



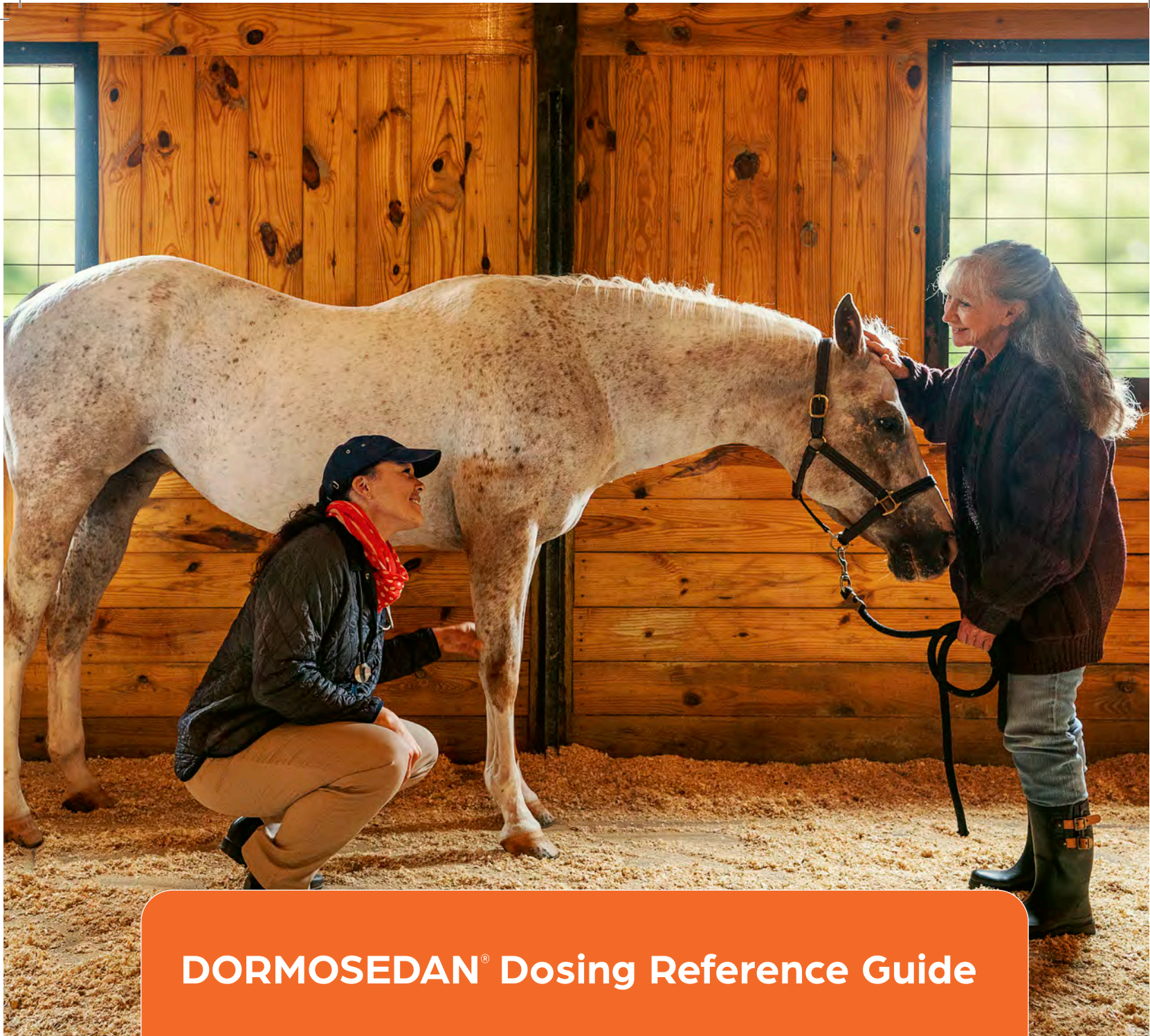
# DORMOSEDAN<sup>®</sup>

(detomidine hydrochloride)

