B. PACKAGE LEAFLET

PACKAGE LEAFLET:

ATONYL 1.5 mg/ml SOLUCIÓN INYECTABLE

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:
CENAVISA, S.L.
Camí Pedra Estela s/n
43205 Reus (SPAIN)
Tel. 34 977 75 72 73

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ATONYL 1.5 mg/ml SOLUCIÓN INYECTABLE
Neostigmine metilsulfate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

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

Excipients:
Methyl parahydroxybenzoate (E218) .....1.0 mg
Propyl parahydroxybenzoate.....0.2 mg
Other excipients q.s.

Clear and colourless solution.

4. INDICATIONS

Bovine, ovine and caprine:
Ruminal atony
Intestinal atony

Horses:
Intestinal atony
Vesical atony

5. 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.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

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

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.

7. TARGET SPECIES

Bovine, ovine, caprine and horses.

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

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

9. ADVICE ON CORRECT ADMINISTRATION

The cap may be safely punctured up to 30 times.

10. WITHDRAWAL PERIODS

Meat: Zero days.
Milk: Zero days.

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.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:
The animal must be monitored for the appearance of cholinergic effects (see section Overdose) 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.

Pregnancy and lactation:
Do not use during pregnancy or lactation.

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.

Overdose (symptoms, emergency procedures, antidotes):
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.

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 size:
Cardboard box with 1 vial containing 40 ml.

Veterinary use – to be supplied only on veterinary prescription
Administration by a veterinarian surgeon or under their direct responsibility.