

CLOTEID 4

suspension for injection
Vaccine against tetanus

**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
683 23 Ivanovice na Hané
Česká republika
tel.: +420 517 318 500
fax: +420 517 318 319
e-mail: comm@bioveta.cz

**2. NAME OF THE VETERINARY
MEDICINAL PRODUCT**

CLOTEID 4 suspension for injection
Vaccine against tetanus

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

One vaccination dose (1ml) contains:

Active substance:

Anatoxinum tetanicum purificatum
RP $\geq$ 1*

*RP = Relative potency (ELISA test)
is expressed by comparing the level
of antibodies in the serum of guinea
pigs with the level of antibodies
in the reference serum obtained
after vaccination of guinea pigs
and its comparison with the
international standard.

Adjuvants:

Algeldrati suspensio 0,1 ml

Excipients:

Thiomersalu 0,15 mg

4. INDICATION(S)

To be used for active immunization
of horses, cattle, sheep, goats
and dogs against tetanus at age
3 months and above.

Onset of immunity: 14 to 21 days
after basic vaccination

Duration of immunity: 2 years
as a minimum, 4 years in horses

5. CONTRAINDICATION

Sick, emaciated and convalescent
animals.

6. ADVERSE REACTION

None known. The vaccine may rarely
cause hypersensitivity. In such case,
symptomatic treatment should be
applied.

If you notice any serious adverse
effects or other reactions not listed
in this leaflet, please tell your
veterinary doctor.

7. TARGET SPECIES

Horses, cattle, sheep, goats
and dogs.

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

Dose – 1 ml, regardless of age,
weight and breed of an individual.

Method of administration:
intramuscularly to gluteal muscles.

Basic vaccination:

2 doses at an interval of 3 weeks
for animals older than 3 months
of age.

Revaccination:

Revaccination is recommended after two years, in horses after 4 years. In indicated cases another booster dose can be administered earlier.

9. ADVICE ON CORRECT ADMINISTRATION

In horses, it is recommended to administer the product by the dry needle method, preferably to the gluteal muscle. In very restless horses, the product may be administered into the cervical or breast muscle.

It is recommended to vaccinate racing, sport and draft horses out of the intensive workload. The vial contents should be shaken before use.

10. WITHDRAWAL PERIOD

Withdrawal period:

Horses, cattle, sheep, goats:

Not applicable.

Dogs: Not intended for food animals.

11. SPECIAL STORAGE PRECAUTION

Keep out of the reach and sight of children.

Store in a refrigerator (2 °C – 8 °C).

Store in a dry and dark place.

Shelf life after first opening the immediate packaging:
10 hours (multidose containers).

Do not use after expiry date indicated on the label.

12. SPECIAL WARNINGS

Vaccinate healthy animals only.

No information is available on the safety and efficacy of this vaccine when administered concurrently with other veterinary medicinal products.

Decision about using this vaccine before or after any other veterinary medicinal product must be based on consideration of individual cases.

Compatibility studies are not available, therefore this veterinary medicinal product must not be mixed with other veterinary medicinal products.

The product can be used during pregnancy and lactation.

In case of accidental self-injection seek medical advice immediately and show the package leaflet or label to a practitioner.

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 discarded according to the local regulations.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2012

15. OTHER INFORMATION

Pack size:

2 × 1 ml, 10 × 1 ml, 20 × 1 ml,
1 × 5 ml, 10 × 5 ml,
1 × 10 ml, 1 × 20 ml.

Not all pack sizes may be marketed.

The veterinary medicinal product is available on a prescription only.

bioveta