**#1 vet-trusted  
equine sedative<sup>1</sup>**

zoetis





# DORMOSEDAN® Dosing Reference Guide

**DOSE:** 20 or 40 mcg/kg = 10 mg or 20 mg/500kg (1100 lb) = 1 or 2 mL/500kg (1100 lb)

**ADMINISTRATION:** IV or IM

Horse Body Weight (kg)	Horse Body Weight (lbs)	IV/IM mg	IV/IM mL	Clinical Effects	IV/IM Sedation Duration	IV Analgesia Duration*
100	220	2 or 4	0.2 or 0.4	Beginning Effects: <b>IV 2-4 minutes</b> <b>IM 3-5 minutes</b>	1 mL per 500kg: <b>30-90 minutes</b>	1 mL per 500kg: <b>30-45 minutes</b>
200	440	4 or 8	0.4 or 0.8			
300	660	6 or 12	0.6 or 1.2			
400	880	8 or 16	0.8 or 1.6			
<b>500</b>	<b>1100</b>	<b>10 or 20</b>	<b>1.0 or 2.0</b>	Optimal Effects for IV and IM: <b>10-15 minutes</b>	2 mL per 500kg: <b>1.5-2 hours</b>	2 mL per 500kg: <b>45-75 minutes</b>
600	1320	12 or 24	1.2 or 2.4			
700	1540	14 or 28	1.4 or 2.8			

\*Analgesia has not been evaluated in IM administration



## Alpha 2 selectivity makes DORMOSEDAN® predictable and effective.

- The  $\alpha_2$  selectivity of DORMOSEDAN (detomidine hydrochloride) allows it to bind specifically to  $\alpha_2$  adrenoceptors.
- DORMOSEDAN allows flexible dosing so you can accurately regulate the depth and length of sedation and analgesia.
- Whether administered IV or IM, DORMOSEDAN produces rapid onset of effect (IV: 2-4 minutes; IM: 3-5 minutes).
- Xylazine can bind with  $\alpha_1$  and non- $\alpha_2$  receptor sites, producing variable neurological effects<sup>2</sup> in rats.
- Sedation effects may be maintained up to 2 hours and analgesia effects may be maintained up to 75 minutes depending on dose level and route of administration.

## DORMOSEDAN. Sedation and analgesia you can count on every time.

There's no need to combine drugs to get the sedation and analgesic effect you want. DORMOSEDAN is completely reliable. It can be used by itself.

## DORMOSEDAN offers a wide margin of safety.

- DORMOSEDAN was tolerated at 10X the label dose when administered IV.<sup>3</sup>
- One key advantage of DORMOSEDAN is that additional doses will prolong, but will not deepen, sedation due to the plateau effect.
- Zoetis does not recommend use at higher than approved label dose.



<sup>1</sup> Data on file: 2020 Equine Pain & Sedation Market Research Study.

<sup>2</sup> Virtanen R, Savola V, et al. Characterization of the selectivity, specificity and potency of medetomidine as an  $\alpha_2$  adrenoceptor agonist. *Eur J Pharmacol* 1988;150:9-14.

<sup>3</sup> Dormosedan Freedom of Information, NADA #140-862, December 1989.

## Here's how it works.

Because DORMOSEDAN (*detomidine hydrochloride*) is an alpha<sub>2</sub> (α<sub>2</sub>) adrenoceptor agonist, it interrupts the nervous system to produce sedation and analgesia.

DORMOSEDAN® inhibits the release of norepinephrine.

Without norepinephrine, the neurons responsible for mediating pain and arousal are suppressed.

norepinephrine 

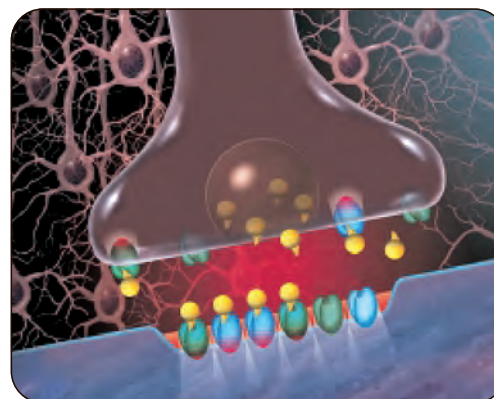
α<sub>1</sub> adrenoceptors 

α<sub>2</sub> adrenoceptors 

DORMOSEDAN 

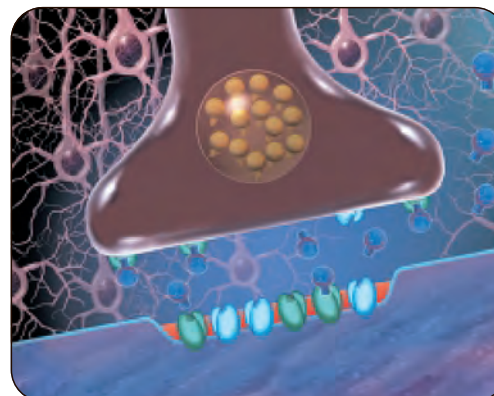
### Normal nerve transmission —————→

1. Normal nerve transmission. Norepinephrine is released and binds with alpha<sub>1</sub> (α<sub>1</sub>) and alpha<sub>2</sub> (α<sub>2</sub>) adrenoceptors to send a nerve impulse or cause a muscle to contract.



