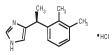
Dexmedesed[®]

(dexmedetomidine hydrochloride) Sterile Injectable Solution-0.5 mg/mL For Intramuscular and Intravenous Use in Dogs and For Intramuscular Use in Cats Sedative, Analgesic, Preanesthetic

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. DESCRIPTION: Dewnedesed (dewnededomidine hydrochloride) is a synthetic alpha-adrenoreceptor agonist with sedative and analgesic properties. The chemical name is (+)-4/11/2.3-dimethylphenyl(lstryl)-1/H-imidizade monohydrochloride. It is a white, or almost white, crystalline, water soluble substance having a molecular weight of 236.7. The molecular formula is G_{11} - H_{12} , W = 100 and the structural formula is:



Each mL of Dexmedesed contains 0.5 mg dexmedetomidine hydrochloride, 1.6 mg methylparaben (NF), 0.2 mg propylparaben (NF), 9.0 mg sodium chloride (USP), and water for injection (USP), q.s.

propylearability (try), so ung source transfer your), and make the intermediate transfer of the initial eclinical INDICATIONS: Demedised is indicated for use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, more surgical procedures, and minor dental procedures. Demedised is also indicated for use as a preanesthetic to general anesthesia in dogs and cats. DOSAGE AND ADMINISTRATION: DUSALE AND ADMINISTRATION: Dogs: Sedation and Analgesia: 500 mcg/m² intramuscularly (IM) or 375 mcg/m² intravenously (IV). Preanesthesia: 125 or 375 mcg/m³ IM. The choice of generactibility close depends on the duration and severity of the procedure as well as the an

Preamsthesia: 125 or 375 mcg/m² ML. The choice of preamsthetic dose depends on the duration and severity of the procedure, as well as the anesthetic the molitory dose that the discussion of the duration and severity of the procedure, as well as the anesthetic the molitory dose decreases as a body weight in direcesses. The comparison dose weight and a 28.1 mcg/hg dosembediamidine hydrochiotiche VC compared to dogs weighing 30.6 kg that are dosed at 28.1 mcg/hg dosembediamidine hydrochiotiche VC compared to dogs weighing 30.6 kg that are dosed at 27.1 mcg/hg dose to the small volume of administration, accurate doing is not possible in dogs weighing 30.8 km 28.1 km 28.1 kg 4.4 kg. bie 1: CANINE SEDATION/ANALGESIA DOSE TABLE: avenues (h) and intramuscular (M) dealing on the basis of body weight

Dexmedesed 0.5 mg/mL						Dexmedesed 0.5 mg/mL						
Sedation/analgesia in dogs						Preanesthesia in dogs						
Dog Weight		Dexmedetomidine hydrochloride 375 mcg/m ² W		Dexmedietomidine hydrochloride 500 mco/m² IM		Da Wei	Dog Weight		Dexmedetomidine hydrochloride 125 mcg/m² IM		Dexmedietomidine hydrochloride 375 mcg/m² IM	
lbs	kg	mog/kg	mL	mca/ka	mL.	lbs	kg	mcg/kg	mL.	mcg/kg	mL.	
4.4-7	2-3	28.1	0.12	40	0.15	4.4-7	2-3	9.4	0.04	28.1	0.12	
7.1-9	3.1-4	25	0.15	35	0.2	7.1-9	3.1-4	8.3	0.05	25	0.15	
9.1-11	4.1-5	23	0.2	30	0.3	9.1-11	4.1-5	7.7	0.07	23	0.2	
11.1-22	5.1-10	19.6	0.29	25	0.4	11.1-22	5.1-10	6.5	0.1	19.6	0.29	
22.1-29	10.1-13	16.8	0.38	23	0.5	22.1-29	10.1-13	5.6	0.13	16.8	0.38	
29.1-33	13.1-15				0.6	29.1-33	13.1-15	5.2	0.15	15.7	0.44	
33.1-44 44.1-55	15.1.20	14.6	0.51	20	0.7	33.1-44	15.1-20	4.9	0.17	14.6	0.51	
44.1-00	25.1-30	13.4	0.69	18	0.9	44.1-55	20.1-25	4.5	0.2	13.4	0.6	
65.1-73	30.1-33	12.6	0.05	16	1	55.1-66	25.1-30	4.2	0.23	12.6	0.69	
73.1-81	30.1-33	12	0.75	15	1.1	66.1-73	30.1-33	4	0.25	12	0.75	
73.1-81 81.1-99	33.1-37	11.6	0.81	15	1.1	73.1-81	33.1-37	3.9	0.25	11.6	0.81	
99.1-110	45.1-50	10.5	0.99	14.0	1.2	81 1-99	37.1-45	3.7	0.3	11	0.9	
110.1-121	50.1-55	10.1	1.06	13.5	1.4	99.1-110	45.1-50	3.5	0.33	10.5	0.99	
121.1-132	55.1-60	9.8	1.13	13	1.5	110.1-121	50.1-55	3.4	0.35	10.1	1.06	
132.1-143	60.1-65	9.5	1.19	12.8	1.6	121.1-132	55.1-60	3.3	0.38	9.8	1.13	
143.1-154	65.1-70	9.3	1.26	12.5	1.7	132 1-143	60.1-65	3.2	0.4	9.5	1,19	
154.1-176	70.1-80	9	1.35	12.3	1.8	143.1-154	65.1-70	3.1	0.42	9.3	1.26	
>176	>80	8.7	1.42	12	1.9	154.1-176	70.1-80	3	0.45	9	1.35	
						>176	>80	2.9	0.45	8.7	1.42	
									2.40			

