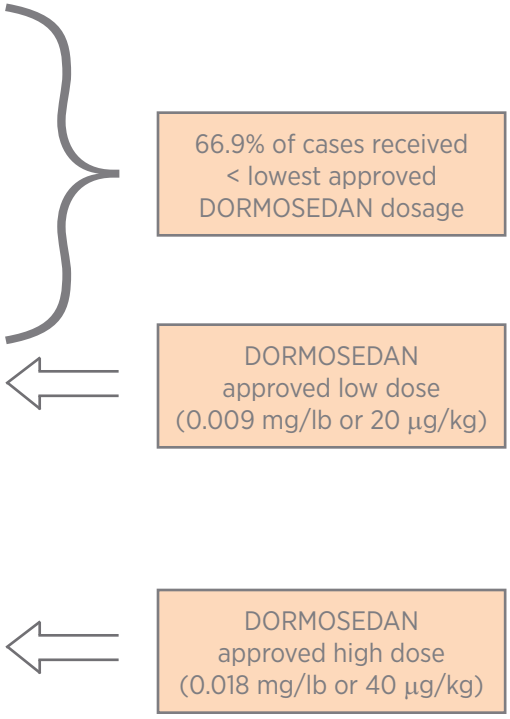
The two most common reasons for needing to re-sedate an animal is:

1. Inadequate level of primary sedation. (too small of a starting dose for that particular animal)
2. Inadequate wait time after giving the sedation before starting the procedure.

All 10 participating veterinarians used DORMOSEDAN in either their primary or secondary protocols. Figure 1 (on page 4) shows the distribution of DORMOSEDAN dosage sizes for 363 cases. In a total of 243 cases (66.9%), the attending veterinarian used DORMOSEDAN at a dosage less than the lowest approved dose of 0.009 mg/lb (20 μg/kg). The highest DORMOSEDAN dose given to any individual horse was 0.016 mg/lb, slightly less than the maximum approved dose of 0.018 mg/lb (40 μg/kg). There were no adverse drug-associated safety events in any horse treated with DORMOSEDAN.

Figure 1 – Distribution of DORMOSEDAN Dosing by Diary Study Participants[5]

Dose Range (mg/lb)	Number of Cases	Percent Cases
< 0.001	29	8.0%
> 0.001, < 0.002	1	0.3%
> 0.002, < 0.003	5	1.4%
> 0.003, < 0.004	33	9.1%
> 0.004, < 0.005	41	11.3%
> 0.005, < 0.006	25	6.9%
> 0.006, < 0.007	72	19.8%
> 0.007, < 0.008	37	10.2%
> 0.008, < 0.009	20	5.5%
> 0.009, < 0.010	18	5.0%
> 0.010, < 0.011	23	6.3%
> 0.011, < 0.012	24	6.6%
> 0.012, < 0.013	10	2.8%
> 0.013, < 0.014	10	2.8%
> 0.014	15	4.1%
TOTAL	363	100%



This chart shows the distribution of DORMOSEDAN dosages for equine dentistry procedures performed by the diary study participants. Only one in three horses (120/363, 33.1%) was treated with DORMOSEDAN at dosages ≥ the minimum approved dose of 0.009 mg/lb (20 µg/kg). The highest DORMOSEDAN dose given to any individual horse was 0.016 mg/lb, less than the maximum approved dosage of 0.018 mg/lb (40 µg/kg).

Xylazine was used at a dose ranging from 0.15 to 0.2 mg/lb, less than the approved equine dosages of 0.22 to 0.45 mg/lb (0.5 to 1.0 mg/kg) for IV administration, or 0.91 to 2 mg/lb (2.0 to 3.0 mg/kg) for IM administration. Butorphanol was used at a dose ranging from 0.002 to 0.005 mg/lb, less than the approved equine dosage of 0.05 mg/lb (0.1 mg/kg) for IV administration.

Sedation Dosing Patterns

Incidence of re-sedation for each of the 10 participating veterinarians is shown in Table 2. The re-sedation rate ranged from 2.5% (for veterinarian 1) to 73.5% (for veterinarian 2). The mean overall resedation rate was 27.8% (101 of 363 cases).