### Administration of DORMOSEDAN —————→

2. Administration of DORMOSEDAN results in sedation and analgesia. DORMOSEDAN selectively binds to the α<sub>2</sub> adrenoceptors, causing the nerve to stop releasing norepinephrine and blocking the nerve impulse.



## DORMOSEDAN can facilitate a wide variety of procedures:

- |   |  |   |   |
|---|--|---|---|
| <ul style="list-style-type: none"><li>• <b>Minor surgical procedures</b><ul style="list-style-type: none"><li>▪ Caslicks suturing</li><li>▪ Castration</li><li>▪ Urinary tract catheterization</li><li>▪ Suturing of skin lacerations</li><li>▪ Peritoneal tap</li><li>▪ Lancing abscesses</li><li>▪ Removing or biopsying tumors</li></ul></li></ul> | <ul style="list-style-type: none"><li>• <b>General examination</b></li><li>• <b>Wound treatment</b><ul style="list-style-type: none"><li>▪ Debridement</li><li>▪ Application of medication</li><li>▪ Application of bandages, casts, splints</li></ul></li><li>• <b>Therapeutic medication following injury or surgery</b></li><li>• <b>Calming fractious horses</b></li></ul> | <ul style="list-style-type: none"><li>• <b>Diagnostic procedures</b><ul style="list-style-type: none"><li>▪ Endoscopy</li><li>▪ Nasogastric tubing</li><li>▪ Diagnosis and initiation of colic treatment</li><li>▪ Radiography</li><li>▪ Transtracheal washes</li><li>▪ Abdominal pain</li><li>▪ Flushing nasal lacrimal ducts</li><li>▪ Flushing guttural pouches</li><li>▪ Scintigraphy</li></ul></li></ul> | <ul style="list-style-type: none"><li>• <b>Transportation</b></li><li>• <b>Dental care</b><ul style="list-style-type: none"><li>▪ Wolf tooth extraction</li><li>▪ Powerfloating</li><li>▪ Dental surgery</li></ul></li><li>• <b>Therapeutic Shoeing</b></li><li>• <b>Clipping</b></li></ul> |
|---|--|---|---|

**As the #1 vet-trusted equine sedative<sup>1</sup>,  
DORMOSEDAN gives you predictability  
you can rely on.**



Make the trusted choice<sup>1</sup>  
for consistent results  
backed by industry-  
leading support from  
Zoetis.

For more information  
contact Zoetis  
representative or visit  
[Dormosedan.com](http://Dormosedan.com) today.

DORMOSEDAN<sup>®</sup> (*detomidine hydrochloride*) provides sedation together with analgesia. When you work with animals as large and unpredictable as horses, a safe and reliable sedative is an absolute must. When that product also delivers a proven level of pain control, it provides a more humane option for your equine patients. DORMOSEDAN does both. The result is effective standing sedation *and* analgesia in a single, non-narcotic medicine. For the equine veterinarian, that means no mixing of products and guesswork dosing. You're free to focus on your patient.

**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.

# DORMOSEDAN®

## (detomidine hydrochloride)

Sedative and Analgesic For Use in Horses Only

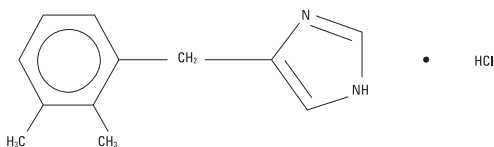
Sterile Solution  
10 mg/mL



**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  $C_{11}H_{13}N_2 \cdot HCl$ .

**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  $\alpha_2$ -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  $\alpha_2$ -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  $\alpha_2$ -agonists.** Reports of mild adverse reactions have resolved uneventfully without treatment. Severe adverse reactions should be treated symptomatically. As with all  $\alpha_2$ -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**  
PHARMA  
Orion Corporation  
Espoo, Finland

**zoetis**

Distributed by:  
Zoetis Inc.  
Kalamazoo, MI 49007

Revised: January 2013

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