

# Atipamezole Hydrochloride Injection 5.0 mg/mL

Safety Data Sheet



Date of issue: 26 Feb 2026

Version:.00

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Name:** Atipamezole hydrochloride Injection sterile injectable solution 5.0 mg/mL

### 1.2. Intended Use of the Product

Atipamezole Hydrochloride Injection is indicated for the reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride, and medetomidine hydrochloride in dogs.

### 1.3. Name, Address of the Responsible Party

Felix Pharmaceuticals Private Limited,  
25-28 North Wall Quay Dublin 1, Ireland

### 1.4. Emergency Telephone Number

**Emergency Number:** Contact Felix Pharmaceuticals Private Limited at 1-833-571-1525.

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

#### Classification (GHS-US)

While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

### 2.2. Label Elements

No known significant effects or critical hazards.

### 2.3. Other Hazards

No additional information available.

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Ingredient Name

Atipamezole hydrochloride

### 3.2. Chemical Formula:

4-(2-ethyl-2,3-dihydro-1H-inden-2-yl)-1H-imidazole hydrochloride

### 3.3. Mixture

| Component                 | Approximate Quantity | CAS number     |
|---------------------------|----------------------|----------------|
| Atipamezole hydrochloride | 5.0 mg/mL            | 104075-48-1    |
| Non-hazardous Ingredients | q.s                  | Not Applicable |

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First Aid Measures

**First-aid Measures After Inhalation:** Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

**First-aid Measures After Skin Contact:** Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

**First-aid Measures After Eye Contact:** Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

**First-aid Measures After Ingestion:** Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

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

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

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled. No specific treatment.

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## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Use an extinguishing agent suitable for the surrounding fire.

**Unsuitable Extinguishing Media:** None known.

### 5.2. Special Hazards Arising from the Substance or Mixture

**Fire Hazard:** In a fire or if heated, a pressure increase will occur and the container may burst.

**Explosion Hazard:** None known.

**Reactivity:** No specific test data related to reactivity available for this product or its ingredients.

**Special Fire Fighting Procedure:** Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** No action shall be taken involving any personal risk or without suitable training.

**Firefighting Instructions:** Keep unnecessary personnel away.

**Protection During Firefighting:** Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**For non-emergency personnel:** Keep unnecessary personnel away.

**For emergency responders:** Keep unnecessary personnel away. If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

### 6.2. Environmental Precautions:

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### 6.3. Methods and Material for Containment and Cleaning Up

**Small spill:** Stop leak if without risk. Move containers from spill area. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

**Large spill:** Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

### 6.4. Reference to Other Sections

For waste disposal, see section 13 of the SDS, and for personal protection, see section 8 of the SDS.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Hygiene Measures:** Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Store at USP controlled room temperature 20° to 25° C (68° - 77° F), with excursions permitted to 15° to 30°C (59° - 86° F). Use within 90 days of first puncture.

**Incompatible Products:** No specific data.

### 7.3. Specific End Use(s)

The result of atipamezole administration in the dog is the rapid recovery from the sedative and analgesic effects produced by the alpha2-adrenergic agonists dexmedetomidine or medetomidine.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

None.

### 8.2. Exposure Controls

- |                                  |   |                                                                                                                                                                                                               |
|----------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Appropriate Engineering Controls | : | Keep air contamination levels below the exposure limits. If airborne exposures are within or exceed exposure limits, wear an appropriate respirator with a protection factor sufficient to control exposures. |
| Personal Protective Equipment    | : | The use of personal protective equipment may be necessary as conditions warrant.                                                                                                                              |

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| Hand Protection          | : | Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.                                                                                                                                                                                                                       |
| Eye Protection           | : | Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with sideshields.                                                            |
| Skin and Body Protection | : | Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. |
| Respiratory Protection   | : | Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.                                                                                                                                      |

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

|                                        |                                |
|----------------------------------------|--------------------------------|
| Physical State                         | : Liquid,                      |
| Appearance                             | : Clear and colorless solution |
| Odor                                   | : No data available            |
| Odor Threshold                         | : No data available            |
| pH                                     | : No data available            |
| Evaporation Rate                       | : No data available            |
| Melting Point                          | : No data available            |
| Freezing Point                         | : No data available            |
| Boiling Point                          | : No data available            |
| Flash Point                            | : No data available            |
| Auto-ignition Temperature              | : No data available            |
| Decomposition Temperature              | : No data available            |
| Flammability (solid, gas)              | : No data available            |
| Vapor Pressure                         | : No data available            |
| Relative Vapor Density at 20 °C        | : No data available            |
| Relative Density                       | : No data available            |
| Solubility                             | : No data available            |
| Partition Coefficient: N-Octanol/Water | : No data available            |
| Viscosity                              | : No data available            |

### 9.2. Other Information: No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- |                                          |   |                                                                                                      |
|------------------------------------------|---|------------------------------------------------------------------------------------------------------|
| 10.1. Reactivity                         | : | No specific test data related to reactivity available for this product or its ingredients.           |
| 10.2. Chemical Stability                 | : | The product is stable.                                                                               |
| 10.3. Possibility of Hazardous Reactions | : | Under normal conditions of storage and use, hazardous reactions will not occur.                      |
| 10.4. Conditions to Avoid                | : | No specific data.                                                                                    |
| 10.5. Incompatible Materials             | : | No specific data. Strong oxidizing agents                                                            |
| 10.6. Hazardous Decomposition Products   | : | Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

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## SECTION 11: TOXICOLOGICAL INFORMATION

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|----------------------------|---|---------------------------------------------------------------------------|
| 11.1. Acute Toxicity       | : | Rat - Subcutaneous - LD50 44 mg/kg<br>Dog - Intramuscular – LDLo >5 mg/kg |
| 11.2. Local Effects        | : | Not Classified                                                            |
| 11.3. Reproductive Effects | : | Not Classified                                                            |
| 11.4. Mutagenicity         | : | Not Classified.                                                           |

## SECTION 12: ECOLOGICAL INFORMATION

- |                                     |   |                                                   |
|-------------------------------------|---|---------------------------------------------------|
| 12.1. Toxicity                      | : | Not available.                                    |
| 12.2. Persistence and Degradability | : | Not available.                                    |
| 12.3. Bio accumulative Potential    | : | Not available.                                    |
| 12.4. Mobility in Soil              | : | Not available.                                    |
| 12.5. Other Adverse Effects         | : | No known significant effects or critical hazards. |

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

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|---------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Waste Disposal Recommendations</b> | : | Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. |
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## SECTION 14: TRANSPORT INFORMATION

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|----------------------------------------------------------------------|
| 14.1. Transport according to all local, state and federal regulation |
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## SECTION 15: REGULATORY INFORMATION

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|--------------------------------------------|
| 15.1. No additional information available. |
|--------------------------------------------|

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

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|------------------------|---|----------------|
| 16.1. Previous Version | : | Effective Date |
| Nil                    | : | Nil            |

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. To the best of Felix's knowledge, the information contained here is accurate. However, neither the above-named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All material may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.