

**Material Safety Data Sheet****Sedastop 5 mg/ml Solution for Injection for Cats and Dogs****SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING****1.1 Product identification**

**Product name(s):** Sedastop 5 mg/ml Solution for Injection for Cats and Dogs  
**Product code(s):** XVD202 (10 ml vial)

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

**Relevant identified uses:** Veterinary medicinal product  
**Uses advised against:** Not for human use. Refer to the product information leaflet  
**Reasons why uses advised against:** Refer to the product information leaflet

**1.3 Details of the supplier of the safety data sheet**

**Company name:** Animalcare Limited  
**Address:** 10 Great Northway  
York Business Park  
Nether Poppleton  
York  
YO26 6RB  
United Kingdom

**1.4 Emergency telephone number**

**Daytime:** +44 (0) 1904 487687

**SECTION 2: HAZARDS IDENTIFICATION****2.1 Classification of the substance or mixture**

**Classification according to Regulation (EC) 1272/2008** This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

**2.2 Label elements**

**Labelling according to Regulation (EC) 1272/2008** This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

**Hazard pictograms:** Not applicable

**Signal word:** Not applicable

**Hazard statements:** Not applicable

**Precautionary statements:** Observe good industrial hygiene practices

**Supplemental information:** Administration of atipamezole causes transient changes in heart rate and blood pressure.  $\alpha$ 2-adrenergic receptor antagonist. Clinical use of this drug has caused nervousness, excitation, vomiting, diarrhoea

**2.3 Other hazards**

**Hazard(s) not otherwise classified (HNOC)** None known

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2 Mixtures

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>% [weight]</i>
Atipamezole hydrochloride	[104075-48-1]	0.5%
Methyl parahydroxybenzoate	[99-76-3]	0.1%
Sodium chloride	[7647-14-5]	Proprietary
Hydrochloric acid	[7647-01-0]	Proprietary
Sodium hydroxide	[1310-73-2]	Proprietary
Water for injections	[7732-18-5]	Proprietary

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Eyes:</b>	Do not rub eyes. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention immediately
<b>Skin:</b>	Wash off with soap and water. Get medical attention if symptoms occur
<b>Ingestion:</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control centre immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions
<b>Inhalation:</b>	Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist

### 4.2 Most important symptoms and effects, both acute and delayed

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Administration of atipamezole causes transient changes in heart rate and blood pressure

### 4.3 Indication of any immediate medical attention and special treatment needed

alpha2-adrenergic receptor antagonist. Treat symptomatically. Monitor respiratory, cardiac and central nervous system. Seek medical advice if required

## SECTION 5: FIRE- FIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable extinguishing media:</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> )
<b>Unsuitable extinguishing media:</b>	Do not use water jet as an extinguisher, as this will spread the fire

### 5.2 Special hazards arising from the substance or mixture

<b>Specific hazards during firefighting:</b>	Not flammable or combustible
<b>Hazardous combustion products:</b>	Decomposition products may include the following materials: Carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> )

### 5.3 Advice for fire-fighters

<b>Special protective equipment for fire-fighters:</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire
<b>Further information:</b>	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

- Advice for non-emergency personnel:** Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained
- Advice for emergency responders:** If specialised clothing is required to deal with the spillage, take note of any information in section 8 on suitable and unsuitable materials

### 6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

### 6.3 Methods and material for containment and cleaning up

- Large spills:** Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water
- Small spills:** Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination

### 6.4 Reference to other sections

- See Section 1 for emergency contact information  
See section 8 for personal protection  
See Section 13 for additional waste treatment information

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

- Advice on safe handling:** Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment
- Hygiene measures:** Observe good industrial hygiene practices

### 7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers:** Keep out of reach of children. Keep in the original packaging
- Storage temperature:** Store below 30 °C. Do not freeze
- Further information on storage conditions:** Protect from direct incidence of light

### 7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. At this time, the other constituents have no known exposure limits

<i>Substance name in the mixture</i>	<i>Type</i>	<i>Value</i>
Atipamezole hydrochloride	not listed	< 10 µg/m <sup>3</sup>

## 8.2 Exposure controls

<b>Engineering measures:</b>	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate
<b>Individual protection measures:</b>	
<b>Hygiene measures:</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants
<b>Eye/face protection:</b>	No specific measures identified
<b>Skin/body protection:</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas
<b>Hand protection:</b>	Wear appropriate chemical resistant gloves
<b>Respiratory protection:</b>	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapours are likely. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.
<b>Environmental exposure controls:</b>	Consider the provision of containment around storage vessels

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Liquid
<b>Colour:</b>	Colourless
<b>Odour:</b>	None
<b>Odour threshold:</b>	No data available
<b>pH:</b>	No data available
<b>Density:</b>	No data available
<b>Melting point:</b>	No data available
<b>Boiling point:</b>	No data available
<b>Flash point:</b>	No data available
<b>Evaporation rate:</b>	No data available
<b>Flammability:</b>	No data available
<b>Water solubility:</b>	Soluble
<b>Partition coefficient:</b>	No data available
<b>Auto-ignition temperature:</b>	No data available
<b>Thermal decomposition:</b>	No data available
<b>Viscosity:</b>	No data available
<b>Vapour pressure:</b>	No data available
<b>Vapour density:</b>	No data available
<b>Explosive properties:</b>	No data available
<b>Oxidizing properties:</b>	The substance or mixture is not classified as oxidizing

## 9.2 Other information

No data available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

### 10.2 Chemical stability

Stable under normal conditions

### 10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

### 10.4 Conditions to avoid

Avoid contact with incompatible materials

### 10.5 Incompatible materials

None Known

### 10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

<b>Acute toxicity:</b>	Atipamezole hydrochloride LD <sub>50</sub> 44 mg/kg (Rat, SC)
<b>Chronic toxicity:</b>	No data available
<b>Skin irritation/sensitization:</b>	Prolonged skin contact may cause temporary irritation. Not a respiratory sensitizer
<b>Reproductive toxicity:</b>	No data available
<b>Carcinogenicity:</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA
<b>Mutagenicity:</b>	No data available

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

No data available

## **12.6 Other adverse effects**

No data available

## **SECTION 13: DISPOSAL CONSIDERATIONS**

### **13.1 Waste treatment methods**

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

## **SECTION 14: TRANSPORT INFORMATION**

Not regulated as dangerous goods

## **SECTION 15: REGULATORY INFORMATION**

### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

This product has been authorised under the provisions of Directive 2001/82/EC

### **15.2 Chemical safety assessment**

For this product, a chemical safety assessment was not carried out

## **SECTION 16: OTHER INFORMATION**

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

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