PACKAGE LEAFLET:

Bonharen IVN 10 mg/ml

Solution for injection for horses and dogs

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:

Contipro a.s., Dolní Dobrouč 401, 561 02 Dolní Dobrouč, Czech Republic
Tel: + 420 465 519 530, Fax: + 420 465 543 793, e-mail: sales@contipro.com

2. Name of the veterinary medicinal product

Bonharen IVN 10 mg/ml solution for injection for horses and dogs
Sodium hyaluronate

3. Statement of the active substance(s) and other ingredients

1 ml of clear, colourless solution for injection contains:
Active substance: Sodium hyaluronate 10 mg

4. Indication(s)

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

5. Contraindications

Do not use in case of known hypersensitivity to exogenous sodium hyaluronate or to any of the excipients.

6. Adverse reactions

None known.

If you notice any side effects, even those not already listed in this information leaflet, please inform your veterinary surgeon.

7. Target species

Horses 

Dogs 

8. Dosage for each species, route(s) and method of administration

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

9. Advice on correct administration

Not applicable.

10. Withdrawal period(s)

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

11. Special storage precautions

Keep out of the sight and reach of children.
Do not freeze.
Protect from light.

Shelf life after first opening the container: use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. Special warning(s)

Special warnings for each 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 for use in animals

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

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.

Pregnancy and lactation

Safety in breeding, pregnant and lactating animals has not been documented. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

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

Overdose (symptoms, emergency procedures, antidotes)

None observed.

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

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

14. Date on which the package leaflet was last approved

To be completed in accordance with national requirements.

15. Other information

Pack size:

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

To be supplied only on veterinary prescription.
For animal treatment only.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Czech Republic
Contipro a.s.
Dolní Dobrouč 401
561 02 Dolní Dobrouč
CZ
Tel: +420 465 526 530
E-mail: sales@contipro.com