# The SmartPak Pharmacy
# Equine Product Information Sheet

## Dormosedan Gel®

**Common Drug Name** – Detomidine

**How Supplied by SmartPak** –Dormosedan Gel is available in 3.0 ml graduated oral dosing syringe.

**Category** – Dormosedan Gel is a synthetic alpha-2-adrenoceptor agonist with sedative properties.

**Caution** - Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**Indications (Uses)** – Dormosedan Gel is for sedation and restraint in horses.

**Dosage and Administration** – Dormosedan Gel produces sedation when administered sublingually at 0.018 mg/lb. Dormosedan Gel must be placed beneath the tongue of the horse and is not meant to be swallowed. The dosing syringe delivers the product in 0.25ml increments. Use impermeable gloves when handling the product. Remove the syringe from the outer carton. While holding the plunger, turn the ring-stop on the plunger until the ring is able to slide freely up and down the plunger. Position the ring in such a way that the side nearest the barrel is at the desired volume marking. Turn the ring to secure it in place. Make sure that the horse's mouth contains no feed. Remove the cap from the tip of the syringe and save for dap replacement. Insert the syringe tip into the horse's mouth from the side of the mouth, placing the syringe tip beneath the tongue at the level of the commissure of the mouth. Depress the plunger until the ring-stop contacts the barrel, depositing the product beneath the tongue. Take the syringe out of the horse's mouth, recap the syringe and return it to the outer carton for disposal. Remove gloves for disposal. For best results, allow adequate time ( minimum of 40 minutes) between administration of Dormosedan Gel and beginning the procedure. In general, horses show sedative effects lasting approximately 90-180 minutes. Withhold food and water until the sedative effects of the product wear off.

**Contraindications** – Dormosedan Gel is contraindicated in horses with known hypersensitivity to detomidine. Intravenous potentiated sulfonamides should not be used in anesthetized or sedated horses as potentially fatal dysrhythmias may occur. Do not use Dormosedan Gel in horses with pre-existing AV or SA blocks, respiratory disease or chronic renal failure.

**Human Warnings** –Not for human use. Keep out of the reach of children. **Use impermeable gloves during drug administration and during procedures that require contact with the horse's mouth.** Following sublingual administration of detomidine oromucosal gel, drug concentrations up to 0.072mg/ml were measured at 30 minutes post dose in equine saliva, equivalent to less than one percent of the original detomidine concentration in the gel. Mean drug concentrations fall to less than 0.010mg/ml by 2 hours after drug administration, after which a slow decline occurs for several additional hours. Dormosedan Gel can be absorbed following direct exposure to skin, eyes, or mouth, and may cause irritation. Skin and mucosal contact with the product should be avoided. Use impermeable gloves at all times. In case of accidental eye exposure, rinse abundantly with fresh water. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing.

Appropriate precautions should be taken while handling and using gel syringes. Accidental exposure could cause adverse reactions, including sedation, hypotension and bradycardia. Seek medical attention immediately but do not drive because sedation or changes in blood pressure may occur. Individuals with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid exposure to this product. Caution should be exercised when handling sedated horses. Handling or any other sudden stimuli, including noise, may cause a defense reaction in an animal that appears to be heavily sedated. Rare cases of human abuse of detomidine products have been reported. Dormosedan Gel should be managed to prevent the risk of diversion, through such measures as restriction of access and the use of drug accountability procedures appropriate to the clinical setting.

**Warnings** –For sublingual use in horses only. Do not use in horses intended for human consumption.

**Precautions** – Dormosedan Gel must be place beneath the tongue of the horse. Unlike most oral veterinary products, this product is not meant to be swallowed. Swallowing could result in ineffectiveness. Dormosedan Gel does not provide analgesia. Do not use for painful procedures. Do not use with other sedative drugs because the effects may be additive. Repeat dosing has not been evaluated. The use of an alpha-2-agonist reversal agent with Dormosedan Gel has not been evaluated. Before initiating any procedure, allow sedation to fully develop. Nervous or excited horses with high levels of endogenous catecholamines may exhibit a reduced pharmacological response to alpha-2-adrenoceptor agonists like detomidine. In agitated horses, the onset of sedative effects could be slowed, or the depth and duration of effects could be diminished or nonexistent. When the product is administered, the animal should be allowed to rest in a quiet place for a minimum of 40 minutes. Do not use Dormosedan Gel in horses with cardiovascular disease, respiratory disorders, liver or kidney diseases, or in conditions of shock, severe debilitation, or stress due to extreme heat, cold, fatigue or high altitude. Protect treated horses from temperature extremes. As with all alpha-2-adrenoeptor agonists, the potential for isolated cases of hypersensitivity, including paradoxical response (excitation) exists. Dormosedan Gel has not been evaluated in ponies, miniature horses, horses younger than one year of age, or for use in breeding, pregnant or lactating horses.

**Adverse reactions (side effects)** – In a field study of 270 horses sedated to facilitate completion of various veterinary and husbandry procedures, the following adverse reactions were reported in 202 horses treated with Dormosedan Gel and 68 horses treated with placebo: sweating, penile relaxation, bradycardia, second degree AV block, frequent urination, piloerection, marked ataxia, facil/oral edema, hypersalivation, nasal discharge, flatulence, muscle tremors, epiphora, pale mucous membranes, swollen sheath.

**Storage Conditions**: Store at controlled room temperature 68-77F with excursions permitted to 59-86F in the original package.

**Distributed by:**
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