VETERINARY MEDICINE

zoetis

ANTISEDAN®

INJECTABLE SOLUTION

SCHEDULING STATUS
S4

PROPRIETARY NAME (and dosage form)
ANTISEDAN® Injectable Solution

COMPOSITION
Each ml contains atipamezole hydrochloride 5 mg and methyl parahydroxybenzoate 1 mg as preservative.

PHARMACOLOGICAL CLASSIFICATION
C 1.4.3 Sedative antagonists

PHARMACOLOGICAL ACTION
Atipamezole is a potent, selective and specific alpha adrenoceptor antagonist exhibiting mainly alpha$_2$-adrenoceptor activity at both central and peripheral receptor sites. The antagonism leads to reversal of the effects of alpha$_2$-adrenoceptor agonists. Atipamezole reverses sedation with medetomidine.

INDICATIONS
The reversal of medetomidine (DOMITOR®) sedation/anaesthesia in dogs and cats.

CONTRA-INDICATIONS
No known contra-indications.

WARNINGS
Safety in pregnancy and lactation
As the use of ANTISEDAN during pregnancy and lactation has not been documented adequately, it should not be used in pregnant or lactating animals.

DOSAGE AND DIRECTIONS FOR USE
ANTISEDAN is administered by intramuscular injection only.
ANTISEDAN is administered immediately after the procedure.
The dose depends on the preceding dose of DOMITOR (medetomidine). In dogs it is usually 4 – 6 times and in cats 3 – 4 times the dose of DOMITOR (µg/kg). The effects of DOMITOR are reversed in 5 – 10 minutes.

DOGS		
DOMITOR® (medetomidine)	ANTISEDAN®	
µg/kg	µg/kg	ml/kg
20	120	0,02
40	200	0,04
80	320	0,06
100	400	0,08

CATS		
DOMITOR® (medetomidine)	ANTISEDAN®	
µg/kg	µg/kg	ml/kg
50	200	0,04
100	200 – 300	0,04 – 0,06
150	300 - 400	0,06 – 0,08

SIDE EFFECTS AND SPECIAL PRECAUTIONS
Side effects
Reported side effects may occur in cases both of accidental administration (prior to the use of medetomidine) and in animals in which the product is used for reversal.
Adverse reactions are highly infrequent. Vomiting or excessive salivation, panting and defecation have been reported but these symptoms are very rare. Rapidly transient hyperactivity and tachycardia may be observed in a few individuals.

Special precautions
The use of atipamezole may promote seizure activity in animals induced with ketamine. These animals should be monitored and treated symptomatically.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Slight transient agitation and tachycardia may be observed.

IDENTIFICATION
Clear, colourless injectable solution.

PRESENTATION
Multidose vial of 10 ml

STORAGE INSTRUCTIONS
Store below 25 °C. Keep out of reach of children and uninformed persons.
After withdrawal of the first dose the broached vial may be stored below 25 °C for 28 days.

REGISTRATION NUMBER
92/1.4.3/4

NAME AND BUSINESS ADDRESS OF THE APPLICANT
Zoetis South Africa (Pty) Ltd
Co. Reg. No. 2012/001825/07
85 Bute Lane, Sandton 2196
South Africa
Tel. (011) 245 3300 or 0860 ZOETIS (0860 963847)

DATE OF PUBLICATION OF THIS PACKAGE INSERT
18 April 2008

105515-8
-05/2015

Date: 18 Aug 2015		**Time: 11:11**	
Description	ANTISEDAN INJ 1x10ML		
Market	South Africa	**Proof N°**	03
Supplier	Orion	**Component**	Leaflet
Supplier N°	105515-8	**Pharma Code**	55
Perigord N°	257937	**PAR**	PAR-2015-0023901
Colours			Black

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TEXT SIZE
The BODY text on this A/W is at:
9.0 pt

Dimensions
148 x 300 mm
Drawing Number
N/A

VETERINÊRE MEDISYNE

zoetis

ANTISEDAN®

INSPUITBARE OPLOSSING

SKEDULERINGSTATUS
S4

EIENDOMSNAAM (en doseervorm)
ANTISEDAN® Inspuitbare Oplossing

SAMESTELLING
Elke ml bevat atipamesoolhidrochloried 5 mg en metielparahidroksiebensoaat 1 mg as preserveermiddel.

FARMAKOLOGIESE KLASSIFIKASIE
C 1.4.3 Kalmeermiddel antagoniste

FARMAKOLOGIESE WERKING
Atipamesool is 'n kragtige, selektiewe en spesifieke alfa-adrenoseptor antagonis wat hoofsaaklik alfa$_2$-adrenoseptor aktiwiteit toon by beide sentrale en perifere reseptor posisies. Die antagonisme veroorsaak omkering van die uitwerking van alfa$_2$-adrenoseptor agoniste. Atipamesool is 'n omkeerder van die kalmerende effek van medetomidien.

INDIKASIES
Die omkeer van medetomidien (DOMITOR®) kalmering/ verdowing in honde en katte.

KONTRA-INDIKASIES
Geen bekende kontra-indikasies nie.

WAARSKUWING
Veiligheid in swangerskap en laktasie
Aangesien die gebruik van ANTISEDAN tydens dragtigheid en laktasie nie voldoende deur dokumentasie gestaaf is nie, behoort dit nie by dragtige of lakterende diere gebruik te word nie.

DOSIS EN GEBRUIKSAANWYSINGS
ANTISEDAN word slegs binnespiers toegedien.
ANTISEDAN word onmiddellik na die prosedure toegedien.
Die dosis is afhanklik van die voorafgaande DOMITOR (medetomidien) dosis. By honde is dit gewoonlik 4 – 6 keer en by katte 3 – 4 keer die dosis DOMITOR (µg/kg). Die uitwerking van DOMITOR word binne 5 – 10 minute omgekeer.

HONDE		
DOMITOR® (medetomidien)	ANTISEDAN®	
µg/kg	µg/kg	ml/kg
20	120	0,02
40	200	0,04
80	320	0,06
100	400	0,08

KATTE		
DOMITOR® (medetomidien)	ANTISEDAN®	
µg/kg	µg/kg	ml/kg
50	200	0,04
100	200 – 300	0,04 – 0,06
150	300 - 400	0,06 – 0,08

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Newe-effekte
Aangemelde newe-effekte mag plaasvind in gevalle van beide toevallige toediening (voor die gebruik van medetomidien) en by diere waar die produk as omkeermiddel gebruik word.
Newe-effekte is hoogs ongereeld. Vomering of oormatige speekselafskeiding, gehyg na asem en ontlasting is aangemeld, maar hierdie simptome is uiters raar. Vinnig verbygaande hiperaktiwiteit en tagikardie mag in 'n paar individue opgemerk word.

Spesiale voorsorgmaatreëls
Die gebruik van atipamesool mag stuiptrekkingsaktiwiteit bevorder by diere wat met ketamien geïnduseer is. Hierdie diere behoort gemoniteer en simptomaties behandel te word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Ligte verbygaande rusteloosheid en tagikardie kan voorkom.

IDENTIFIKASIE
'n Helder, kleurlose oplossing vir inspuiting.

AANBIEDING
Multidosis flessie van 10 ml

BERGINGSAANWYSINGS
Berg benede 25 °C. Hou buite bereik van kinders en oningeligte persone.
Na onttrekking van die eerste dosis mag die flessie benede 25 °C vir 28 dae geberg word.

REGISTRASIENOMMER
92/1.4.3/4

NAAM EN BESIGHEIDSADRES VAN APPLIKANT
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