ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aceprolab 5 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Acepromazine maleate 5 mg
(Equivalent to 3.68 mg of acepromazine)

Excipients:
Benzoic acid (E-210) 1.125 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Dogs and cats:
- Tranquiliser for the handling of difficult animals and / or to stressful situations for the animal (clinical examinations, diagnostic tests, motion sickness, etc.).
- Premedication before anaesthesia, allowing to reduce the necessary doses of analgesics and general anaesthetics and counteracting the emetic effect of opiates.
- In the postoperative, to provide a quiet awakening.

4.3 Contraindications

Do not use in animals debilitated, (old, leucopenic, etc.), dehydrated, anaemic, hypotensive, hypovolemic or in shock.
Do not use in case of hepatic, cardiac or renal dysfunction.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended doses.
The product should be injected aseptically, due to the high risk of bacterial contamination in the administration area

Acepromazine is not recommended in animals with a history of epileptic seizures or syncope due to sinoatrial block.
Brachycephalic breed dogs, especially the Boxer, seem to be especially susceptible to the cardiovascular effects of acepromazine, so this drug should be used with caution in such breeds.
Use with caution in young animals, due to the effects of acepromazine on the thermoregulation capacity.

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

- This product contains a potent sedative. Care should be taken, when handling and administering the product, to avoid accidental self-exposure. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician but DO NOT DRIVE as sedation may occur. Symptomatic treatment may be required.
- People with known hypersensitivity to acepromazine should avoid contact with the veterinary medicinal product.
- This product might be irritant to skin, eyes and mucous membranes. Therefore, contact of the product with skin, eyes and mucous membranes should be avoided. In case of accidental skin and/or ocular contact, wash immediately with plenty of water. If symptoms appear, seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

On very rare cases it can occur:
- Hypotension, bradycardia, bradypnea and decrease in body temperature.
- Excitation, especially when excessive doses are given or in very sensitive animals.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during the last third of gestation.
Fertility
Do not use in animals treated with testosterone.

4.8 Interaction with other medicinal products and other forms of interaction

Acepromazine enhances the toxicity of organophosphates, thereby it should not be used to control the tremors associated with organic phosphate poisoning, nor together with organophosphates, vermifuge or ectoparasiticides, including flea collars.
Acepromazine also enhances the action of barbiturates, chloral hydrate, analgesics and procaine hydrochloride.
Tranquillisers are additive to the action of centrally depressant drugs and will potentiate general anaesthesia.

4.9 Amounts to be administered and administration route

Administration routes: intravenous, intramuscular

According to data from studies conducted, when used as a preanesthetic-enhancer of general anaesthesia, the dose of the anaesthetic can be reduced by 30 to 50%.

Dogs:
Tranquilisation without subsequent anaesthesia:
0.1 - 0.2 mg acepromazine maleate / kg (0.2 - 0.4 ml / 10 kg of b.w.) intramuscularly.
Premedication for anaesthesia
0.01 - 0.05 mg acepromazine maleate / kg (0.02 - 0.1 ml / 10 kg of b.w.) intramuscularly.
Postoperative sedation:
0.01 - 0.05 mg acepromazine maleate / kg (0.02 - 0.1 ml / 10 kg of b.w.) intravenously.

Cats:
Tranquilisation without subsequent anaesthesia:
0.1 - 0.2 mg acepromazine maleate / kg (0.02 - 0.04 ml / kg of b.w.) intramuscularly.
Premedication for anaesthesia
0.05 - 0.1 mg of acepromazine maleate / kg (0.01-0.02 ml / kg of b.w.) intramuscularly.
Postoperative sedation:
0.01 - 0.05 mg acepromazine maleate / kg (0.002 - 0.01 ml / kg of b.w.) intravenously.

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

In case of intoxication there is a depression of the central nervous system, which can lead to excessive sedation, bradycardia, bradypnea, mucous pallor, incoordination, inability to get up and, at higher doses, unconsciousness, epileptic seizures, circulatory collapse and death of the animal.
Epinephrine is contraindicated in the treatment of acute hypotension caused by phenothiazine derivatives. Other vasopressor amines such as norepinephrine, phenylephrine, ethylphenylephrine, amphetamine and methylamphetamine are the drugs of choice in cases of overdose or poisoning.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Psycholeptics. Acepromazine.
ATC vet code: QN05AA04.