The use of dexmedetomidine hydrochloride as a preanesthetic markedly reduces anesthetic requirements in dogs, injectable induction drug requirements for inturation will be reduced between 30% and 65%, depending on the choice of anesthetic and the deameddetomic hydrochloride preasthetic does. In concentration of Intriatation maintenance anesthetic will be reduced between 40% and 65%, depending on the dose of deameddetomidine hydrochlorid. The anesthetic does should durys be thated agains the response of the patient. The choice of anesthetic durys choice of anesthetic does should durys be thated agains the response of the patient. The choice of anesthetic durys choice. The anesthetic does should durys be thated agains the response of the patient. The choice of anesthetic durys choice. The anesthetic does should durys be thated agains the response of the patient. The choice of anesthetic durys choice. The area the durys dur

hydrochriotine. The anesthetic lose should always be titrateid against the response of the patient. The choice of an is left to the discretion of the veterinaria. Cats: Stedation, Analgesia and Preanesthesia: 40 mcg/kg intramuscularly (M), This does can also bue cads as a premeasibilitie can this been shown to marked/by reduce anesthetic requirement cads. Injectable anesthetic drug requirements for intubation were reduced up to 49%, depending on the choice of induction drug. The constraints of inflatation minimators are substitutive and takes, depending on the choice of an other than the constraints of inflatation minimators are substitutive and explose them 35% and 44%, depending on the choice of induction drug. The anesthetic does should always be fitting against the response of the patient. The following label may be used to determine the correct determinedeminidin hydrochrinde desage for cada based in the following label and the substitutive the correct determinedeminidin hydrochrinde desage for cada based in the following label and begin the correct determinedeminidin hydrochrinde desage for cada based in the following label and begin the correct determinedeminidin hydrochrinde desage for cada based in the following label and begin the determined based based

Table 3: FELINE DOSE TABLE:

	Dexmedesed	i 0.5 mg/mL	
Sed:	ation/analgesia and	l preanesthesia in ca	ls
C: Wei		Dexmedete hydrochi 40 mcg/	oride
lbs	kg	mcg/kg	mL
2-4	1-2	40	0.1
4.1-7	2.1-3	40	0.2
7.1-9	3.1-4	40	0.3
9.1-13	4.1-6	40	0.4
13.1-15	6.1-7	40	0.5
15.1-18	7.1-8	40	0.6
18.1-22	8.1-10	40	0.7

It is recommended that dogs and cats be fasted for 12 hours before treatment with Dexmedesed. An eye lubricant should be applied to cats to prevent comeal desicration that may result from a reduction in the blink reflex. Following ligication of Dexmedesed; the animal should be allowed to rest quietly for 15 minutes; sedation and analgesia occur within 5 to 15 minutes, with peak effects at 30 minutes after dexmedetomilian hydrochirotile.

