

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytobel 10 IU/ml solution for injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats

Oxytocin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Oxytocin 10 IU/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
5 x 10 ml
12 x 10 ml
25 ml
10 x 25 ml
50 ml
12 x 50 ml
100 ml
12 x 100 ml

5. TARGET SPECIES

Horses, cattle, pigs, sheep, goats, dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IV, IM, SC
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat, offal, milk: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Exp.

Once opened, use by: _____

Shelf-life after first opening: 7 days

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

Store in a refrigerator.

Once opened do not store above 25°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 41816/4000

17. MANUFACTURER'S BATCH NUMBER

Lot.

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{Bottle 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytobel 10 IU/ml solution for injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats

Oxytocin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Oxytocin 10 IU/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, pigs, sheep, goats, dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
IV, IM, SC

8. WITHDRAWAL PERIOD

Meat, offal, milk: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Exp.
Once opened, use by: _____

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.
Store in a refrigerator.
Once opened do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

[Not required on the immediate label]

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 41816/4000

17. MANUFACTURER'S BATCH NUMBER

Lot.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Bottle 10 ml, 25 ml, 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytobel 10 IU/ml solution: Horses, cattle, pig, sheep, goats, dogs and cats
Oxytocin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Oxytocin 10 IU/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
25 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IV, IM, SC

5. WITHDRAWAL PERIOD

Meat, offal, milk: zero days

6. BATCH NUMBER

Lot.

7. EXPIRY DATE

Exp.
Once opened, use by: _____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Oxytobel 10 IU/ml solution for injection for horses, cattle, pigs, sheep, goats, dogs and cats

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:

Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta
Germany

Distributor

Bimeda Animal Health Limited,
2 / 3 / 4 Airton Close,
Tallaght, Dublin 24,
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytobel 10 IU/ml solution for injection for horses, cattle, pigs, sheep, goats, dogs and cats

Oxytocin

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

1 ml contains:

Active substance:

Oxytocin 16.6 µg
(equivalent to 10 IU Oxytocin)

Excipients:

Chlorobutanol hemihydrate 3.0 mg

Clear colourless solution.

4. INDICATION(S)

In the mare, cow, sow, ewe, nanny, bitch and queen the product is indicated for:

- Obstetric use (stimulation of uterine contraction to facilitate parturition in the presence of a fully dilated cervix, promotion of involution of the post partum uterus, aid in the control of post partum haemorrhage).
- Promotion of milk let-down in cases of agalactia.

5. CONTRAINDICATIONS

Do not use in cases of obstructive dystocia and/or in cases of non-dilatation of the uterine cervix.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

None.

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.

Alternatively you can report via your national reporting system {national system details}.

For details regarding the national system please contact NCA.

7. TARGET SPECIES

Horses (mares), cattle (cows), pigs (sows), sheep (ewes), goats (nanny), dogs (bitches) and cats (queen)

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

Administered by subcutaneous or intramuscular injection.

Mare & Cow	4 – 6 ml
Sow	1 – 3 ml
Ewe & Nanny	1 – 2 ml
Bitch & Queen	0.25 – 1 ml

For treatment of agalactia the stated higher dosage level should be used.

The product may be administered by slow intravenous injection at dose rates one third of the above.

Enhanced dose rates will not result in proportionally increased pharmacological effects.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Meat and offal: zero days.

Milk: zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the container in the outer carton in order to protect from light.

Store in a refrigerator (2°C – 8°C).

Once opened do not store above 25°C.

Shelf-life after first opening the immediate packaging: 7 days

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

12. SPECIAL WARNING(S)

Special warnings for each target species

Adrenaline at physiological levels markedly reduces the effect of Oxytocin on the uterus or mammary gland. For this reason the animal should not be frightened when complete Oxytocin effect is desired to cause either milk "let-down" or uterine contractions.

Special precautions for use in animals

When Oxytobel 10 IU/ml is used as an aid in parturition cervical dilation must be confirmed prior to administration to prevent risk of foetal death and possible uterine rupture.

User Warnings

Pregnant or lactating women should avoid handling the product as it could cause smooth muscle (e.g. uterine) contraction.

When administering the product, care should be taken to avoid accidental self-injection.

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

Use during pregnancy, lactation or lay

The product is indicated for use, as appropriate, during parturition and lactation. Do not use during pregnancy except at the time of parturition.

Interaction with other medicinal products and other forms of interaction

This veterinary medicinal product may be used concurrently with antibiotics in the treatment of endometritis.

Stimulation of β -adrenergic receptors may reduce oxytocin's effects on the uterus and mammary gland.

If sympathomimetic agents or other vasoconstrictors are used concurrently with oxytocin, post-partum hypertension may result.

Overdose (symptoms, emergency procedures, antidotes), if necessary

Excessive doses of the veterinary medicinal product may delay parturition by producing uncoordinated uterine contractions which interfere with the progress of the foetus especially in multiple pregnancies.

Treatment of overdose is palliative and there are no specific antidotes.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

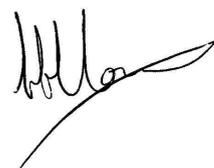
{MM/YYYY}

15. OTHER INFORMATION

Pack sizes:

- 1 x 10 ml in a cardboard box
- 5 x 10 ml in a cardboard box
- 12 x 10 ml in a cardboard box
- 1 x 25 ml in a cardboard box
- 10 x 25 ml in a cardboard box
- 1 x 50 ml in a cardboard box
- 12 x 50 ml in a cardboard box
- 6 x (1 x 50 ml) wrapped with clear foil (multipack)
- 1 x 100 ml in a cardboard box
- 12 x 100 ml in a cardboard box
- 6 x (1 x 100 ml) wrapped with clear foil (multipack)

Not all pack sizes may be marketed.



Approved 11 July 2019

