Zenalpha®
(medetomidine and vatinoxan hydrochlorides injection)

Key Feature #1:
Zenalpha® contains 0.5 mg/mL medetomidine hydrochloride and 10 mg/mL vatinoxan hydrochloride.

- Medetomidine is an alpha-2 agonist responsible for sedative and analgesic properties.
- Vatinoxan is an alpha-2 antagonist, acting in the periphery without crossing the blood-brain barrier.

Its Benefit:
Combination of medetomidine and vatinoxan helps minimize unwanted cardiovascular side effects while preserving reliable sedation and analgesia. Zenalpha® improves the sedation monitoring experience by keeping the patient's heart rate and blood pressure closer to normal.

Zenalpha® is for use in dogs only. Not intended for use in cats.

Key Feature #2:
Zenalpha® offers a short time to onset (5-15 minutes) and a short duration of sedation (~45 minutes) in most dogs.*

*Field study means were 14 minutes for time to onset of sedation and 38 minutes for duration of sedation.

Its Benefit:
Patients recover rapidly and can return home sooner. And due to the quick recovery time, the use of reversal agents may not be needed, which can save time and decrease costs.

As with all alpha-2 adrenoceptor agonists, onset of sedation may be delayed or may be inadequate in some dogs. The analgesic effect of Zenalpha® will not last longer than the sedative effects. Additional analgesic(s) should be administered as needed.

Key Feature #3:
Zenalpha® is effective for a broad range of common clinical procedures including nail trims, diagnostic imaging, and end-of-life procedures.

Its Benefit:
Using procedural sedation with Zenalpha® is consistent with low-stress handling techniques and helps facilitate best practices. It may help reduce a patient's fear, anxiety, and stress, improve comfort, and minimize accidental injuries.

Due to the pronounced cardiovascular effects of alpha-2 adrenoceptor agonists, only clinically healthy dogs (American Society of Anesthesiologists [ASA] classes I and II) should be administered Zenalpha®. Dogs should be monitored frequently during sedation for changes in heart rate, blood pressure, respiratory rate and body temperature.

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Dechra

www.Zenalpha.us

Zenalpha®

(medetomidine and vatinoxan hydrochlorides injection)

An innovative alpha-2 combination drug that improves the sedation experience from start to finish.

Zenalpha® is indicated for use as a sedative and analgesic in dogs to facilitate clinical examinations, clinical procedures, and minor surgical procedures.

TIME TO ONSET

5-15 Minutes

in most cases*

*Field study mean was 14 minutes for time to onset of sedation.

DURATION OF SEDATION

~45 Minutes

in most cases*

*Field study mean was 38 minutes for duration of sedation.

IMPORTANT SAFETY INFORMATION

As with all drugs, side effects may occur. For use in dogs only. Not intended for use in cats. Not for use in humans. Avoid skin, eye or mucosal contact. In case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the physician. DO NOT DRIVE as sedation, loss of consciousness, and changes in blood pressure may occur. People with cardiovascular disease and pregnant women should exercise special caution to avoid exposure. As with all alpha-2 adrenoceptor agonists, onset of sedation may be delayed or may be inadequate in some dogs. The analgesic effect of Zenalpha will not last longer than the sedative effects. Additional analgesic(s) should be administered as needed. Do not use Zenalpha in dogs with cardiac disease, respiratory disorders, shock, severe debilitation, that have hypoglycemia or are at risk of developing hypoglycemia, or are stressed due to extreme heat, cold or fatigue. Zenalpha should not be administered in the presence of pre-existing hypotension, hypoxia or bradycardia. Due to the pronounced cardiovascular effects of alpha2-adrenoceptor agonists, only clinically healthy dogs (American Society of Anesthesiologists [ASA] classes I and II) should be administered Zenalpha. Dogs should be monitored frequently during sedation for changes in heart rate, blood pressure, respiratory rate and body temperature. Tachycardia may occur in some dogs after recovery from sedation. The following adverse reactions have been reported: diarrhea, muscle tremors and colitis. Refer to the prescribing information for complete details or visit www.dechra-us.com.

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CHECK-OFF & ECHO NOTES

First, always ask if a Dechra representative has been in contact recently:

Doctor, have you recently been introduced to Zenalpha® (medetomidine and vatinoxan hydrochlorides injection)?

If **Yes**, confirm and discuss benefits.

If No, engage/detail the customer as the primary contact.

Confidence

I believe Zenalpha® will become an important tool for increasing procedural efficiency in your clinic and provide less stress for your veterinary team.

Neutral invitation

Let's take a look at some basic information about Zenalpha®...

It's the customer's decision

...so you can decide whether Zenalpha® is a sedative you'll consider using with your canine patients for clinical exams and procedures.