Table 2 – Re-Sedation Rate

Veterinarian	Re-sedation rate	
	No/total cases	%
1	1/40	2.5
2	25/34	73.5
3	11/39	28.2
4	8/40	20.0
5	27/40	67.5
6	2/16	12.5
7	8/40	20.0
8	8/40	20.0
9	7/40	17.5
10	4/34	11.84
Total/Average	101/363	27.8

The two most common causes of re-sedation were:

- A sub-optimal initial sedative dose.
- Failure to allow adequate time (at least 5 minutes) to elapse between administration of the sedative and initiation of the power floating procedure.

Table 3 summarizes the average fees charged for sedation and nonsedation services, average procedure completion times, and average EHBR for nonsedation charges. Average time to completion of the equine dentistry procedure was 5.54 minutes (28%) longer for horses requiring re-sedation compared to those that did not (25.27 vs 19.73 mins). The average time to completion for all cases was 20.98 minutes.

Table 3 – Summary of Average Fees and Completion Times for Equine Dentistry Cases Requiring Re-sedation vs Primary Sedation Only[5]

Case parameter	(1) All cases	(2) Cases requiring re-sedation	(3) Cases requiring only primary sedation	(4) Difference between 2 and 3
No. cases	363 (100%)	101 (27.8%)	262 (72.2%)	
Average sedation fee	$44.09	$57.18	$39.15	$18.03 (46.1%)
Average nonsedation fee	$97.02	$103.94	$94.46	$9.48 (10.0%)
Average total case fee	$140.59	$160.06	$133.31	$26.75 (20.1%)
Ratio nonsedation fee to total fee	0.69	0.65	0.71	0.06
Average completion time (minutes)	20.98	25.27	19.73	5.54 (28.2%)
Average nonsedation EHBR	$277.46	$246.79	$287.26	$40.47 (14.1%)

EHBR=effective hourly billing rate

Table 4 – Average Re-sedation Rate, Quality of Sedation, Duration of Procedure, and EHBR for Equine Dentistry Procedures Performed by Veterinarians with the Three Highest and Three Lowest Re-sedation Rates[5]

Group	Mean re-sedation rate (range)	Mean quality of sedation score*	Mean duration of procedure	Average nonsedation fee	Average nonsedation fee EHBR
(1) Veterinarians with 3 lowest re-sedation rates	8.8% (2.5-12.5%)	4.22	18.6 mins	$102.40	$330.32
(2) Veterinarians with 3 highest re-sedation rates	55.5% (27.5-71.4%)	3.15	21.4 mins	$104.43	$290.08
(3) Total group (n = 10)	27.8% (2.5-73.5%)	3.89	20.98 mins	$97.02	$277.46

*1 = lowest, 5 = highest
EHBR=effective hourly billing rate

As expected, cases requiring re-sedation had a higher average sedation fee ($57.18 vs $39.15), a difference of $18.03 (46.1%) compared to cases requiring primary sedation only. The cases requiring re-sedation also had a somewhat higher average nonsedation fee ($103.94 vs $94.46) and a higher total fee ($160.06 vs $133.31). The average nonsedation fee was a proportionally larger component of the total average fee for cases not requiring re-sedation compared to those that did (ratio of 0.71 vs 0.65), indicating greater time efficiency for the cases not requiring re-sedation. Overall, fees for sedation represented 31% of the average total fee. The average EHBR for the nonsedation fee was $246.79 for cases requiring re-sedation versus $287.26 for those that did not, a difference of $40.47 per hour (14.1%). The average EHBR for all cases was $277.46.

Outcomes for High- and Low-Efficiency Veterinarians

Re-sedation rates, length of procedure, and EHBR for nonsedation charges were calculated for the three veterinarians with the highest re-sedation rates (representing 113 cases) and the three with the lowest re-sedation rates (representing 96 cases). In effect, data for these two groups compared outcomes for high-efficiency and low-efficiency practitioners. As shown in Table 4, there was a 6.3-fold difference between the three lowest and three highest average re-sedation rates (8.8% vs 55.5%), and a 3-fold difference between the average of the three lowest rates and the group average (8.8% vs 27.8%).

There was a linear relationship between the resedation rate and quality of sedation and length of procedure in the comparison of the high- and low efficiency veterinarians (Table 4). The veterinarians with the three lowest re-sedation rates had a mean quality-of-sedation score of 4.22 versus a mean score of 3.15 for the veterinarians with the three highest resedation rates. The mean score for the group overall was 3.89. The average procedure duration was 21.4 minutes for the veterinarians with the three highest re-sedation rates versus 18.6 minutes for those with the three lowest re-sedation rates, a 15% difference. The group mean was 20.98 minutes.

The veterinarians with the three highest re-sedation rates had a mean EHBR for nonsedation charges of $290.08 compared to $330.32 for the veterinarians with the three lowest re-sedation rates, a $40.24 (13.8%) difference. The nonsedation mean EHBR for the three high-efficiency practitioners with an

average 8.8% re-sedation rate exceeded the overall group mean EHBR by $52.86 ($330.32, see Table 4). The nonsedation EHBR for the three high-efficiency veterinarians was $83.53 (33.8%) greater compared to that for all 101 re-sedation cases ($246.79, Table 3).

Discussion

Re-sedation is a consequence of inadequate initial sedation, an outcome that occurred in more than one-fourth of the cases followed in this study. This remarkable rate of re-sedation with its clear-cut adverse effect on procedure time, quality, cost, and income, reflects poorly on sedation protocols used in equine veterinary practice where suboptimal dosages of individual drugs are given. A comparable rate of initial sedation failures in human medicine would be clearly unacceptable.[6,7] For example, a retrospective study of outpatient oral surgery at a major U.S. hospital reported an IV sedation failure rate of 1.6% (9 of 539 cases), more than 17 times the rate reported in the equine dental study described here.[8]

The study revealed that there was little uniformity in sedation protocols for the routine procedure being evaluated. Lack of a consistent sedation protocol resulted in widely divergent outcomes in terms of re-sedation rates, procedure completion times, and EHBR. The broad variation in the sedation agents and dosages (see Table 1 and Figure 1) used by participating veterinarians explains the inconsistency in re- sedation rates, which ranged from 2.5% to 73.5% Various combinations of two alpha-2 agonists (DORMOSEDAN and xylazine), an opioid (butorphanol), and two anxiolytic agents (acepromazine and diazepam) were used. In some cases, there was no consistency even within practices. For example, veterinarian five (see Table 1) used different agents for primary sedation than they did for re-sedation, in some cases using a cocktail of up to three different agents.

There was a wide variation in dosage sizes of the two alpha-2 agonists used, which were generally underdosed. In the case of DORMOSEDAN, dosage varied > 16-fold, from < 0.001 to 0.016 mg/lb (see Figure 1).

Six of the 10 study participants preferred multidrug primary combinations (see Table 1). Combination regimens explain the reduced DORMOSEDAN dosages used in most cases, where veterinarians used partial doses of two or more agents. Diary notations revealed that higher resedation rates were primarily the result of low initial dosages and in some cases due to inadequate time between administration of the sedative agent and initiating the dentistry procedure.

As shown in Figure 1, DORMOSEDAN was given at doses well below the minimum approved level in the majority of horses, in some cases at a fraction of the lowest approved dose. This approach, explained by an attempt to save costs by giving DORMOSEDAN at suboptimal levels, runs the risk of shallow, shortlived sedation and the need for re-sedation in order to complete the procedure. Using partial doses of DORMOSEDAN because of a concern for costs or an overabundance of caution is unnecessary. The safety of DORMOSEDAN at the approved dosages (0.2 or 0.4 mL per 100 kg or 220 lbs) has been convincingly demonstrated.[9] The rapid and profound sedation that occurs following administration is selflimiting. When maximum sedation is reached, excess doses prolong but do not increase the sedative effect of DORMOSEDAN.[10]

Our economic analysis assumes that the increased drug cost resulting from re-sedation will be passed along to the horse owner. In reality, the veterinarian often absorbs the additional drug costs from re-sedation rather than charge the client extra. In such cases, re-sedation not only takes more time but imposes excess drug costs on the veterinarian, making the procedure even less profitable than if re-sedation had not been required.