CONTRAINDICATIONS: Do not use Dexmedesed in dogs or cats with cardiovascular disease, respiratory disorders, or kidney diseases, or in conditions of shock, severe debilitation, or stress due to extreme heat, cold or fatigue. As with all ainvir-airmonrowntr monits: the contential for isolated cases of hypersensitivity, including paradoxical As with all alpha₂-adrenoceptor agor response (excitation), exists.

WARNINGS:

WARNINGS: Human safety: Not for human use. Keep out of neach of children. Dewnedenmine hydrochionide can be absorbed following direct exposure to skin, eyes, or mouth, and may cause initiation. In case of accidential eye exposure, flush with water for 15 minutes. In case of accidential sion exposure, wash with scap and water. Remove contaminated clothing. Appropriate precautions should be taken while handling and using lifed sympase. Accidential provide processor, can exposure by nijection could cause adverse cardionascular disease for example, hypertension or ischemic heart disease) should take special precautions to avoid any exocore to this router.

conformational releases for complex hypertension of ischemic heart disease) should take special proclusions to arou any exposure to this product. Caldion should be exercised when harding sedated animals. Handing or any other sudden stimuli, including noise, may cause a determe reaction in an animal that appears to be havely sedated. The material stelly data sheet (MSD) contains more detailed occupations stelly information. To report adverse More to physicians in this more appears and the adverse stelly and the stellar details of the stellar

Intermentations introcessary to allow antestinetic overfolde. **PRESUNDUS**, Agroups and you can will demoderational hypotrochoride use. In the event of appress, additional anygen should be supplied, demonstration of atgramediate hode to the warrantifier when tappes to accompanies by brackporteal and spearchor muccus membranes. Adverse station reports for demonstrational environment severe dyapmes and respiratory crackles diagnosed to access how ensulting the access provide in cass in turbanes. Some of these acute and delevely name ratiosces us to three days that demonsteaming the hydroxibinal adverse intelle clinical field acids with domendetamine hydroxibinal explorations adverse to the deleved onset of the discussion of the data with domendetamine hydroxibinal explorations and the statistical exploration and the discussion of the data with domendetamine hydroxibinal explorations and the data attractional adverse may be notified with a statistical and adverse the effects of desmedetaminies Stope analogies are used as spektra affective. With new results the effects of desmedetaminies Stope analogies are used as spektra affective. With new results the maximum measurement measurement to activate and the stope analogies are used as a spektra affective. With new results the effects of desmedetaminies Stope analogies are used as spektra affective. With new results the maximum measurement measurement to activate the stope analogies are used as a spektra affective. With new results the maximum and the stope and

hydrochiodia. Shore analgesic as well as sockaive effects will be reversed, pain management may need to be addressed. In cats, atgamezole has not been evaluated as a routine desmedetemidine hydrochiodide reversal agent. In cats, cases of dyspane following atgamezole administration have been reportance to the presense thetics in cats. Although not beenvel in the feature and tautophrank. Desmedetemidine hydrochiodine has not been evaluated in the presence of other presensethetics in cats. Although not beenvel in the feature and buschprank. Conjunction with leatamine and buschprank. Desmedetemidine hydrochiodine in the solem report lost as the ceiving desmederationaline hydrochiodine in conjunction with testamine and buschprank. Destingent of the sole administration of desmedetemidine hydrochiodide agences as aneded. Following administration of desmedetemidine hydrochiodide, a decrease in body temperature is likely to occur unless externally maintend.

postportarile of postprinceature are provided in the production of a decrease in body temperature is were a externally maintained. One stabilished, hypothermia may persist longer than sedation and analgesia. To prevent hypothermia, theated animals should be kept warm and at a constant temperature during the procedure, and until ful recorety. Theremotological recores the hypothermia may be an extension of the decrease of the hypothermia (heptothermia), there are a sub-stability of the decrease of the hypothermia may be an extension of the decrease of the decrease of the hypothermia (heptothermia) (heptothermia)

