LABELING AND PACKGAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Revertor 5 mg/ml Solution for Injection for Dogs and Cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of solution for injection contains:
Active substance: Atipamezole hydrochloride 5 mg
Excipients: Methyl parahydroxybenzoate (E218) 1 mg
Sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

Carton with one injection vial containing 10 ml solution for injection.
Carton with 5 injection vials each containing 10 ml solution for injection (5 x 10 ml).
Carton with 10 injection vials each containing 10 ml solution for injection (10 x 10 ml).

5. TARGET SPECIES

Dogs and Cats.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For single intramuscular injection.
Atipamezole hydrochloride is administered 15-60 min after medetomidine or dexmedetomidine hydrochloride administration.
The recovery time is shortened to approximately 5 minutes. The animal becomes mobile after approximately 10 minutes after administration of the product.

8. WITHDRAWAL PERIOD

Withdrawal period: Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

See section ‘Special warnings’ in the package leaflet.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 28 days
Once broached/opened, use by ….

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

UK: "Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority."

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

PL: For animal treatment only. Subject to medical prescription. Administration only by a veterinary surgeon.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH
Ostlandring 13
DE - 31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER(S)

400936.00.00

17. MANUFACTURER’S BATCH NUMBER

BN:
Note to GAT: Distribution category within a box and the statement ‘To be supplied only on a veterinary prescription’ need to be added.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Revertor 5 mg/ml Solution for Injection for Dogs and Cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml of solution for injection contains:
Active substance: Atipamezole hydrochloride 5 mg
Excipients: Methyl parahydroxybenzoate (E218) 1 mg
Sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular injection.

5. WITHDRAWAL PERIOD

Withdrawal period: Not applicable.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 28 days
Once broached/opened, use by ….

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET
Revertor 5 mg/ml Solution for Injection for Dogs and Cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

CP-Pharma Handelsges. mbH
Ostlandring 13
DE - 31303 Burgdorf
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Revertor 5 mg/ml Solution for Injection for Dogs and Cats
Atipamezole hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml of clear colourless solution for injection contains:
Active substance: Atipamezole hydrochloride 5 mg
Excipients: Methyl parahydroxybenzoate (E218) 1 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in:
- Breeding animals
- Animals suffering from liver- or renal diseases

6. ADVERSE REACTIONS

A transient hypotensive effect has been observed during the first 10 minutes post-injection of atipamezole hydrochloride. In rare cases hyperactivity, tachycardia, salivation, atypical vocalisation, muscle tremor, vomiting, increased respiratory rate, uncontrolled urination and uncontrolled defecation may occur. In very rare cases recurrence of sedation may occur or the recovery time may not be shortened after administration of atipamezole.

In cats, when using low doses to partially reverse the effects of medetomidine or dexmedetomidine, the possibility of hypothermia (even when aroused from sedation) should be guarded against.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and Cats.

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

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 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 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 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 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 product.

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Keep the vial in the outer carton.
Protect from light.
Shelf-life after first opening the container: 28 days
Do not use after the expiry date which is stated on the label after EXP.

UK: When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

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. 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 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 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. If accidental ingestion or self-injection occurs, seek medical attention immediately, showing a copy of the package leaflet.

Use during pregnancy, lactation or lay

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.

Interaction with other medicinal products and other forms of interaction

A simultaneous administration of atipamezole with other centrally acting medicinal products such 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 (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.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products in the same syringe.

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

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

UK: "Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority."

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

XX/XX/XXXX

15. OTHER INFORMATION

Carton with 1 vial containing 10 ml
Carton with 5 vials containing 10 ml
Carton with 10 vials containing 10 ml

Not all pack sizes may be marketed.

Note to GAT: Distribution category within a box and the statements ‘To be supplied only on a veterinary prescription’ and ‘For Animal Treatment Only’ need to be added.