

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Outer package of 10 ml glass vial

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dorbene vet® 1 mg/ml solution for injection for dogs and cats  
Medetomidine hydrochloride

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains 1 mg medetomidine hydrochloride equivalent to 0.85 mg medetomidine; Methyl parahydroxybenzoate and Propyl parahydroxybenzoate.

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

10 ml

**5. TARGET SPECIES**

Dogs and cats

**6. METHOD AND ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

**7. WITHDRAWAL PERIOD**

Not applicable

**8. SPECIAL WARNINGS, IF NECESSARY**

Read the package leaflet before use.

**9. EXPIRY DATE**

EXP (month/year)  
Shelf life of broached vial: 28 days.  
Once broached , use by \_\_\_\_\_

**10. SPECIAL STORAGE CONDITIONS**

Store in the original package in order to protect from light.

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| <b>11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY</b> |
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Disposal: Read package leaflet.

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| <b>12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable</b> |
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For animal treatment only – to be supplied only on veterinary prescription.

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| <b>13. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”</b> |
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Keep out of the reach and sight of children.

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| <b>14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b> |
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Laboratorios SYVA S.A.U.  
Avda. Párroco Pablo Díez 49-57  
24010 León  
Spain

|                                           |
|-------------------------------------------|
| <b>15. MARKETING AUTHORISATION NUMBER</b> |
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|                                        |
|----------------------------------------|
| <b>16. MANUFACTURER’S BATCH NUMBER</b> |
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Batch:

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|-------------------------------------------------------------------------|
| <b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</b> |
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| <b>10 ml glass vial</b> |
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|----------------------------------------------------|
| <b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b> |
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Dorbene vet® 1 mg/ml solution for injection for dogs and cats  
Medetomidine hydrochloride

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| <b>2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES</b> |
|---------------------------------------------------------------|

10 ml

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| <b>3. ROUTE(S) OF ADMINISTRATION</b> |
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Dogs: intravenous or intramuscular use  
Cats: intramuscular or subcutaneous use

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| <b>4. BATCH NUMBER</b> |
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Batch:

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| <b>5. EXPIRY DATE</b> |
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EXP: (month/year)  
Once broached, use by 28 days.

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| <b>6. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b> |
|-------------------------------------------------|

For animal treatment only.

## **B. PACKAGE LEAFLET**

## **PACKAGE LEAFLET**

Dorbene vet 1 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**

Laboratorios SYVA S.A.U., Avda. Párroco Pablo Díez 49-57, 24010 León, Spain

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dorbene vet 1 mg/ml solution for injection for dogs and cats.

Medetomidine hydrochloride

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

1 ml solution for injection contains:

#### **Active substance:**

Medetomidine hydrochloride 1.0 mg  
(equivalent to 0.85 mg medetomidine)

#### **Excipients:**

Methyl parahydroxybenzoate (E 218) 1.0 mg  
Propyl parahydroxybenzoate (E 216) 0.2 mg

### **4. INDICATIONS**

*In dogs and cats:*

Sedation to facilitate handling. Premedication prior to general anaesthesia.

*In cats:*

In combination with ketamine for general anaesthesia for minor surgical procedures of short duration

### **5. CONTRAINDICATIONS**

Do not use in animals with:

- Severe cardiovascular disease or respiratory diseases or impaired liver or kidney function.
- Mechanical disturbances of the gastro-intestinal tract (torsio ventriculi, incarcerations, oesophageal obstructions).
- Diabetes mellitus.
- State of shock, emaciation or serious debilitation.

Do not use concomitantly with sympathomimetic amines.

Do not use in cases of known hypersensitivity to the active substance or to any other excipients.

Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.

### **6. ADVERSE REACTIONS**

A decrease in heart rate and rate of respiration should be expected following administration. Bradycardia with atrioventricular block (1<sup>st</sup> and 2<sup>nd</sup> degree) and occasionally extrasystolia. Vasoconstriction of coronary artery. Decreased cardiac output. Blood pressure will increase initially after administration and then return to normal, or slightly below normal.

The product may have an emetic effect, particularly in cats. This occurs within a few minutes of administration. Cats may also vomit on recovery. Hypersensitivity to loud noise may also occur.

Increased diuresis, hypothermia, respiratory depression, cyanosis, pain at injection site and muscle tremor may be seen. In individual cases reversible hyperglycaemia due to depression of insulin secretion has been observed. Pulmonary oedema has been reported as a rare adverse reaction after use

of medetomidine. In circulatory and respiratory depression manual ventilation and an oxygen supplement may be indicated. Atropine may increase the cardiac rate.

Dogs with a body weight of less than 10 kg may show the undesirable effects mentioned above more often.

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

Dorbene vet is intended for:

Dogs: Intramuscular or intravenous injection.

Cats: Intramuscular or subcutaneous injection.

Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dogs:

For sedation Dorbene vet should be administered at the rate of 750 µg medetomidine hydrochloride i.v. or 1000 µg medetomidine hydrochloride i.m. per square meter of body surface, corresponding to dose of 20-80 µg medetomidine hydrochloride per kg body weight.

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 from 30 – 180 minutes.

Dorbene vet dosages for sedation in ml and corresponding amount of medetomidine hydrochloride in µg /kg bw. For pre-medication use 50% of the dose indicated in the table:

| body weight (kg) | intravenous injection (ml) | corresponding to (µg/kg bw) | intramuscular injection (ml) | corresponding 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 Dorbene vet 1 mg/ml should be administered at a dosage of 10-40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1-0.4 ml Dorbene vet 1 mg/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:

For moderate-deep sedation and restraint of cats Dorbene vet 1 mg/ml should be administered at a dosage of 50 – 150 µg medetomidine hydrochloride /kg bw (corresp. to 0.05 – 0.15 ml Dorbene vet 1 mg/ml / kg bw). The speed of induction is slower when subcutaneous route of administration is used.

For anaesthesia Dorbene vet 1 mg/ml should be administered at a dosage of 80 µg medetomidine hydrochloride / kg bw (corresp. to 0.08 ml Dorbene vet 1 mg/ml / kg bw) and 2.5 to 7.5 mg ketamine / kg bw. Using this dosage anaesthesia occurs within 3 – 4 minutes and is apparent for 20 – 50 minutes. For longer lasting procedures administration has to be repeated by using ½ of the initial dose (i.e. 40 µg medetomidine hydrochloride (corresp. to 0.04 ml Dorbene / kg bw) and 2.5 - 3.75 mg ketamine / kg bw) or 3.0 mg ketamine / kg bw alone. Alternatively, for longer lasting procedures anaesthesia may be extended by use of the inhalation agents isoflurane or halothane, with oxygen or oxygen/nitrous oxide.

## 9. ADVICE ON CORRECT ADMINISTRATION

Animals should be fasted 12 hours before anaesthesia.

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store in the original package in order to protect from light.

Do not use after the expiry date which is stated on the label.

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

## 12. SPECIAL WARNING(S)

Medetomidine may not provide analgesia throughout the entire period of sedation, therefore consideration should be given to providing additional analgesia for painful procedures.

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 (e.g. ketamine, thiopental, propofol, halothane), because of its marked anaesthetic sparing effects. The dose of the anaesthetic should be reduced accordingly and titrated to response due to considerable variability in requirements between patients. Before using any combinations, the warnings and contra-indications in the product literature for the other products should be observed. 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 allowed 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.

Medetomidine may cause respiratory depression and under these circumstances, manual ventilation and oxygen may be administered.

To reduce the recovery time following anaesthesia or sedation the effect of Dorbene can be reversed by administration of an alpha-2 antagonist e.g. atipamezole or yohimbine. As ketamine alone can elicit cramps, alpha-2 antagonists should be administered not before 30-40 min. after ketamine.

The safety of this veterinary medicinal product has not been established during pregnancy and lactation. Therefore it should not be used during pregnancy and lactation.

Overdose will cause delayed recovery after sedation or anaesthesia. In some cases circulatory or respiratory depression may also occur. For treatment of these cardio-respiratory effects of an overdose it is recommended to administer an alpha-2 antagonist e.g. atipamezole or yohimbine, provided that reversal of sedation is not dangerous to the patient (atipamezole does not reverse the effects of ketamine which may cause seizures in dogs and elicit cramps in cats when used alone). Alpha-2 antagonists should be administered not before 30-40 min. after ketamine. In dogs, the dose of atipamezole is 5 times that for medetomidine. For example, if 1ml Dorbene (1mg medetomidine) has been administered, a dose of 5 mg atipamezole is required. In cats, the dose of atipamezole is 2.5 times that for medetomidine. For example, if 1 ml Dorbene (1 mg medetomidine) has been administered, a dose of 2.5 mg atipamezole is required.

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

In cases of delayed recovery, care should be taken to ensure that the animal remains quiet and warm.

Depending on the situation, the animal may also be ventilated with oxygen and receive intravenous fluids to prevent hypovolaemia. The maintenance of body temperature during sedation and recovery is especially important; in cases of hypothermia, increasing the body temperature to the normal level for the particular species will hasten recovery.

The concomitant use of other CNS depressants should be expected to potentiate the effect of either active substance. Appropriate dose adjustments should be made.

Medetomidine has marked anaesthetic sparing effects.

The effects of medetomidine may be antagonized by administration of atipamezole or yohimbine.

Do not use concomitantly with sympathomimetic amines or sulfamides + trimethoprim.

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

In case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert or label 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.

**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**

Package size: 1 vial (10 ml)

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