Tables realists in the service of the service of the same time or after desmedetomidine hydrochoide could lead to adverse cardiovascular effects (secondary tadycardia, prolonged hypotension, and cardiac antryfinnias¹⁻¹). However, an artichnicing' chargen by a diaminiserized to dags at least 10 minutes after desmedetomidine hydrochoide is hydrochoide for the prevention of the downedetomidine hydrochoide hydrochoide in dags or adverse the hydrochoide of the prevention of the downedetomidine hydrochoider downedetomidine hydrochoide in dags or adverse and the service of the downedetomidine hydrochoider and the service and the service of the downedetomidine hydrochoider downedetomidine hydrochoider downedetomidine hydrochoider downedetomidine hydrochoider and a service are service and the service are service and the service the service are service and the service the service are service the service are service the service are service the servi e of anticnolinergics simultanded (see ANIMAL SAFETY) ous muscle contractions /htt tching) can be expected in some dogs sedated with dexmedetomidine

hydrocholide. Demodelenniallen hydrocholide has been evaluated only in fasted dogs; therefore, its effects on fed dogs (for example, the occurrence of womiting) have not been characterized. In cats, there is a high frequency of womition whether fed or fasted; therefore, fasting is recommended to reduce storand: contrats. Demodelbrandler hydrocholide has not been evaluated in dogs younger than 16 weeks of age, in cats younger than 12

weeks of age, or in geriatric dogs and cats. Dexmedetomidine hydrochloride has not been evaluated for use in breeding, pregnant, or lactating dogs or cats.

ADVERSE REACTIONS: esia field study: In the field study safety analysis, 106 dogs received dexmedetomidine sceived medetomidine. Dogs ranged from 16 weeks to 16 years of age, representing 49 breeds er of dogs displaying each cilicati observation forsme dogs experienced more than one adverse Canine sedation/analgesia netu suu hydrochloride and 107 received mede Table 4 shows the number of dogs dis

rrence of ausculted unidentified arrhythmias (some at multiple time points) decreased following the

administration of alignamezie. Canine presentations field study: The presententies failed study safety analysis included 192 dogs, between 5 months and 15 years of age, representing 45 breeds enrolled for elective procedures conducted under general anesthesia. Table 5 shows the number of dogs within a transmit group that showed each clinical sign of dogs may have experimented more adverse reaction). There clinical sign adverse in adopt streated with dewinedetomidine hydrochloride include decreased respiratory rate and

hypothermia. Fellne sedation/analgesia field study: The field study safety analysis included 242 cats (122 received deemeideformidine hydrochindre, 120 received systamio, 6 months to 17 years of age, and representing 19 breeds. Table 6 shows the number of cats reported with an adverse recution (cats may have experimented innote than one adverse

reaction). The most frequently observed adverse reaction was vomiting in both fasted and fed cats. Other infrequent clinical signs observed in cats treated with dexmedetomidine hydrochloride included fatioue, anorexia, cystitis, and oerioheral vascular disorder. One incidence of dyspnea was reported, 43 minutes after dexmedetomidine hydrochloride administration during an oral examination/dental procedure. Prior to dexmedetomidine hydrochloride, the cat was free of clinical signs, but had a

These y assume are requestly intercent. The cat responde successfully to traditional hydrochindric 68 increated successfully analysis included 184 cats (116 increated successful and hydrochindric 68 increated same, 12 weeks to 16 years of age, and representing 11 threads. Biah 2 shows the un-or cats reported with an adverse reaction cats may have experiment of more than or adverse reaction. One case of agness was reported in a cat that necessful externine as the induction agent. This cat required attribution of the read of agness was reported in a cat that necessful externine as the induction agent. This cat required attribution of the read of agness was reported in a cat that necessful externine as the induction agent. This cat required attribution of the read of the procedure unit 30 similarities into occurs when the cat begins to breath or on its own. The cat re

To report suspected adverse events, for technical assistance or to obtain a copy of the MSDS, contact Dechra at (866) 933-2472.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or http://www.fda.gov/Animal/Veterinary/SafetVHealth.