5.1 Pharmacodynamic properties

Acepromazine is a phenothiazine with the following mechanisms of action on the organism:
Behavioral changes:
Decrease of the spontaneous motor activity and reduction in conditioned reflexes responses, caused by dopaminergic receptors blockade on the limbic system and basal ganglia. The autonomic nervous system modifies its functions, due to the blockade of the adrenergic and muscarinic receptors. Acepromazine has a high affinity towards α-1 receptors and a little lower towards dopaminergic receptors. This blockade of α-1 adrenergic receptors is responsible for hypotension and lack of thermoregulation.
Antiemetic effect: by dopaminergic block in the chemoreceptors of the trigger zone of the spinal cord.
Antispasmodic action:
Acepromazine, as other phenothiazines, decreases smooth muscle tone and peristalsis due to its central effect or the peripheral anticholinergic action. Therefore, a delay in gastric emptying is produced.

5.2 Pharmacokinetic particulars

The pharmacokinetics of acepromazine have been studied in horses after intravenous administration. After an injection of 0.3 mg / kg a broad distribution was produced by the organism, which was adjusted to a two-compartment model, with a drug binding to plasma proteins greater than 99%. The volume of distribution was 6.6 l / kg and the elimination half-life was 3 h. Using a dose of 0.15 mg / kg, the volume of distribution was 4.5 l / kg and the half-life was 1.6 h. The metabolism takes place mainly in the liver and excretion through urine.

Although there are few data on the kinetics of acepromazine in dogs, it is believed that this is comparable to that observed in horses, since the start and duration of anesthesia in both species is similar (the maximum effect occurs at 30 minutes of administration, with a duration of sedation between 1 and 3 hours).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzoic acid (E-210)
Sodium citrate
Citric acid
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Type II amber glass vials provided with chlorobutyl rubber stoppers and aluminium caps.

Package sizes:
Card box containing a 25 ml vial
Card box containing a 100 ml vial

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.
Venus, 26. 08228 Terrassa
(Barcelona) Spain

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY} {DD month YYYY}

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only. To be supplied only on veterinary prescription.
Administration: Intravenous administration only by a veterinary surgeon.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aceprolab 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Acepromazine maleate 5 mg
(Equivalent to 3.68 mg of acepromazine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

25 ml
100 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

Dispose of waste material in accordance with local requirements.

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.

14. 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

Labiana Life Sciences, S.A.
Venus, 26. 08228 Terrassa
(Barcelona) Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{100 ml Vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aceprolab 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Acepromazine maleate 5 mg
(Equivalent to 3.68 mg of acepromazine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

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.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.
Venus, 26. 08228 Terrassa
(Barcelona) Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{25 ml vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aceprolab 5 mg/ml solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Active substance:
Acepromazine maleate 5 mg
(Equivalent to 3.68 mg of acepromazine)

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

25 ml

4. ROUTE(S) OF ADMINISTRATION

IM IV

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch{number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Aceprolab 5 mg/ml solution for injection

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:

Labiana Life Sciences, S.A.
Venus, 26. 08228 Terrassa
(Barcelona) Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aceprolab 5 mg/ml solution for injection
Acepromazine maleate

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

Each ml contains:

Active substance:
Acepromazine maleate 5 mg
(Equivalent to 3.68 mg of acepromazine)

Excipients:
Benzoic acid (E-210) 1.125 mg
Other excipients, q.s.

Clear yellow solution

4. INDICATION(S)

Dogs and cats:
- Tranquiliser for the handling of difficult animals and / or to stressful situations for the animal (clinical examinations, diagnostic tests, motion sickness, etc.).
- Premedication before anaesthesia, allowing to reduce the necessary doses of analgesics and general anaesthetics and counteracting the emetic effect of opiates.
- In the postoperative, to provide a quiet awakening.

