

MELOXICAM Bioveta 1.5 mg/ml oral suspension for 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:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MELOXICAM Bioveta 1.5 mg/ml oral
suspension for dogs
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml contains:

Active substance:

Meloxicam 1.5 mg

Excipients:

Sodium benzoate 5 mg

Yellow or green-yellow suspension.

4. INDICATION(S)

Alleviation of inflammation and pain in both
acute and chronic musculoskeletal disorders in
dogs.

5. CONTRAINDICATIONS

Do not use in pregnant and lactating animals.
Do not use in animals suffering from
gastrointestinal disorders such as irritation and
haemorrhage, impaired hepatic, cardiac or
renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the
active substance or to any of the excipients.
Do not use in dogs under 6 weeks of age.

6. ADVERSE REACTIONS

Typical adverse drug reactions of NSAIDs such as
loss of appetite, vomiting, diarrhoea, faecal
occult blood, apathy and renal failure have
occasionally been reported. In very rare cases,
haemorrhagic diarrhoea, haematemesis,
gastrointestinal ulceration and elevated liver
enzymes have been observed.

These side effects occur generally within the
first treatment week and are in most cases
transient and disappear following termination of
the treatment. In very rare cases they may be
serious or fatal.

If adverse reactions occur, discontinue
treatment and consult a veterinarian.

The frequency of adverse reactions is
characterised according to the following rules:

- very common (adverse reactions occurred in
more than 1 in 10 treated animals)

- common (more than 1 but less than 10 in
100 treated animals)

- uncommon (more than 1 but less than 10
in 1 000 treated animals)

- rare (more than 1 but less than 10 in
10 000 treated animals)

- very rare (less than 1 in 10 000 treated
animals, including isolated reports)

If you notice any serious effects or other effects
not mentioned in this leaflet, please inform your
veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

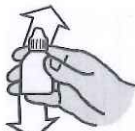
Oral administration, in feed or directly into the
animal's mouth.

Shake well before use.

Initial treatment is a single dose of 0.2 mg
meloxicam/kg body weight, i.e. 1 ml of the
product/7.5 kg bw on the first day. Treatment
should be continued with administration of a
maintenance dose of 0.1 mg meloxicam/kg
body weight, i.e. 1 ml of the product/15 kg bw
once daily at 24-hour intervals.

For longer term treatment, once a clinical
response has been observed (after ≥ 4 days),
the dose of the product can be adjusted to the
lowest effective individual dose reflecting that
the degree of pain and inflammation associated
with chronic musculoskeletal disorders may
vary over time.

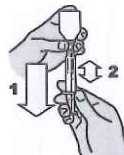
Particular attention should be paid to accurate
dosing.



Shake the vial well.

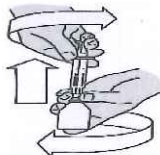
Press and unscrew the cap.

Put the applicator into the
dosing insert in the vial neck.



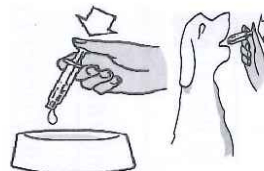
Turn the vial upside down.

Suck the desired dose
into the applicator.



Turn the vial into the original position.

Disconnect the applicator by circular motion.



Press the plunger to empty the applicator
on the feed or directly into the mouth.

A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10
days at the latest if no clinical improvement is apparent.

Alternatively, therapy may be initiated with the veterinary medicinal product MELOXICAM Bioveta
5 mg/ml solution for injection.

Avoid introduction of contamination during use.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

10. WITHDRAWAL PERIOD(S)

Not intended for food-producing animals.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Protect from frost.

Keep the vial in the carton in order to protect
from light.

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

refers to the last day of that month.

Shelf life after first opening the immediate
packaging: 6 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Avoid use in dehydrated, hypovolaemic or
hypotensive animals as there may be a
potential risk of increased renal toxicity.

This product is intended for dogs and must n
be given to cats because it is not suitable for
this species.

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

People with known hypersensitivity to NSAIDs
should avoid contact with the veterinary
medicinal product.

In case of accidental ingestion seek medical
advice immediately and show the package
leaflet or label to the practitioner.

Pregnancy and lactation:

The safety of the veterinary medicinal product
has not been established for use during
pregnancy and lactation (see section 5).

Interaction with other medicinal products and other forms of interaction:

Other NSAIDs, diuretics, anticoagulants,
aminoglycoside antibiotics and substances with
high protein binding may compete for binding
and thus lead to toxic effects. The product must
not be administered in conjunction with other
NSAIDs or glucocorticoids.

Pre-treatment with anti-inflammatory
substances may result in additional or
increased adverse effects and accordingly a
treatment-free period with such veterinary
medicinal products should be observed for at
least 24 hours before commencement of
treatment. The treatment-free period, however,
should take into account the pharmacological
properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes):

Symptomatic treatment should be initiated in
case of overdose.

Incompatibilities:

None known.

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

March 2019

15. OTHER INFORMATION

For animal treatment only.

Veterinary medicinal product subject to
prescription.

Pack size: 10 ml, 30 ml, 100 ml

Not all pack sizes may be marketed.