The ratio of nonsedation fees to total fees was 0.65 for re-sedation cases and 0.71 for non-re-sedation cases, reflecting the relatively greater contribution of the fixed procedural fee to the EHBR. Inadequate sedation increases the drug costs but not the fixed-fee (ie, procedure-related) component of the total fee on a percentage basis, thereby reducing

the EHBR for nonsedation charges. By using a consistent, reliable sedation protocol that minimizes re-sedation, the practitioner reduces total drug costs, which can be passed along to the client, and minimizes excess procedure time, the value of which accrues to the veterinarian.

The study revealed five consequences of re-sedation compared to cases where re-sedation is not required:

- Longer time to procedure completion
- Lower quality of sedation
- Higher sedation fees to the client
- Higher sedation costs to the veterinarian
- A lower EHBR for nonsedation charges

Although not evaluated in this study, subpar sedation may also be assumed to cause a drop-off in quality of technique and procedural efficacy. Study results for time, quality-of-sedation, and EHBR parameters for the veterinarians with the three lowest and three highest re-sedation rates provided a real-world perspective since all veterinarians experience some percentage of sedation failures. Results for the three high-efficiency veterinarians indicate that a re-sedation rate of ≤ 10% is both an achievable goal and an important benchmark associated with superior case outcomes as determined by time, quality, and compensation (see Table 4). The three high-efficiency veterinarians scored a whole quintile (> 20%) better on the five-point quality-of-sedation scale than their low-efficiency peers. Additionally, the three high-efficiency veterinarians completed the procedure nearly three minutes (> 15%) faster and had a > $40 (13.8%) better EHBR for nonsedation charges versus the three low-efficiency veterinarians. In other words, re-sedation rates ≤ 10% were associated with markedly better sedation quality, faster procedure completion time, and a substantial improvement in effective compensation. The differential in time to complete the power dentistry procedure was even greater when total cases requiring re sedation (n = 101) are compared with total cases requiring initial sedation only (n = 262). Re-sedation cases took an average of 5.56 minutes longer than non-re-sedation cases, 25.27 vs 19.73 minutes respectively (see Table 2), a 28.2% difference.

Based on extensive consultative experience with equine practitioners, the authors recommend that veterinarians adopt a sedation protocol that focuses on achieving consistently successful initial sedation rather than on the cost of drugs. One author's concern (JMD) is that sedation combinations in some cases are devised to reduce the total cost of the sedative dose for the horse. The EHBR results in this study indicate that re-sedation detracts from the veterinarian's efficiency and compensation potential. Practitioners can establish an effective sedation protocol by using an equine approved sedative at a dose sufficient to consistently provide an adequate response, then tracking the incidence of re-sedation and adjusting the protocol accordingly. The goal should be an initial sedation failure rate of ≤ 10%, the standard demonstrated by the three high-efficiency veterinarians described in this report. This approach can be applied not only to power floating but to any repetitive procedure in equine practice.

The study indicated that equine veterinarians can benefit from the following approach to standing sedation:

- For power dentistry procedures, minimize the frequency of re-sedation in order to improve the EHBR and to reduce costs to the client.
- Select a sedation protocol and dose that minimizes frequency of re-sedation.
- Monitor the frequency of re-sedation to determine if changes are needed to the sedation protocol or the procedure being performed.
- Consider applying these methods to all repetitive procedures in equine practice that require sedation.

Study results support the merits of single-drug sedation using DORMOSEDAN, the alpha-2 agonist with the greatest depth and duration of sedation at the approved equine dose.[1-4] As one of the three high-efficiency veterinarians who successfully used DORMOSEDAN as a stand-alone sedative noted, "Why use multiple drugs if one will suffice?"[11] DORMOSEDAN has the advantage of dosing flexibility (IM or IV, high- or lowdose

size) and has demonstrated safety and efficacy as a stand-alone equine sedative with the added benefit of providing clinically significant analgesia.[10] DORMOSEDAN is a simple approach to pharmaceutical restraint. The result is safe and reliable sedation of the equine patient that minimizes the disruptive and costly effects of intraoperative re-sedation.

Acknowledgement

The authors acknowledge the contribution of Mark Dana of Scientific Communications Services in the writing and editing of this report.

