

OXYTOCIN BIO 5 IU/ml injection solution

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, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXYTOCIN BIO 5 IU/ml injection solution

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

1 ml of the product contains

Active substance:

Oxytocin 5.0 IU

Excipients:

Chlorobutanol hemihydrate 4.0 mg

4. INDICATION

To support delivery in case of primary
and secondary depression of contractions
and to accelerate the expulsive phase
of delivery.

During the puerperal period:
depression of uterine muscle contractility;
To stimulate involution in case of placenta
retention and exometra (the product
is administered immediately after delivery
or caesareotomy and two to four hours later),
to remove the pathological contents of uterus,
endometritis, pyometra.

Agalaxia in consequence of milk production
disorder in all target species. To remove
residual milk and toxic material from the udder
after delivery and during the treatment
of infectious mastitis in cows.

5. CONTRAINDICATIONS

Do not use for complicated deliveries
(too big foetus, foetus abnormal position,
torsio uteri etc.).
Do not use at insufficient release of cervix
in case of pyometra.
Do not use in case of uterine muscle
hypertension.

6. ADVERSE REACTIONS

Hypercontractions, uterine spasms or rupture
in case of overdose.
High doses of oxytocin may cause uterine
spasms which may result, especially in pigs,
in a longer litter, increased hypoxia of born

piglets and reduced number of live-born
piglets.

7. TARGET SPECIES

Cows, mares, sheep, goats, sows, bitches.

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

Posology:

Cows

Uterus inaction, milk ejection, mastitis,
uterus involution:
20 – 40 IU (i.m. or s.c.), 2.5 – 10 IU (i.v.).

Mares

Uterus inaction:
20 – 40 IU (i.m. or s.c.), 2.5 – 10 IU (i.v.).
Placenta retention: 10 – 20 IU (i.m. or s.c.).
Milk ejection, uterus involution:
40 IU (i.m. or s.c.), 10 IU (i.v.)

Sheep, goats

Uterus inaction:
10 IU (i.m. or s.c.), 0.5 – 2.5 IU (i.v.).
Milk ejection, uterus involution:
10 – 20 IU (i.m. or s.c.), 0.5 – 2.5 IU (i.v.).

Sows

Uterus inaction, uterus involution, placenta
retention, milk ejection:
10 – 30 IU (i.m. or s.c.), 0.5 – 2.5 IU (i.v.).

Bitches

Uterus inaction, uterus involution, placenta
retention, milk ejection:
2 – 10 IU (i.m. or s.c.), 0.5 IU (i.v.)

9. ADVICE ON CORRECT ADMINISTRATION

The product may be applied intramuscularly
(i.m.), subcutaneously (s.c.) or intravenously
(i.v.). For the intravenous infusion the product
may be diluted with physiological solution
or 5% glucose solution.

In obstetric indications, a slow intravenous,
subcutaneous or intramuscular application
is possible. Repeated administration of small
doses is preferred to one big dose. In sheep,
the intramuscular application should be
preferred.

The slow intravenous application is used
to produce ejection of residual milk
and retained placenta.

For the intravenous application of small doses
the respective product should be diluted
in a higher amount of physiological solution.

If oxytocin is used for the management
of delivery, it is necessary to verify that
the cervix is dilated in order to prevent
the death of foetus or a possible rupture
of uterus.

10. WITHDRAWAL PERIOD

None.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store in a refrigerator (2°C – 8°C).

Protect from frost.

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

Shelf-life after first opening the container
is 28 days.

12. SPECIAL WARNINGS

The treated animals should not be stressed
as epinephrine released during stress may
reduce the oxytocin effect. Exogenous oxytocin
is not recommended as a control tool
to increase the milk production.

This product should be administered while
observing the general principles of hygiene
and good clinical practice.

The injected product should be administered
carefully to prevent accidental self-injury.
In case of accidental self-administration
seek medical attention immediately
and show the package leaflet or the label
to your physician.

Pregnant women should avoid handling
with this veterinary medicinal product.

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

July 2008

15. OTHER INFORMATION

Interaction with other medicinal products and other forms of interaction

Oxytocin is not efficient if administered shortly
after beta2-adrenergic agonists.
Prostaglandine F2alpha and oxytocin
strengthen mutually their effects
on the uterus.

Incompatibilities

None known.

Pharmacodynamic properties

Oxytocin is a natural nonapeptide released
from the posterior lobe of hypophysis.

Oxytocin shows uterotonic activity
and supports the ejection of milk.

The stimulation of uterine muscle during
delivery is of particular physiological
importance. This stimulation is enabled
by activating of MAP (mitogen activating
protein) kinase through the medium
of G protein of myometrium cells. Oxytocin
stimulates releasing of prostaglandin E₂
by amnion cells, which also plays
an important part in initiating of delivery.
Moreover, oxytocin stimulates intensively
the secretion of prostaglandin PGF_{2α}
by endometrium cells, which produces
luteolysis in non-pregnant animals.

This oxytocin effect is mediated by its bonding
to membrane receptors and by activating
of phospholipase C, which leads to activating
of intracellular cascade by the reaction which
mobilizes arachidonic acid from membrane
phospholipides. The mobilized arachidonic
acid is oxygenized to prostaglandin PGH₂
through the medium of prostaglandin H₂
endoperoxide synthetase PGHS-2
and is converted to PGF_{2α} by PGF
synthetase. Oxytocin increases
the concentration of PGHS-2 mRNA,
which influences the secretion of PGF_{2α}.
This prostaglandin, similarly to prostaglandin
E₂, influences the contractility of myometrium.

Pharmacokinetic particulars

At the intravenous application the onset
of oxytocin effect is very fast in all target
species (in 20 – 30 seconds) and the time
of effect is short (5 – 10 minutes).

The half-life is about 20 minutes
in dependence on the treated species.

At the intramuscular or subcutaneous
application the onset of oxytocin effect
is between 5 and 10 minutes and the time
of effect is between 20 and 30 minutes.
The efficacy decreases in the course
of following 20 minutes.

In case of milk ejection stimulation
the onset of oxytocin effect is quite fast
and ¾ of the udder volume are ejected
on average in 3 minutes after the application.

bioveta



Dimensions (mm):

Colours:

Prepared by:

Date:

A6 (105 × 148 mm) duplex printing

black

Doleželová

18. 12. 2024

Approved by:

Date: