

HYALURONAN BIOVETA 10 mg/ml solution for injection

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:

Bioveta, a.s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HYALURONAN BIOVETA 10 mg/ml solution for
injection
Natrii hyaluronas

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml of the solution for injection contains:

Active substance:

Sodium hyaluronate 10 mg
Clear colourless fluid.

4. INDICATIONS

Orthopaedic:

- Acute and chronic osteoarthritis,
polyosteoarthritis
- Subacute and chronic arthritis
- Acute and chronic tendovaginitis, tendinoses
and bursitis
- Osteochondroses

Ophthalmologic:

- Acute and chronic keratitis
- Conjunctivitis, keratoconjunctivitis
- Dry keratoconjunctivitis
- Corneal ulcer
- Corneal injury

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Not known.

These were not reported during the preclinical
tests or during the clinical evaluation of the
product in veterinary medicine.

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

Horses, dogs, cats.

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

Administration route:

1) Intravenous administration

a) Horses:

Dose: usually 6 ml (60 mg).

Number of doses: 3 - 7 doses, optimum 5.

Interval between doses: 3 - 9 days, optimum 7.

b) Dogs, cats:

Dose: slightly lower, usually 3 - 5 ml.

Number of doses: 3 - 7 doses, optimum 5.

Interval between doses: 3 - 9 days, optimum 7.

2) Topical administration to the conjunctival
sac:

Dose/number of doses: 1 - 2 drops to the eye
(conjunctival sac) every 2 - 12 hours.

Period of administration: 5 - 60 days, possibly
permanently (acute inflammation 5 - 7 days,
chronic inflammation until improvement/cure).

9. ADVICE ON CORRECT ADMINISTRATION

-

10. WITHDRAWAL PERIOD(S)

Horses: meat and milk: No withdrawal periods.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store at a temperate below 25 °C.

Protect from light.

Protect from frost.

Do not use this veterinary medicinal product
after the expiry date which is stated on the box
and label after EXP.

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

12. SPECIAL WARNINGS

Special warnings for each target species:

None. The product has no effect on behaviour,
it is not reducing work performance, it has no
effect on somnolence, etc.

Special precautions for use in animals

Special attention should be paid to aseptic
intravenous administration. The product is
recommended in case of severe eye
impairments for administration either with
antibiotics or corticoids or should be
administered alternately.

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

Do not eat, smoke and drink during
administration.

Accidental self injection with the product could

result in mild irritation of the site of injection.

Seek medical advice in case of complications.

In the case of accidental ingestion of the
preparation, seek medical advice immediately
and show the package insert or label to the
treating physician.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and
other forms of interaction:

Do not administer simultaneously with cationic
antimicrobial substances (erythromycin,
amoxicillin, cefchinom), which cause
precipitation.

Other groups of substances: corticoids, non-
steroidal anti-inflammatory drugs, vitamins,
minerals and ophthalmological products are
fully compatible with hyaluronan.

Overdose (symptoms, emergency procedures,
antidotes):

Not applicable. Hyaluronan, as an active
ingredient inherent to the body, is synthesized
in target tissues and it is removed mainly by
the liver. Metabolism of hyaluronan is fast (half
life in blood is several minutes). Concentration
of hyaluronan in blood is increased in some
diseases, during which there is reduced its
degradation (e.g. cirrhosis) or increased its
production (e.g. inflammation).

Even an extremely high dose (exceeding by
orders the administered dose) is removed
rapidly from the body without consequences.

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 products should be disposed of in
accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2018

15. OTHER INFORMATION

For animal treatment only.

Veterinary medicinal product subject to
prescription.

Pack size: 5 × 6 ml.



Dimensions (mm): A6 (105 × 148 mm) duplex printing
Colours: black
Prepared by: Hanáková
Date: 07. 10. 2021

Approved by:

Date: