[Version 9,03/2022] corr. 11/2022

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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzoic acid (E-210)	1.125 mg
Sodium citrate	
Citric acid	
Water for injections	

Clear yellow solution for injection, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats and horses not intended for human consumption.

3.2 Indications for use for each 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.

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

3.3 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.

3.4 Special warnings

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

3.5 Special precautions for use

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.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypotension Bradycardia Bradypnoea Decreased body temperature Excitation[1]

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

Horses not intended for human consumption:

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

[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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05AA04.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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

5.3. Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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

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

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/2020

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

04/2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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