

Cats and dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For single intramuscular injection in cats and dogs. Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes. Atipamezole is generally administered 15 - 60 minutes after the medetomidine or dexmedetomidine injection.

Dogs: The 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 ingredient (atipamezole hydrochloride) in this 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 1.0 mg/ml solution for injection Dosage:	Atipam 5.0 mg/ml solution for injection Dosage:
0,04 ml/kg body weight (bw), i.e. 40 $\mu\text{g}/\text{kg}$ bw	0,04 ml/kg bw, i.e. 200 $\mu\text{g}/\text{kg}$ bw
Dexmedetomidine 0.5 mg/ml solution for injection Dosage:	Atipam 5.0 mg/ml solution for injection Dosage:
0,04 ml/kg body weight (bw), i.e. 20 $\mu\text{g}/\text{kg}$ bw	0,04 ml/kg bw, i.e. 200 $\mu\text{g}/\text{kg}$ bw

Cats: The 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 ingredient (atipamezole hydrochloride) in this 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 product to that of the previously administered medetomidine or dexmedetomidine should be given.

Dosage example cats:

Medetomidine 1.0 mg/ml solution for injection Dosage:	Atipam 5.0 mg/ml solution for injection Dosage:
0,08 ml/kg body weight (bw), i.e. 80 $\mu\text{g}/\text{kg}$ bw	0,04 ml/kg bw, i.e. 200 $\mu\text{g}/\text{kg}$ bw
Dexmedetomidine 0.5 mg/ml solution for injection Dosage:	Atipam 5.0 mg/ml solution for injection Dosage:
0,08 ml/kg body weight (bw), i.e. 40 $\mu\text{g}/\text{kg}$ bw	0,04 ml/kg bw, i.e. 200 $\mu\text{g}/\text{kg}$ bw

The recovery time is shortened to approximately 5 minutes. The animals become mobile after approximately 10 minutes after administration of the product=

9. ADVICE ON CORRECT ADMINISTRATION

In the absence of compatibility studies this veterinary medicinal product must not be mixed

with other veterinary medicinal products in the same syringe.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Store below 30°C.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the label after EXP

Shelf-life after first opening the container: 28 days.

Any remaining content of the product should be disposed of after this period.

12. SPECIAL WARNING(S)

Special precautions for use in animals

After administration of the product, the animals should be allowed to rest in a quiet place.

During recovery time animals should not be left unattended.

Due to different dosing recommendations caution should be taken if using the product off-label in animals other than the target species.

If sedatives other 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 administer atipamezole within 30 – 40 minutes of prior administration of ketamine.

Make sure the animal has regained normal swallowing reflex before any food or drink is offered.

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 product should be avoided. In case of accidental contact of the product with skin or eyes rinse abundantly with fresh 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 to the physician.

Use during pregnancy and lactation

The safety of the product has not been documented adequately during pregnancy and lactation. Therefore the use is not recommended during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction

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

Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdose of atipamezole hydrochloride may result in transient tachycardia and over-alertness (hyperactivity, muscle tremor). If necessary, these symptoms may be reversed by a 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2013

15. OTHER INFORMATION

Pack sizes: 5, 10 or 20 ml.

Not all pack sizes may be marketed

Registration number: 150-96-33760-00

License holder: ABIC VETERINARY PRODUCTS LTD. INDUSTRIAL ZONE, POB 489,
BEIT SHEMESH