1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BONHAREN IVN 10 mg/ml solution for injection for horses and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Sodium hyaluronate 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Water for injections

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target Species

Horses, dogs.

3.2 Indications for use for each target species

For the treatment of joint diseases associated with non-infectious synovitis.

3.3 Contraindications

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

3.4 Special warnings

This product does not contain an antimicrobial preservative. Any solution remaining in the vial following the withdrawal of the required dose should be discarded.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Dogs: Due to the lack of information, we do not recommend using the product in animals with known defect in hyaluronan metabolism (e.g. Cutaneous mucinosis in Shar-pei dogs).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental contact with the skin, wash with soap and water.
Avoid contact with eyes. In case of accidental contact with the eyes, blurred vision may occur because of the viscous nature of the product. Rinse the eyes immediately with plenty of clean water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to exogenous sodium hyaluronate or to any of the excipients should

administer the veterinary medicinal product with caution.

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

3.6 Adverse events

None known.
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 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 and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

The product precipitates with cationic antibacterial substances (erythromycin, amoxicillin, cefquinome etc.).

3.9 Administration routes and dosage

Intravenous use.
Dosage:
a) Horses: 60 mg of sodium hyaluronate (i.e. 6 ml of the product) per animal
b) Dogs: 30 – 50 mg of sodium hyaluronate (i.e. 3 - 5 ml of the product) per animal, depends on the size of the dog
Number of doses: 5 doses
Interval between doses: 7 days

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None observed.

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

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Horses:	Meat and offal:	Zero days
	Milk:	Zero hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM09AX01

4.2 Pharmacodynamics

Hyaluronan (hyaluronic acid and salts thereof, HA) maintains morphological and functional integrity in a cellular microenvironment.
HA is produced by many cell types in most of the tissues, including the endothelial cells forming the inner layer of blood vessels. HA is a part of specific protective glycocalyx coating the lumen of blood vessel. HA in glycocalyx plays an important role including the protection against leucocyte adhesion and extravasation, barrier against protein and macromolecule movement and against proteinuria. The interaction of exogenous intravenously applied HA has been described as protection against the inflammatory stimuli like LPS (bacterial endotoxin). This decrease of vascular permeability might be the mechanism responsible for HA beneficial effects on osteoarthritis (OA) progression, as OA and other chronic inflammatory diseases are characterized by higher vascular leakage.
Main molecular structures interacting with HA are known as hyaladherins, group of proteins or glycoproteins able to bind specifically to HA. Main cell surface receptor and hyaladherin is CD44, which plays important role in proliferation, migration and signal transduction.

4.3 Pharmacokinetics

In lymph, the concentration of HA is significantly higher than in plasma as the lymphatic system is main clearance route for endogenous HA.
The principal place of plasma HA metabolism is in the liver. On the surface of sinusoidal endothelial liver cells is present the HA receptor for endocytosis (HARE) which binds HA and mediates its endocytosis from the bloodstream. Endocytosed HA is degraded intracellularly by hyaluronidases to oligosaccharides which are then cleaved to monosaccharides by specialized enzymes. Monosaccharides are metabolized further in pentose cycle or glycolysis. Very low-molecular-weight fragments of HA (oligosaccharides) are also cleared through kidneys.
In an organism, HA is metabolized completely and quickly. After the intravenous administration, the elimination half time from
plasma in rabbits is 2.5 - 4.5 min, in rats it is 3.7 min. The terminal half-life of intravenously applied HA in horses was very short (43+/-29 mins) and after a delay of 3 h, the plasma concentration returned to control values.

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: 3 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Protect from light.
Do not freeze.

5.4 Nature and composition of immediate packaging

Glass vials (type I), closed by a bromobutyl rubber stopper with an aluminium flip-off cap. The vials are packed in a paper box.

Pack sizes:
6 x 6 ml, 5 x 6 ml, 3 x 6 ml.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Contipro a.s.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22837/001/001

8. DATE OF FIRST AUTHORISATION

17/01/2020

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

25/11/2025

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*).