5. CONTRAINDICATIONS

Do not use in animals debilitated, (old, leucopenic, etc.), dehydrated, anaemic, hypotensive, hypovolemic or in shock.
Do not use in case of hepatic, cardiac or renal dysfunction.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

On very rare cases it can occur:
- Hypotension, bradycardia, bradypnea and decrease in body temperature.
- Excitation, especially when excessive doses are given or in very sensitive animals.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs and cats.

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

Administration routes: intravenous, intramuscular

According to data from studies conducted, when used as a preanesthetic-enhancer of general anaesthesia, the dose of the anaesthetic can be reduced by 30 to 50%.

Dogs:
Tranquilisation without subsequent anaesthesia:
0.1 - 0.2 mg acepromazine maleate / kg (0.2 - 0.4 ml / 10 kg of b.w.) intramuscularly.
Premedication for anaesthesia
0.01 - 0.05 mg acepromazine maleate / kg (0.02 - 0.1 ml / 10 kg of b.w.) intramuscularly.
Postoperative sedation:
0.01 - 0.05 mg acepromazine maleate / kg (0.02 - 0.1 ml / 10 kg of b.w.) intravenously.

Cats:
Tranquilisation without subsequent anaesthesia:
0.1 - 0.2 mg acepromazine maleate / kg (0.02 - 0.04 ml / kg of b.w.) intramuscularly.
Premedication for anaesthesia
0.05 - 0.1 mg of acepromazine maleate / kg (0.01-0.02 ml / kg of b.w.) intramuscularly.
Postoperative sedation:
0.01 - 0.05 mg acepromazine maleate / kg (0.002 - 0.01 ml / kg of b.w.) intravenously.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
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 immediate packaging: 28 days

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Do not exceed the recommended doses.
The product should be injected aseptically, due to the high risk of bacterial contamination in the administration area
Acepromazine is not recommended in animals with a history of epileptic seizures or syncope due to sinoatrial block.
Brachycephalic breed dogs, especially the Boxer, seem to be especially susceptible to the cardiovascular effects of acepromazine, so this drug should be used with caution in such breeds.
Use with caution in young animals, due to the effects of acepromazine on the thermoregulation capacity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- This product contains a potent sedative. Care should be taken, when handling and administering the product, to avoid accidental self-exposure. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician but DO NOT DRIVE as sedation may occur. Symptomatic treatment may be required.
- People with known hypersensitivity to acepromazine should avoid contact with the veterinary medicinal product.
- This product might be irritant to skin, eyes and mucous membranes. Therefore, contact of the product with skin, eyes and mucous membranes should be avoided. In case of accidental skin and/or ocular contact, wash immediately with plenty of water. If symptoms appear, seek medical advice.

Pregnancy:
Do not use during the last third of gestation.

Fertility
Do not use in animals treated with testosterone.

Interaction with other medicinal products and other forms of interaction:
Acepromazine enhances the toxicity of organophosphates, thereby it should not be used to control the tremors associated with organic phosphate poisoning, nor together with organophosphates, vermifuge or ectoparasiticides, including flea collars.
Acepromazine also enhances the action of barbiturates, chloral hydrate, analgesics and procaine hydrochloride.
Tranquillisers are additive to the action of centrally depressant drugs and will potentiate general anaesthesia.

Overdose (symptoms, emergency procedures, antidotes):
In case of intoxication there is a depression of the central nervous system, which can lead to excessive sedation, bradycardia, bradypnea, mucous pallor, incoordination, inability to get up and, at higher doses, unconsciousness, epileptic seizures, circulatory collapse and death of the animal.
Epinephrine is contraindicated in the treatment of acute hypotension caused by phenothiazine derivatives. Other vasopressor amines such as norepinephrine, phenylephrine, ethylphenylephrine, amphetamine and methylamphetamine are the drugs of choice in cases of overdose or poisoning.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes:
Card box containing a 25 ml vial
Card box containing a 100 ml vial

Not all pack sizes may be marketed.

For animal treatment only. To be supplied only on veterinary prescription.
Administration: Intravenous administration only by a veterinary surgeon.