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

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Zenalpha®

(medetomidine and vatinoxan hydrochlorides injection)
Sedative, Analgesic
For Use in Dogs Only

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

BRIEF SUMMARY: (for full prescribing information, see package insert)

DESCRIPTION: Zenalpha is a combination of medetomidine and vatinoxan hydrochlorides. Each mL of Zenalpha contains 0.5 mg medetomidine hydrochloride, 10 mg vatinoxan hydrochloride, 32.5 mg mannitol (USP), 4.16 mg citric acid monohydrate (USP), 1.8 mg methylparaben (NF), 0.2 mg propylparaben (NF).

INDICATION: Zenalpha is indicated for use as a sedative and analgesic in dogs to facilitate clinical examination, clinical procedures and minor surgical procedures.

CONTRAINDICATIONS: Do not use Zenalpha in dogs with cardiac disease, respiratory disorders, shock, severe debilitation, that have hypoglycemia or are at risk of developing hypoglycemia, or are stressed due to extreme heat, cold or fatigue.

Zenalpha is contraindicated in dogs with a known sensitivity to medetomidine or vatinoxan.

WARNINGS:

Human User Safety Warnings

Not for use in humans. Keep this and all medications out of reach of children and pets.

Avoid skin, eye or mucosal contact. Use caution while handling and using filled syringes. Absorption of the active ingredients is possible following exposure via the skin, eye or mucosa. In case of accidental eye exposure, flush eyes with water for 15 minutes, remove contact lenses then continue to flush. In case of accidental skin exposure, wash with soap and water and remove contaminated clothing. If symptoms occur, seek the advice of a physician.

In case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the physician. DO NOT DRIVE as sedation, loss of consciousness, and changes in blood pressure may occur.

Persons with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid any exposure to this product.

Pregnant women should exercise special caution to avoid exposure. Uterine contractions and decreased fetal blood pressure may occur after accidental systemic exposure.

Persons with known hypersensitivity to any of the ingredients should avoid contact with Zenalpha.

Caution should be exercised when handling sedated animals. Handling or any other sudden stimuli, including noise, may cause a defense reaction in an animal that appears to be heavily sedated.

Note to physician: Zenalpha contains medetomidine, an alpha$_2$-adrenoceptor agonist, in combination with vatinoxan, a peripherally selective alpha$_2$-adrenoceptor antagonist. Symptoms after absorption or accidental self-injection may include dose-dependent sedation, respiratory depression, bradycardia, tachycardia, and hypotension.

Animal Safety Warnings

Zenalpha should not be administered in the presence of pre-existing hypotension, hypoxia or bradycardia. Due to the pronounced cardiovascular effects of alpha$_2$-adrenoceptor agonists, only clinically healthy dogs (American Society of Anesthesiologists [ASA] classes I and II) should be administered Zenalpha. Dogs should be monitored frequently for cardiovascular function and body temperature during sedation.

Zenalpha is not intended for use in cats. The use of Zenalpha in cats has been associated with hypotension.

PRECAUTIONS: Dogs should be monitored frequently during sedation for changes in heart rate, blood pressure, respiratory rate and body temperature. Tachycardia may occur in some dogs after recovery from sedation.

In the event of hypoxia or apnea, supplemental oxygen should be administered.

Following administration of Zenalpha, a decrease in body temperature may occur and an external heat source may be needed to maintain body temperature. Hypothermia may persist longer than sedation and analgesia.

The analgesic effect of Zenalpha will not last longer than the sedative effects. Additional analgesic(s) should be administered as needed.

Nervous, excited or agitated dogs with high levels of endogenous catecholamines may exhibit a reduced pharmacological response to Zenalpha (ineffectiveness). The onset of sedative/analgesic effects could be slowed, or the depth and duration of effects could be diminished or nonexistent. Therefore, allow the dog to rest quietly for 10 to 15 minutes after injection.

With the alpha$_2$-adrenoceptor agonist drug class, including Zenalpha, the potential for isolated cases of hypersensitivity, including paradoxical response (excitation) exists.

Repeat dosing with Zenalpha has not been evaluated.

Zenalpha has only been evaluated in fasted dogs; therefore, the effects on fed dogs (for example occurrence of vomiting) have not been characterized.

The concurrent use of anticholinergic medications and Zenalpha has not been evaluated.

Zenalpha may decrease serum glucose in healthy dogs and this effect may persist longer than sedation.

The safe use of Zenalpha has not been evaluated in dogs with hepatic or renal impairment, dogs younger than 4.5 months old, or dogs that are pregnant, lactating, or intended for breeding.

ADVERSE REACTIONS: The most common adverse reactions observed in the field study were decreased body temperature (not requiring external heat support), reduced respiratory rate, diarrhea, muscle tremor, signs of colitis, hypothermia (requiring external heat support).

To report suspected adverse events, for technical assistance or to obtain a copy of the SDS, contact Dechra Veterinary Products at (866) 933-2472. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae.

MANUFACTURED FOR:

Dechra Veterinary Products
7015 College Boulevard, Suite 525
Overland Park, KS 66211 USA

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