IMPORTANT SAFETY INFORMATION: Do not use DORMOSEDAN STERILE SOLUTION in horses with pre-existing atrioventricular (AV) or sinoatrial (SA) block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Intravenous potentiated sulfonamides should not be used in anesthetized or sedated horses. Careful consideration should be given to horses approaching or in endotoxic or traumatic shock, to horses with advanced liver or kidney disease, or to horses under stress from extreme heat, cold, fatigue, or high altitude. Do not use in horses intended for human consumption. Handle dosing syringes with caution to avoid direct exposure to skin, eyes, or mouth. See full Prescribing Information, attached.

Zoetis does not endorse the use of DORMOSEDAN in combination with other products or in doses different from the approved label.

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DORMOSEDAN®

(detomidine hydrochloride)

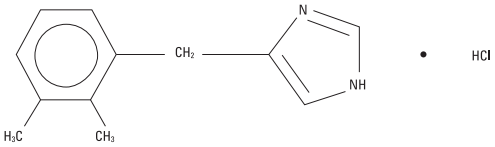
Sedative and Analgesic For Use in Horses Only

Sterile Solution
10 mg/mL

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Dormosedan® is a synthetic alpha-2 adrenoreceptor agonist with sedative and analgesic properties. The chemical name is 1H imidazole, 4-[(2,3-dimethylphenyl) methyl]- hydrochloride and the generic name is detomidine hydrochloride. It is a white, crystalline, water-soluble substance having a molecular weight of 222.7. The molecular formula is $C_{12}H_{14}N_2$•HCl.

CHEMICAL STRUCTURE:



Each mL of Dormosedan® contains 10.0 mg detomidine hydrochloride, 1.0 mg methyl paraben, 5.9 mg sodium chloride, and water for injection, q.s.

CLINICAL PHARMACOLOGY: Dormosedan®, a non-narcotic sedative and analgesic, is a potent α_2-adrenoreceptor agonist which produces sedation and superficial and visceral analgesia which is dose dependent in its depth and duration. Profound lethargy and a characteristic lowering of the head with reduced sensitivity to environmental stimuli (sounds, etc.) are seen with detomidine. A short period of incoordination is characteristically followed by immobility and a firm stance with front legs well spread. The analgesic effect is most readily seen as an increase in the pain threshold at the body surface. Sensitivity to touch is little affected and in some cases may actually be enhanced.

With detomidine administration, heart rate is markedly decreased, blood pressure is initially elevated, and then a steady decline to normal is seen. A transient change in the conductivity of the cardiac muscle may occur, as evidenced by partial atrioventricular (AV) and sinoauricular (SA) blocks. This change in the conductivity of the cardiac muscle may be prevented by IV administration of atropine at 0.02 mg/kg of body weight.

No effect on blood clotting time or other hematological parameters was encountered at dosages of 20 or 40 mcg/kg of body weight. Respiratory responses include an initial slowing of respiration within a few seconds to 1–2 minutes after administration, increasing to normal within 5 minutes. An initial decrease in tidal volume is followed by an increase.

INDICATIONS: Dormosedan® is indicated for use as a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings. It has been used successfully for the following: to calm fractious horses, to provide relief from abdominal pain, to facilitate bronchoscopy, bronchoalveolar lavage, nasogastric intubation, nonreproductive rectal palpations, suturing of skin lacerations, and castrations. Additionally, an approved, local infiltration anesthetic is indicated for castration.

CONTRAINDICATIONS: Dormosedan® should not be used in horses with pre-existing AV or SA block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Intravenous potentiated sulfonamides should not be used in anesthetized or sedated horses as potentially fatal dysrhythmias may occur.

Information on the possible effects of detomidine hydrochloride in breeding horses is limited to uncontrolled clinical reports; therefore, this drug is not recommended for use in breeding animals.

WARNINGS: Do not use in horses intended for human consumption. Not for human use. Keep out of reach of children.

HUMAN SAFETY INFORMATION: Care should be taken to assure that detomidine hydrochloride is not inadvertently ingested as safety studies have indicated that the drug is well absorbed when administered orally. Standard ocular irritation tests in rabbits using the proposed market formulation have shown detomidine hydrochloride to be nonirritating to eyes. Primary dermal irritation tests in guinea pigs using up to 5 times the proposed market concentration of detomidine hydrochloride on intact and abraded skin have demonstrated that the drug is nonirritating to skin and is apparently poorly absorbed dermally. However, in accordance with prudent clinical procedures, exposure of eyes or skin should be avoided and affected areas should be washed immediately if exposure does occur. As with all injectable drugs causing profound physiological effects, routine precautions should be employed by practitioners when handling and using loaded syringes to prevent accidental self-injection.

