LABELLING AND PACKAGE LEAFLET

OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormilan 1 mg/ml solution for injection for dogs and cats
Medetomidine hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:

Medetomidine hydrochloride .....1.0 mg
(equivalent to medetomidine .....0.85 mg)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs and cats.

6. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs: IM or IV use
Cats: SC, IM or IV use

Read the package leaflet before use.

7. WITHDRAWAL PERIOD

Not applicable.

8. SPECIAL WARNING(S), IF NECESSARY

Alpha-2-agonists can cause serious adverse reactions. Read the package leaflet before use.

9. EXPIRY DATE

EXP
Shelf-life after first opening the immediate packaging: 28 days

10. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Protect from light.
Protect from frost.

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

Disposal: read package leaflet

12. 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.

13. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 Barcelona
SPAIN

Distributed by:
LINTBELLS LIMITED
West Barn, Fairclough Hall Farm, Halls Green, Weston
Hitchin
Hertfordshire
SG4 7DP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32509/4001

17. MANUFACTURER'S BATCH NUMBER

Batch

LABEL vial of 10 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormilan 1 mg/ml solution for injection for dogs and cats
Medetomidine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Not applicable

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

Dogs: IM or IV route
Cats: SC, IM or IV route

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP
Once opened, use by _____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

Distributed by:
LINTBELLS LIMITED
West Barn, Fairclough Hall Farm, Halls Green, Weston
Hitchin
Hertfordshire
SG4 7DP

PACKAGE LEAFLET FOR:

Dormilan 1 mg/ml solution for injection for dogs and cats
Medetomidine hydrochloride

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

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 Barcelona
Spain

Manufacturer responsible for batch release:
INDUSTRIAL VETERINARIA, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat
Spain

CHEMICAL IBÉRICA PV, S.L.
Ctra. Burgos-Portugal, Km. 256,
Calzada de Don Diego, 37448 (Salamanca)
Spain

Distributed by:
LINTBELLS LIMITED
West Barn, Fairclough Hall Farm, Halls Green, Weston
Hitchin
Hertfordshire
SG4 7DP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormilan 1 mg/ml solution for injection for dogs and cats
Medetomidine hydrochloride

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

Clear and colourless solution

Each ml contains:

Active substance:

Medetomidine hydrochloride .....1.00 mg
equivalent to medetomidine .....0.85 mg

Excipients:

Methyl parahydroxybenzoate (E218) .....1.0 mg
Propyl parahydroxybenzoate .....0.2 mg

4. INDICATION(S)

In dogs and cats:
- Sedation in order to facilitate the restraint of animals during clinical examinations.
- Premedication prior to general anaesthesia.

5. CONTRAINDICATIONS

Do not use in animals with serious cardiovascular disease, respiratory disease or hepatic or renal disorders.
Do not use in case of mechanical disorders of gastrointestinal tract (torsion of the stomach, imprisonment, obstruction of the oesophagus).
Do not administer in conjunction with sympathomimetic amines.
Do not use in case of known hypersensitivity to the active substance or any excipients.
Do not use in animals with diabetes mellitus.
Do not use in animals with state of shock, emaciation or serious debilitation.
Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.

6. ADVERSE REACTIONS

The following adverse reactions may occur:
- Cardiovascular effects : bradycardia with atrioventricular block (1st and 2nd degree) and occasional extrasystoles, vasoconstriction of coronary artery, decreased cardiac output.
- Increase of blood pressure just after the administration of product and then return to the normal value or slightly below.
- Some dogs and most cats vomit 5-10 minutes after injection. Cats may also vomit on recovery.
- Sensitivity to loud noises has been observed in some animals.
- An increase of diuresis, hypothermia, respiratory depression, cyanosis, a pain at the injection site and muscle tremors may also occur.

The following may also be observed:
- Cases of reversible hyperglycaemia due to a depression of insulin secretion.
- Cases of pulmonary oedema.

In cases of cardiovascular and respiratory depression, assisted ventilation and administration of oxygen may be indicated. Atropine can increase the

cardiac rate.
Dogs weighing less than 10 kg can present frequently with the above-mentioned adverse reactions.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

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

Dogs: intramuscular or intravenous injection

For sedation:
For sedation the product should be administered at the rate of 15-80 µg of medetomidine hydrochloride per kg of body weight I.V., or 20-100 µg of medetomidine hydrochloride per kg of body weight I.M.
Use the table below to determine the correct dosage on the basis of body weight.
Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting 30 to 180 minutes.

Dormilan dosages in ml and corresponding amount of medetomidine hydrochloride in µg /kg bw:

body weight [kg]	i.v.- Injection [ml]	corresp. to [µg/kg bw]	i.m.- Injection [ml]	corresp. to [µg/kg bw]
1	0.08	80.0	0.10	100.0
2	0.12	60.0	0.16	80.0
3	0.16	53.3	0.21	70.0
4	0.19	47.5	0.25	62.5
5	0.22	44.0	0.30	60.0
6	0.25	41.7	0.33	55.0
7	0.28	40.0	0.37	52.9
8	0.30	37.5	0.40	50.0
9	0.33	36.7	0.44	48.9
10	0.35	35.0	0.47	47.0
12	0.40	33.3	0.53	44.2
14	0.44	31.4	0.59	42.1
16	0.48	30.0	0.64	40.0
18	0.52	28.9	0.69	38.3
20	0.56	28.0	0.74	37.0

25	0.65	26.0	0.86	34.4
30	0.73	24.3	0.98	32.7
35	0.81	23.1	1.08	30.9
40	0.89	22.2	1.18	29.5
50	1.03	20.6	1.37	27.4
60	1.16	19.3	1.55	25.8
70	1.29	18.4	1.72	24.6
80	1.41	17.6	1.88	23.5
90	1.52	16.9	2.03	22.6
100	1.63	16.3	2.18	21.8

For premedication:

10-40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1-0.4 ml per 10 kg body weight. The exact dose depends on the combination of drugs used and the dosage(s) of the other drug(s). The dose should furthermore be adjusted to the type of surgery, length of procedure and patient temperament and weight. Premedication with medetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. Before using any combinations, product literature for the other products should be observed.

Cats: intramuscular injection, intravenous injection and subcutaneous injection

For moderate-deep sedation and restraint of cats the product should be administered at a dosage of 50 – 150 µg medetomidine hydrochloride /kg bw (corresp. to 0.05 – 0.15 ml/ kg bw). The speed of induction is slower when subcutaneous route of administration is used.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not refrigerate or freeze.
Protect from light.
Protect from frost.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 28 days

When the container is broached 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 :

It is possible that medetomidine does not provide analgesia throughout the entire sedation period. The use of additional analgesics should be considered during painful surgical procedures.

During its use in premedication, the dosage of anaesthetic will be reduced in proportion and established according to the reaction of the animal, depending on the variability of response between animals. Special warnings and contraindications included in the literature of the other products should be respected before carrying out any association.

Medetomidine can produce respiratory depression; in such case, manual ventilation and administration of oxygen may be conducted.

A clinical examination should be carried out in all animals before the use of veterinary medicinal products for sedation and/or general anaesthesia.

Higher doses of medetomidine should be avoided in large breed dogs. Care should be taken when combining medetomidine with other anaesthetics or sedatives because of its marked anaesthetic sparing effects. Animals should be fasted 12 hours before anaesthesia.

The animal should be placed in a calm and quiet surrounding to let the sedation gain its maximum effect. This takes about 10-15 minutes. One should not start any procedure or give other medicines before maximum sedation is reached.

Treated animals should be kept warm and at a constant temperature, both during the procedure and recovery.

The eyes should be protected by a suitable lubricant.

Nervous, aggressive or excited animals should be given the possibility to calm down before initiation of treatment

Sick and debilitated dogs and cats should only be premedicated with medetomidine before induction and maintenance of general anaesthesia based on a risk-benefit assessment.

Care should be taken with use of medetomidine in animals with cardiovascular disease, or which are elderly or in general poor health. Liver and kidney function should be evaluated prior to use.

In order to reduce the recovery time after anæsthesia or sedation, the effect of medetomidine can be reversed by the administration of an alpha-2-antagonist such as atipemazole.

Atipamezole does not reverse the effect of ketamine. As ketamine alone can elicit cramps, alpha-2 antagonists should not be given less than 30-40 min. after the administration of ketamine.

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

In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.

Avoid skin, eye or mucosal contact.
Wash the exposed skin immediately after exposure with large amounts of water.
Remove contaminated clothes that are in direct contact with skin.
In the case of accidental contact of the product with eyes, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to doctors:
Medetomidine is an alpha2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported.
Respiratory and haemodynamic symptoms should be treated symptomatically.

Use during pregnancy and lactation :

The safety of the product has not been established during pregnancy and lactation. Therefore, do not use the drug during pregnancy and lactation.

Interaction with other medicinal products and other forms of

interaction :

The concomitant administration of other central nervous system depressants should be expected to potentiate the effect of either product and appropriate dose adjustment should be made.

Medetomidine has marked anaesthetic sparing effects.

The effects of medetomidine can be antagonised by the administration of atipamezole.

Do not administer concomitantly with sympathomimetics or sulfamides and trimethoprim.

Overdose (symptoms, emergency procedures, antidotes):

In cases of overdosage, the principal signs are prolonged anaesthesia or sedation. In some cases, cardiorespiratory effects may occur. The treatment consists of the administration of an alpha-2 antagonist, as atipamezole, provided that reversal of sedation is not dangerous for the animal (atipamezole does not reverse the effects of ketamine, which used alone can produce convulsions in dogs and cramps in cats). Alpha-2-antagonists should not be given less than 30-40 minutes after the administration of ketamine.

Atipamezole hydrochloride is administered by intramuscular route at the following dosage: 5 times the initial dose of medetomidine hydrochloride administered to dogs (µg/kg) and 2.5 times for cats. The volume of atipamezole hydrochloride 5 mg/ml is equal to volume of drug administered to dogs; for cats half of this volume should be used.

If it is imperative to reverse bradycardia but to maintain sedation, atropine may be used.

Incompatibilities :

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes :
- Box containing 1 x 10 vial

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.