1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Revertor 5 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Atipamezole hydrochloride 5.0 mg
(equivalent to 4.27 mg atipamezole)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.0 mg
Sodium chloride	
Hydrochloric acid (for pH-adjustment)	
Sodium hydroxide (for pH-adjustment)	
Water for injections	

Clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats.

3.2 Indications for use for each target species

Atipamezole hydrochloride is a selective α2-Antagonist and indicated for reversal of the sedative effects of medetomidine and dexmedetomidine in dogs and cats.

3.3 Contraindications

Do not use in:
- breeding animals.
- animals suffering from liver- or renal diseases.
- cases of hypersensitivity to the active substance or to any of the excipients.

See also section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

After administration of the veterinary medicinal product, the animals should be allowed to rest in a quiet place. During recovery time animals should not be left unattended. Make sure that the animal has regained a normal swallowing reflex before any food or drink is offered.
Due to different dosing recommendations caution should be taken if using the veterinary medicinal product off-label in animals other than the target species.
If other sedatives than medetomidine are given it must be kept in mind that the effects of those other agents may persist after reversal of (dex)medetomidine.
Atipamezole does not reverse the effect of ketamine, which may cause seizures in dogs and elicit cramps in cats when used alone. Do not use atipamezole earlier than 30 - 40 minutes after concomitant administration of ketamine.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Due to the potent pharmacological activity of atipamezole, skin-, eye- and mucous membrane- contact with this veterinary medicinal product should be avoided. In case of accidental spillage wash the affected area immediately with clean running water. Seek medical attention if irritation persists. Remove contaminated clothes that are in direct contact with the skin.
Care should be taken to avoid accidental ingestion or self-injection. In case of accidental ingestion or self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. .

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs, cats:

Rare (1 to 10 animals / 10 000 animals treated):	Hyperactivity, vocalisation[1] Tachycardia Increased salivation, vomiting, involuntary defecation Muscle tremor Increased respiratory rate Involuntary urination
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Sedation[2]
Undetermined frequency (cannot be estimated from the available data)	Hypotension[3] Hypothermia[4]

[1] Atypical.
[2] Recurrence of sedation may occur or the recovery time may not be shortened.
[3] Transient; has been observed during the first 10 minutes post-injection.
[4] In cats, when using low doses to partially reverse the effects of medetomidine or dexmedetomidine.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Therefore, the use is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

A simultaneous administration of atipamezole with other centrally acting veterinary medicinal products such as diazepam, acepromazine or opiates is not recommended.

3.9 Administration routes and dosage

Intramuscular use.
For single intramuscular injection.

Atipamezole hydrochloride is administered 15 - 60 min after medetomidine or dexmedetomidine hydrochloride administration.

Dogs: the intramuscular atipamezole hydrochloride dose [in µg] is five times that of the previous medetomidine hydrochloride dose or ten times that of the dexmedetomidine hydrochloride dose. Due to the 5-fold higher concentration of the active substance (atipamezole hydrochloride) in this veterinary medicinal product compared to that of preparations containing 1 mg medetomidine hydrochloride per ml and the 10-fold higher concentration compared to that of preparations containing 0.5 mg dexmedetomidine hydrochloride, an equal volume of each preparation is required.

Dosage example Dogs:

Medetomidine 1 mg/ml solution for injection dosage	**Revertor 5 mg/ml solution for injection for dogs dosage**
0.04 ml/kg body weight (bw), i.e. 40 µg/kg bw	0.04 ml/kg bw, i.e. 200 µg/kg bw
Dexmedetomidine 0.5 mg/ml solution for injection dosage	**Revertor 5 mg/ml solution for injection for dogs dosage**
0.04 ml/kg body weight (bw), i.e. 20 µg/kg bw	0.04 ml/kg bw, i.e. 200 µg/kg bw

Cats: the intramuscular atipamezole hydrochloride dose [in µg] is two-and-a-half times that of the previous medetomidine hydrochloride dose or five times that of the dexmedetomidine hydrochloride dose. Due to the 5-fold higher concentration of the active substance (atipamezole hydrochloride) in this veterinary medicinal product compared to that of preparations containing 1 mg medetomidine hydrochloride per ml and the 10-fold higher concentration compared to that of preparations containing 0.5 mg dexmedetomidine hydrochloride, half the volume of the veterinary medicinal product to that of the previously administered medetomidine or dexmedetomidine should be given.

Dosage example Cats:

Medetomidine 1 mg/ml solution for injection dosage	**Revertor 5 mg/ml solution for injection for cats dosage**

0.08 ml/kg body weight (bw), i.e. 80 µg/kg bw	0.04 ml/kg bw, i.e. 200 µg/kg bw
Dexmedetomidine 0.5 mg/ml solution for injection dosage	**Revertor 5 mg/ml solution for injection for cats dosage**
0.08 ml/kg body weight (bw), i.e. 40 µg/kg bw	0.04 ml/kg bw, i.e. 200 µg/kg bw

The recovery time is shortened to approximately 5 minutes. The animal becomes mobile after approximately 10 minutes after administration of the veterinary medicinal product.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdose of atipamezole hydrochloride may result in transient tachycardia and over-alertness (hyperactivity, muscle tremor). If necessary, these symptoms may be reversed by a (dex)medetomidine hydrochloride dose which is lower than the usually used clinical dose.
If atipamezole hydrochloride is inadvertently administered to an animal not previously treated with (dex)medetomidine hydrochloride, hyperactivity and muscle tremor may occur. These effects may persist for about 15 minutes.
Over-alertness in the cat is best handled by minimising external stimuli.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QV03AB90

4.2 Pharmacodynamics

Atipamezole is a potent and selective α2-receptor blocking agent (α2-antagonist), which promotes the release of the neurotransmitter noradrenaline in the central as well as in the peripheral nervous systems. This leads to activation of the central nervous system due to sympathetic activation. Other pharmacodynamic effects as for example influence on the cardiovascular system are only mild – but a transient decrease of blood pressure may be seen within the first 10 minutes after injection of atipamezole hydrochloride.
As a α2-antagonist, atipamezole is capable of eliminating (or inhibiting) the effects of the α2-receptor agonist, medetomidine or dexmedetomidine. Thus, atipamezole reverses the sedative effects of (dex)medetomidine hydrochloride in dogs and cats to normal and may lead to a transient increase in heart rate.

4.3 Pharmacokinetics

Atipamezole hydrochloride is rapidly absorbed after intramuscular injection. The maximal concentration in the central nervous system is reached in 10 - 15 minutes. Volume of distribution (V_d) is about 1 – 2.5 l/kg. The half-life ($t_{½}$) of atipamezole hydrochloride is reported to be approximately 1 hour. Atipamezole hydrochloride is rapidly and completely metabolised. The metabolites are mainly excreted in urine and in a small amount in faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
See also section 3.8.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Clear glass (type I) vial with bromobutylrubber stopper (type I) secured with aluminium crimp caps.
Cardboard box with 1, 5 or 10 vial(s) containing 10 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP- Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10810/004/001

8. DATE OF FIRST AUTHORISATION

25/04/2008

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

26/11/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).