Table 4: Adverse reactions during the canine sedation/analgesia field study Table 5: Adverse reactions during the canine preanesthesia field study

	Dexmedetomidine	Medetomidine		Treatment Groups					
	hydrochloride Total n=106	Total n=107	Induction Anesthetic:	Propofol			Barbiturate		
Ausculted unidentified amhyfhmias	19	20	Preanesthetic dose:	0 mcg/m ² n=32	125 mcg/m ² n=32	375 mcg/m ² n=32	0 mcg/m² n=32	125 mcg/m ² n=32	375 mcg/m ² n=32
Severe bradycardia requiring treatment	1	1	Ernesis	4	7	4	2	3	6
Aprea requiring treatment	1	0	Ventricular premature contractions	0	2	0	4	1	0
Slow onset of sedation (exceeding 30 minutes)	1	1	Dianthea	1	0	0	3	1	1
Ineffectiveness	3	2	Self trauma	0	2	1	2	1	0
(dog standing throughout the study)			Severe bradycardia	0	0	1	0	0	1
Severe hypothermia requiring treatment	2	0	Tachycardia	0	0	0	1	1	0
Prolonged recovery	1	4	Urinary incontinence	0	0	0	0	0	1

le 6: Adverse reactions during the feline sedation/ Igesia field study Table 7: Adverse reactions during the feline preanesthesia field study

	Dexmedetomidine hydrochloride n=122	Xylazine n=120	Induction Anesthetic:		Ketamine		Propofol
Vomiting	70	82	Preanesthetic	Saline n=37	Dexmedetomidine hydrochloride n=64	Saline n=31	Dexmedetomidine hydrochloride n=52
Urinary incontinence	6	11	Emesis	2	20	1	12
Hypersalivation	4	5	Pale mucous membranes		11		9
Involuntary defecation	4	1	Decreased body temperature		4		
Hypothermia	2	1	Retching		1	1	3
Diantea	2	0	-				-
Arrhythmia	1	2	Heart murmur				2
Correal ulcar		0	Loose stool		2		
		0	Corneal injury	1			
Cyanosis	1	U	Acres		1		
Dyspnea	1	0	Rebavioral				
			change			1	
			Fluid in endo- tracheal tube			1	

POST APPROVAL EXPERIENCE: The following adverse events were obtained from post-approval adverse drug events reported for dexmedetemidine hydrochloride from 2007-2008. Not all adverse reactions accure drug events reactions occurred when downsidetimetime hydrochloride used allow for sedations, most occurred when dexmedetomidine hydrochloride two used and the sedation must occurred with demotediational to hydrochloride two used in the presence of anexthetics and/or other presentabilities. It is not always possible to reliably element the frequency of an adverse event or to establish a causal relationship to the drug, especially when multiple drugs are administred. The biolowing reported alverse events are elected in decreasing order of frequency: the biolowing reported alverse events are elected in decreasing order of frequency: decreaded temperature, and delayed sedation. descreaded temperature, and delayed sedation. heteroadet to the context of the context and the advective temperature and the advective temperature hydrocarda, cyanotic muccus membranes, sedation to brief, and degreen.

INFORMATION FOR OWNERS: Owners should notify their veterinarian immediately if their cat experiences difficulty breathing due to the rare possibility of delayed onset of pulmonary edema which has been associated with administration of adjrak_adherengric gamists in cats.

Belleting up to be an easy demonstration of the second sec EFFECTIVENESS:

hydrochiorike. Voniting in racis has been associated with alpha,-adrenergic agonist, central stimulation of the brain¹. **EFFECTIVEESS: Canice sociations and structures and structures and structures and structures and structures and structures. Canice sociations and structures and the structures and the structures and structu**

saline controls. Recovery times were does dependent, averaging 15-32 minutes to exhibition and 71-131 minutes to standing recovery fonger times correspond to higher doemedetimient hydrochloride does, Recovery times also depended on the induction ansettation. Recovery times blocking babitratis induction were torger (20 minutes to exhibition and 11 to induction ansettation. Recovery times blocking babitratis induction were torger (20 minutes to exhibition and 12 to induction ansettation. The recovery times block and the recovery times also depended on the induction ansettation. The recovery time block and the recovery times also depended on the control and the recovery times block and the recovery times and the recovery times and based with class the incidence of any PGOs, supremetricing terminative comparity deserved antifythmian incident ventication premainse complexes (PGOs, supremetricing the remainse, 3* degree AV block, and sinus arres). The reso comparity deserved antifythmian and the prediction premainse complexes, 3* degree AV block, and sinus arress. Adverse events included bradycardia, tachycardia, VPCs, vomiting, diarrhea, urinary incontinence, and self trauma (see ADVERSE REACTIONS). The results of the reconcentration of the results of the resul