PRECAUTIONS: Before administration, careful consideration should be given to administering Dormosedan® to horses approaching or in endotoxic or traumatic shock, to horses with advanced liver or kidney disease, or to horses under stress from extreme heat, cold, fatigue, or high altitude. Protect treated horses from temperature extremes. Some horses, although apparently deeply sedated, may still respond to external stimuli. Routine safety measures should be employed to protect practitioners and handlers. Allowing the horse to stand quietly for 5 minutes before administration and for 10–15 minutes after injection may improve the response to Dormosedan®.

Dormosedan® is a potent α_2-agonist, and extreme caution should be exercised in its use with other sedative or analgesic drugs for they may produce additive effects.

When using any analgesic to help alleviate abdominal pain, a complete physical examination and diagnostic work-up are necessary to determine the etiology of the pain.

Food and water should be withheld until the sedative effect of Dormosedan® has worn off.

ADVERSE REACTIONS: Occasional reports of anaphylactic-like reactions have been received, including 1 or more of the following: urticaria, skin plaques, dyspnea, edema of the upper airways, trembling, recumbency, and death. **The use of epinephrine should be avoided since epinephrine may potentiate the effects of α_2-agonists.** Reports of mild adverse reactions have resolved uneventfully without treatment. Severe adverse reactions should be treated symptomatically. As with all α_2-agonists, the potential for isolated cases of hypersensitivity exist, including paradoxical response (excitation).

SIDE EFFECTS: Horses treated with Dormosedan® exhibit hypertension. Bradycardia routinely occurs 1 minute after injection. The relationship between hypertension and bradycardia is consistent with an adaptive baroreceptor response to the increased pressure and inconsistent with a primary drug-induced bradycardia. Piloerection, sweating, salivation, and slight muscle tremors are frequently seen after administration. Partial transient penis prolapse may be seen. Partial AV and SA blocks may occur with decreased heart and respiratory rates. Urination typically occurs during recovery at about 45–60 minutes posttreatment, depending on dosage. Incoordination or staggering is usually seen only during the first 3–5 minutes after injection, until animals have secured a firm footing.

Because of continued lowering of the head during sedation, mucus discharges from the nose and, occasionally, edema of the head and face may be seen. Holding the head in a slightly elevated position generally prevents these effects.

OVERDOSAGE: Detomidine hydrochloride is tolerated in horses at up to 200 mcg/kg of body weight (10 times the low dosage and 5 times the high dosage). In safety studies in horses, detomidine hydrochloride at 400 mcg/kg of body weight administered daily for 3 consecutive days produced microscopic foci of myocardial necrosis in 1 of 8 horses.

DOSAGE AND ADMINISTRATION:

For Sedation: Administer Dormosedan® IV or IM at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL of Dormosedan® per 100 kg or 220 lb), depending on the depth and duration of sedation required. Onset of sedative effects should be reached within 2–4 minutes after IV administration and 3–5 minutes after IM administration. Twenty mcg/kg will provide 30–90 minutes of sedation and 40 mcg/kg will provide approximately 90 minutes to 2 hours of sedation.

For Analgesia: Administer Dormosedan® IV at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL of Dormosedan® per 100 kg or 220 lb), depending on the depth and duration of analgesia required. Twenty mcg/kg will usually begin to take effect in 2–4 minutes and provide 30–45 minutes of analgesia. The 40 mcg/kg dose will also begin to take effect in 2–4 minutes and provide 45–75 minutes of analgesia.

For Both Sedation and Analgesia: Administer Dormosedan® IV at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL of Dormosedan® per 100 kg or 220 lb), depending on the depth and duration of sedation and analgesia required.

Before and after injection, the animal should be allowed to rest quietly.

STORAGE: Store at controlled room temperature 15°–30°C (59°–86°F) in the absence of light.

HOW SUPPLIED: Dormosedan® is supplied in 5- and 20-mL multidose vials.

NADA #140-862, Approved by FDA

Manufactured by:
Orion Corporation
Espoo, Finland

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

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