B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Aceprolab 5 mg/ml solution for injection

2.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

Clear yellow solution for injection, free from visible particles.

3. Target species

Dogs, cats and horses not intended for human consumption.

4. Indications for use

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.

Horses not intended for human consumption:
- Tranquilization without subsequent anaesthesia.
- Premedication before anaesthesia
- Coadjuvant in equine colic treatment

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. Special warnings

Special warnings:
Not permitted for use in horses whose meat or milk is used for human consumption.

Special precautions for safe use in the target species:
Do not exceed the recommended doses.
The veterinary medicinal 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.

Special precautions for the protection of the environment:
Not applicable.

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:
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.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

Dogs and cats:

Very rare	Hypotension

(<1 animal / 10,000 animals treated, including isolated reports):	Hypotension Bradycardia Bradypnea Decrease in body temperature Excitation[1]

[1] especially when excessive doses are given or in very sensitive animals.

Horses not intended for human consumption:

Very common (>1 animal / 10 animals treated):	Hypotension[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Penile protrusion [2] Disorientation[3] Convulsion[3] Death[3] Third eyelid protrusion [4]

[1] Peripheral vasodilation and, consequently, hypotension. In healthy animals, this hypotension is compensated by physiological mechanisms. In decompensated hypotensive animals, the use of these substances without prior stabilization would be contraindicated.
[2] In whole or castrated horses can cause paralysis of the retractor muscle of the penis, in which case it should be monitored so that irreversible damage does not occur.
[3] accidental intracarotid injection.
[4] transient paralysis.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Intravenous or intramuscular use.

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 veterinary medicinal product / 10 kg of b.w.) intramuscularly.
Premedication for anaesthesia:
0.01 – 0.05 mg acepromazine maleate / kg (0.02 – 0.1 ml veterinary medicinal product / 10 kg of b.w.) intramuscularly.
Postoperative sedation:
0.01 – 0.05 mg acepromazine maleate / kg (0.02 – 0.1 ml veterinary medicinal product / 10 kg of b.w.) intravenously.

Cats:
Tranquilisation without subsequent anaesthesia:

0.1 – 0.2 mg acepromazine maleate / kg (0.02 – 0.04 ml veterinary medicinal product / kg of b.w.) intramuscularly.
Premedication for anaesthesia:
0.05 – 0.1 mg of acepromazine maleate / kg (0.01-0.02 ml veterinary medicinal product / kg of b.w.) intramuscularly.
Postoperative sedation:
0.01 – 0.05 mg acepromazine maleate / kg (0.002 – 0.01 ml veterinary medicinal product / kg of b.w.) intravenously.

Horses not intended for human consumption:
Tranquilization without subsequent anesthesia: 0.05 – 0.1 mg acepromazine maleate / kg (0.1 – 0.2 ml veterinary medicinal product / 10 kg live weight) intramuscularly.
Premedication for anesthesia:
0.03 – 0.05 mg acepromazine maleate / kg (0.06 – 0.1 ml veterinary medicinal product / 10 kg live weight) intramuscularly
or alternatively
0.02 – 0.03 mg acepromazine maleate / kg (0.04 – 0.06 ml veterinary medicinal product / 10 kg live weight)) intravenously.
Coadjuvant in the treatment of spasmodic colic:
0.02 – 0.04 mg acepromazine maleate / kg (0.04 – 0.08 ml veterinary medicinal product / 10 kg live weight) intramuscularly or intravenously.

9. Advice on correct administration

The product should be injected aseptically, due to the high risk of bacterial contamination in the administration area.

10. Withdrawal periods

Not authorised for use in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.
Not authorised for use in animals producing milk for human consumption.

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 and carton 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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA number: XXXXX

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

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

04/2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Labiana Life Sciences S.A. – Calle Venus 26-Can Parellada – E-08228 Terrassa (Barcelona) - Spain.

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information