

AMOXICILLIN Bioveta 150 mg/ml LA injection suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Bioveta, a. s., Komenského 212,
Ivanovice na Hané

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

**AMOXICILLIN Bioveta
150 mg/ml LA
injection suspension**
Amoxicillin

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

1 ml of milk suspension contains:

Active substance:

Amoxicillin
(ut Amoxicillin trihydrate) 150 mg

Ingredients:

Benzylalcohol (E 1519)
9 mg
Butylhydroxytoluene (E 321)
0.2 mg

4. INDICATIONS

Treatment of diseases caused
by microorganisms sensitive
to amoxicillin in cattle, pigs
and dogs.

Especially local, gastrointestinal,
respiratory and urogenital
infections are concerned.

5. CONTRAINDICATIONS

Do not use in animals for which
the product is not indicated.

Do not use in case of infections
caused by penicillinase
producing microorganisms.

Do not use in case
of hypersensitivity to penicillin.

6. ADVERSE REACTIONS

Allergies to amoxicillin may
occur in rare cases. Transient
local reaction may occur
in the application site.

7. TARGET SPECIES

Cattle, pigs, dogs.

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

Intramuscular administration.
The usual dose is 10 mg
of amoxicillin per kg live body
weight per day or 1ml per 15kg
live body weight per day.

9. ADVICE ON CORRECT ADMINISTRATION

The product must be thoroughly
shaken before use. It must
not be mixed with aqueous
solutions and other products.

The needles and syringes used
for administration of the product
must be dry to avoid hydrolysis
of the active substance.

Do not apply more than
20ml of the product to one site.

Massage of the administration
site may be performed
to increase penetrability.

10. WITHDRAWAL PERIOD

Meet:

– Cattle: 15 days.

– Pigs: 42 days.

Milk: 72 hours.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Protect from light.

Store in a dry place.

Keep out of the reach of children!

Shelf life after first opening
of the immediate packaging:
28 days

Do not use after the expiry date
stated on the label.

12. SPECIAL WARNINGS

The medicinal product must not
be used after the expiry date
stated on the packaging.

Penicillins and cephalosporins
may cause hypersensitivity
(allergy) after injection, ingestion
or contact with skin.

Hypersensitivity to penicillins
may cause cross-reactions
with cephalosporins and vice-
versa.

Occasionally the allergic
reactions to these substances
may be serious

People with known
hypersensitivity to penicillins
and cephalosporins should
avoid contact with a veterinary
medicinal product.

If post-exposure symptoms
develop such as rash, seek
medical assistance and show
the package insert or label
to your general practitioner.

Edema of the face, lips,
eyes or breathing problems
are serious symptoms
and it is recommended
to seek emergent medical care.

Wash you hands after handling
the product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

All unused veterinary medicinal
product or waste from this
product must be disposed
according to the local
regulations.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED June 2010

bioveta

