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Zenalpha (*medetomidine / vatinoxan*)

An overview of Zenalpha and why it is authorised in the EU

What is Zenalpha and what is it used for?

Zenalpha is a medicine used to sedate (calm down) dogs during non-invasive, non-painful or mildly painful veterinary procedures lasting less than 30 minutes that require the animal to be restrained or sedated and made less sensitive to pain.

Zenalpha contains the active substances medetomidine and vatinoxan.

How is Zenalpha used?

Zenalpha is provided as a solution for injection and can only be obtained with a prescription.

The medicine is given as an intramuscular (into the muscle) injection and the dose is based on the dog's body surface area (calculated using bodyweight).

For more information about using Zenalpha, see the package leaflet or contact your veterinarian or pharmacist.

How does Zenalpha work?

Zenalpha contains two active substances. The first, medetomidine, is an alpha2-adrenoceptor agonist. It works by attaching to receptors (targets) known as alpha2-adrenergic receptors and preventing the release of the neurotransmitter noradrenaline from nerve cells in the body. A neurotransmitter is a substance that nerve cells use to communicate with neighbouring cells. Since noradrenaline is involved in maintaining alertness and arousal, reducing its release decreases the level of consciousness, including the sensation of pain. The second active substance, vatinoxan, is an adrenoreceptor antagonist. It works by attaching to and blocking alpha2-adrenoceptors in the heart and blood vessels, minimising unwanted cardiovascular (affecting the heart and blood vessels) effects that may be caused by medetomidine.

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What benefits of Zenalpha have been shown in studies?

A field study at six sites in the USA compared the effect of Zenalpha with that of a medicine containing dexmedetomidine (an active substance closely related to medetomidine) in 223 dogs undergoing non-invasive, potentially mildly painful procedures which required restraint and sedation.

The study found that the procedures could be successfully completed in 95% of dogs given Zenalpha and 90% of those given dexmedetomidine. In addition, pain control was comparable between both treatment groups 15 and 30 minutes after administration. The study also consistently found that heart rate dropped less at all time points following administration of Zenalpha compared with administration of dexmedetomidine.

What are the risks associated with Zenalpha?

The most common side effects with Zenalpha (which may affect more than 1 in 10 animals) are hypothermia (low body temperature), slow heartbeat and rapid heartbeat. Other side effects (which may affect up to 1 in 10 animals) include diarrhoea, colitis (inflammation in the large intestines) and muscle tremors.

For the full list of side effects of Zenalpha, see the package leaflet.

Zenalpha must not be used in dogs with cardiovascular disease, respiratory (lung) disease, liver or kidney problems, hypoglycaemia (low blood sugar) or those at risk of hypoglycaemia. It must also not be used in dogs that are in shock or severely debilitated or as a pre-anaesthetic medicine (to sedate dogs before bringing about general anaesthesia).

For the full list of restrictions, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Safety information has been included in the summary of product characteristics and the package leaflet for Zenalpha, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers, in particular for pregnant women.

In case of skin or eye contact the affected area should be rinsed immediately with water and any contaminated clothes should be removed.

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

Why is Zenalpha authorised in the EU?

The European Medicines Agency decided that Zenalpha's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Zenalpha

Zenalpha received a marketing authorisation valid throughout the EU on 15/12/2021.

Further information on Zenalpha can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/zenalpha.

This overview was last updated in 11-2021.