ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ATONYL 1.5 mg/ml SOLUTION FOR INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Neostigmine metilsulfate .....1.5 mg

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear and colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Bovine, ovine, caprine and horses.

4.2 Indications for use, specifying the target species

Bovine, ovine and caprine:
Ruminal atony
Intestinal atony

Horses:
Intestinal atony
Vesical atony

4.3 Contraindications

Do not use in cases of mechanical obstruction of the gastrointestinal or the urinary tract, peritonitis and doubtful viability of the intestinal wall.
Do not use in pregnant animals. See section 4.7.
Do not use in cases of hypersensitivity to the active substance 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

The animal must be monitored for the appearance of cholinergic effects (see section 4.10) as adverse effects are dose-related.

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

Neostigmine is an acetylcholinesterase enzyme inhibitor. Do not use this medicinal product if your doctor has told you that you should not work with anticholinesterase substances.
Neostigmine and esters of parahydroxybenzoic acid may cause allergic reactions. People with known hypersensitivity to neostigmine or to any of the excipients should avoid contact with the veterinary medicinal product.
The veterinary medicinal product should not be administered by pregnant women.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Adverse effects to neostigmine are dose-dependent and are related to excessive cholinergic stimulation. (See section 4.10).

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

Do not use during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer together with other cholinesterase inhibitors, or with depolarizing neuromuscular blockers (succinylcholine).
Corticosteroids may decrease the anticholinesterase activity of neostigmine. After stopping corticosteroid therapy, neostigmine may cause increased anticholinesterase activity.
Theoretically, dexpanthenol may have additive effects with neostigmine.
Parenteral administration of magnesium antagonizes the anticholinesterase effect of neostigmine because of its depressant effect on the musculoskeletal system.

4.9 Amounts to be administered and administration route

Subcutaneous or intramuscular via.
0.022 mg (22 µg)/kg body weight of neostigmine metilsulfate (equivalent to 0.15 ml/10 kg body weight).

The cap may be safely punctured up to 30 times.

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

In case of overdose, the main clinical signs are marked muscle weakness, vomiting, colic, diarrhea, miosis, dyspnea, bradycardia, hypotension. Death occurs due to respiratory failure.
Antidote: Atropine.
The practitioner must have injectable atropine available when administering this veterinary medicinal product.

4.11 Withdrawal periods

Meat: Zero days.
Milk: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anticholinesterases.
ATC vet code: QN07AA01

5.1 Pharmacodynamic properties

Neostigmine is an anticholinesterase substance. It binds to cholinesterase and prevents it from breaking down the neurotransmitter, acetylcholine.
On the intestinal tract, it produces a contraction of smooth muscle, which increases peristaltic movements (10-30 min after parenteral administration) and their secretions.
On the respiratory system it produces contraction of bronchial smooth muscle, increased ciliary activity and bronchial secretions.
On the urinary system it produces contraction of the smooth muscle of the bladder.
On the skeletal muscle it has anticuraric effect.

5.2 Pharmacokinetic particulars

No information is available on the target species.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate
Sodium chloride
Propylene glycol
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

Amber glass type II vials, with Ph. Eur. Type I bromobutyl rubber stopper and aluminium cap with FLIP-OFF seal.

Pack sizes:

Cardboard box with 1 vial containing 40 ml.

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

CENAVISA, S.L.
Camí Pedra Estela s/n
43205 Reus (SPAIN)

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Dispensing conditions: To be supplied only on veterinary prescription.
Administration conditions: Administration by a veterinarian surgeon or under their direct responsibility.