Adverse events included bradycardis, tarbycardis, UPCs, vontilling, darrhea, urinary incontinence, and self trauma (see VAPRESE REACTIONS), mores in fed subjection of the transmission of the probability of the probability

ended architectures accessed will ECG even structures and explosition and accessed information. The structure of the structure back compares and non-indicators of antirotectures back. Departments and explosition menotic memory accessing regiments and explosition and accessing acces

Lencary satisfactory. All calls encovered from changes induced by desmediatomiline hydrochloride. Nearlies included vomities (70, unreprinted in the second state of the second state of

procedures If the velenitarian deembe in increasing increasing and an entry element and entry elements and e

minutes to extuation and 161 and 131 minutes to standing, negocitively for downedleminitien hydrochinoli-rested Domestediminitie individuality of the provide the

returns returns that with the commendation of the study study described with the study in the study of the st

to the tore analy dogs a does up to the times the recomminated user. **Canice safety study in an artichologing**: In another biocharaby safety study, one of three doese of an IM antichologing; drug or saline was administered 10 minutes before, at the same time, or 15 minutes after 500 mog/m² deemeddeminities hydrochinich. Be was administered 10 minutes before, at the same time, or 15 minutes after 500 mog/m² deemeddeminities hydrochinich. Be and tradichining; drug was given for the prevention or treatment of deemeddeminities hydrochinich. Be and reduction in heart rate: In a crossover design; 16 dogs were used in a total of 72 this, its evaluate the safety of domentionities hydrochinic used with an articholengic drug. Dogs be study (some dogs experienced more than one arthythmia).

Table 8: Arrhythmias recorded during the canine laboratory safety study*

Type of arrhythmia	Number of dogs (of 18)		
Second degree AV block	18		
Supraventricular tachycardia (SVT) or SVPCs	16		
Ventricular escape beats	16		
Ventricular premature contractions	14		
Third degree AV block	6		
Idioventricular rhythm	1		
Paroxysmal VT	1		
Ventricular bigeminy; SVPCs; pulse alternans	1		
Junctional escape beat	1		

 Implicit and implicit and the presence or absence of anticholinergic drug. Arhythmias were approximately a second drug and the presence or absence of the artholinergic drug. Arhythmias were approximately approximately

STORAGE INFORMATION: Store at controlled room temperature 68-77°F (20-25°C). Protect from freezing. In use shelf life: 28 days at 77°F (25°C).

HOW SUPPLIED: Dexmedesed is supplied in 10-mL, multidose vials containing 0.5 mg of dexmedetomidine hydrochloride per mL NDC 17033-005-10

REFERENCES:
REFERENCES:
ADJ, Fox SMF, Mandsager RE. Effects of preemptive atropine administration on incidence of medetomidine-induced tradycardia in dogs. J Am Vet Med Assoc 2001; 21:8:52–88.
Alithat Hit, Carler KVL, Lee YH, et al. Cardioplumonary effects of combinations of medetomidine hydrochloride and atropine subplate in dogs. Vet Rev 1999; 13:81:11-33.
Short, CE. Effects of anticholinergic treatment on the cardiac and respiratory systems in dogs sedated with medetomidine. Vet Rev 1991; 12:93:10-313.
Hitkasar, Makaa I, Iano Y et al. Central apha-admoceptor subtypes involved in the emetic pathway in cats. Eur / Phermacel 1992; 22:92:41:251

Manufactured for: Dechra Veterinary Products 7015 College Boulevard, Suite 525 Overland Park, KS 66211

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DIRECTIONS

