NEOSKILAB

1.5 mg/ml solution for injection for cattle, sheep, goats and horses

DATA SHEET



INDICATIONS FOR USE:

Cattle, sheep and goats:

- Ruminal atony
- Intestinal atony

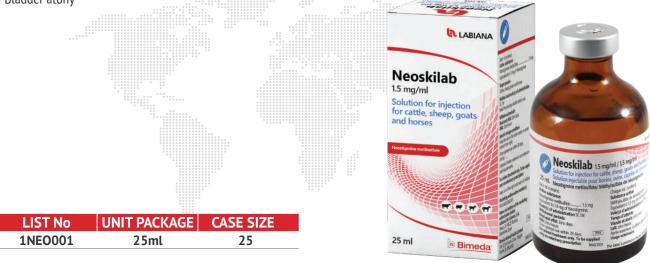
Horses:

Intestinal atony

Bladder atony

BENEFITS

- Subcutaneous or intramuscular use.
- For use in multiple species.



For full usage instructions, see overleaf

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Neoskilab 1.5 mg/ml solution for injection for cattle, sheep, goats and horses



ACTIVE SUBSTANCE

Neostigmine metilsulfate 1.5 mg/ml (Equivalent to 1.0 mg/ml of Neostigmine)

Solution for injection. Clear and colourless solution free from particles.

TARGET SPECIES

Cattle, sheep, goats and horses.

INDICATIONS FOR USE

Cattle, sheep and goats:

- Ruminal atony
- Intestinal atony
- Horses:
- Intestinal atony
- Bladder atony

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Subcutaneous or intramuscular use.

0.022 mg/kg b.w. of neostigmine metilsulfate or 0.015 mg/kg b.w of neostigmine (equivalent to 0.15 ml/10 kg b.w. of the product).

Dosage requirements should be adjusted by the veterinarian.

The rubber stopper of the vial may be safely punctured up to 20 times

WITHDRAWAL PERIOD(S)

Meat and offal: Zero days.

Milk: Zero hours

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 animals with known cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in case of proximal disorders of the enteral tract in horses.

Do not use in pregnant or lactating animals.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS

The animal must be monitored for the appearance of cholinergic effects as adverse effects are dose-related. The product should be used with caution in the following conditions:

-Bronchial asthma (mainly in horses)

-Cardiac arrhythmia (risk of bradycardia)

-Peptic ulcer disease (because of increase of gastric secretions)

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 advised you that you should not work with anticholinesterase substances.

Neostigmine, propylene glycol and esters of parahydroxybenzoic acid may cause allergic reactions. People with known hypersensitivity to neostigmine or any of the excipients should avoid contact with the veterinary medicinal product.

The veterinary medicinal product should not be administered by pregnant women.



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In case of accidental self-injection, the following adverse effects may occur: myosis, gastro-intestinal troubles (nausea, vomiting, diarrhea), muscular cramps or fasciculations. Seek medical advice immediately and show the package leaflet or the label to the physician.

ADVERSE REACTIONS

Adverse reactions to neostigmine are dose dependent and are associated with excessive cholinergic stimulation.

Adverse effects should be rare at therapeutic doses (more than 1 but less than 10 animals in 10,000 animals treated).

USE DURING PREGNANCY OR LACTATION

Do not use during pregnancy.

Do not use during lactation because the tolerance of the veterinary medicinal product has not been established in the suckling off-spring in the target species.

Product can be used in cows who are lactating and are not pregnant, where the milk is being supplied for human consumption only.

Product cannot be used in cows where their milk is being supplied to calves or calves are suckling.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS

Do not administer together with other cholinesterase inhibitors or depolarizing neuromuscular blocking agents (succinylcholine).

Corticosteroids may decrease the anticholinesterase activity of neostigmine. After stopping the corticosteroid treatment, neostigmine can increase the anticholinesterase activity.

Administration of magnesium by the parenteral route antagonises the anticholinesterase activity of neostigmine, because of its direct depressor effect on skeletal muscle.

Atropine reverses muscarinic effects of neostigmine.

OVERDOSE

In case of overdose, the main clinical signs are notable muscular weakness, vomiting, colic, diarrhoea, miosis, dyspnoea, bradycardia, hypotension, bronchospasm. Death results from respiratory failure. In case of overdose, atropine can be used for reversing muscarinic effects of neostigmine.

PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Anticholinesterases.

Neostigmine metilsulfate is an anticholinesterase. It acts by binding to some points of the cholinesterase molecule preventing it from reacting with acetylcholine. The drug blocks the active site of acetylcholinesterase so the enzyme can no longer breakdown the acetylcholine molecules before they reach the postsynaptic membrane receptors. Therefore, with theacetylcholinesterase blocked, acetylcholine can bind to the few receptors and trigger a muscular contraction. In addition, neostigmine indirectly stimulates both nicotinic and muscarinic receptors.

Neostigmine has a quaternary nitrogen; hence, it is polar and does not cross the blood-brain barrier and enter the CNS.

The intensity and duration of the anticholinesterasic action depends on the binding intensity and the speed of spontaneous reversibility of that binding.

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- It produces a contraction of the intestinal smooth fibre of spontaneous reversibility of the digestive tract. Therefore, the peristaltic movements as well as the secretions are increased (10-30 minutes after the parenteral administration).

- On the respiratory tract it produces a contraction of the bronchial smooth muscle, an increase of the ciliar activity and bronchial secretions.

- On the circulatory system, it produces a reduction of the heart rate and contractility and vasodilatation.

- On the urinary tract, it produces a contraction of the bladder smooth muscle.

- On the skeletal muscle it has an anticuraric effect.

PHARMACOKINETIC PARTICULARS

No available information on the target species.

MAJOR INCOMPATIBILITIES

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

SHELF-LIFE

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 28 days

SPECIAL PRECAUTIONS FOR STORAGE

Keep the vial in the outer carton in order to protect from light. This veterinary medicinal product does not require any

special temperature storage conditions.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS

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

MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A. C/Venus, 26 08228 Terrassa Spain

MARKETED IN IRELAND BY

Bimeda® Animal Health Limited 2, 3 & 4 Airton Close, Airton Road Tallaght, Dublin 24, Ireland Tel: +353 (0) 1 466 7900

MARKETING AUTHORISATION NUMBER VPA10402/004/001

LEGAL CATEGORY

Use Medicines Responsibly

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