PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin-S, 10 iu/ml, solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Oxytocin-S (0,18 mg/ml)

Preservative chlorbutanol 5 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection-

4. PACKAGE SIZE

25 ml

5. TARGET SPECIES

Cattle, horses, pigs, sheep, goats, cats and dogs

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer by deep intramuscular injection. Subcutaneous or intravenous routes can be used, see package leaflet for further information. Avoid accidental self-injection.

8. WITHDRAWAL PERIOD(S)

Cattle, sheep, pigs, horses and goats: Meat – Zero days
Cattle, sheep and goats: Milk – Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Avoid introduction of contamination during use. Observe asepsis.

10. EXPIRY DATE

EXP...-….

11. SPECIAL STORAGE CONDITIONS

Store in refrigerator (+2°C to +8°C).
Protect from light.

Once vial is broached use within 28 days. Keep container in outer carton.

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

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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.
POM-V

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43877/4012

17. MANUFACTURER'S BATCH NUMBER

Lot

Read package leaflet for directions, disposal advice and warnings before use.

Adverse events should be reported to the MAPI holder.
To report an adverse event, ring +44 7905 759121

Manufactured by Intervet Nederland B.V.
Procured from within the EU and repackaged by the licence holder:
Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin-S, 10 iu/ml, solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Oxytocin-S (0,18 mg/ml)

Preservative chlorbutanol 5 mg/ml

3. PHARMACEUTICAL FORM

-

4. PACKAGE SIZE

25 ml

5. TARGET SPECIES

Cattle, horses, pigs, sheep, goats, cats and dogs

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM+SC+IV

8. WITHDRAWAL PERIOD(S)

Cattle, sheep, pigs, horses and goats: Meat – Zero days
Cattle, sheep and goats: Milk – Zero hours

Following withdrawal of first dose, use within 28 days.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid accidental self-injection of this product. Avoid introduction of contamination during use. Keep container in outer carton.

10. EXPIRY DATE

Once opened, use by: / /

EXP...-….

11. SPECIAL STORAGE CONDITIONS

Store in refrigerator (+2°C to +8°C).
Protect from light.

12. SPECIFIC 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.
POM-V

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43877/4012

17. MANUFACTURER'S BATCH NUMBER

Lot

Read package leaflet for directions, disposal advice and warnings before use.

Adverse events should be reported to the MAPI holder.
To report an adverse event, ring +44 7905 759121

Manufactured by Intervet Nederland B.V.
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Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

PACKAGE LEAFLET FOR:

Oxytocin-S, 10 iu/ml, solution for injection

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

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

Manufacturer for batch release:
Intervet Nederland B.V.
Postbus 50
5830 AB Boxmeer

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin-S, 10 iu/ml, solution for injection
Clear aqueous solution

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

Oxytocin-S (0,18 mg/ml)

Preservative chlorbutanol 5 mg/ml

4. INDICATION(S)

Injections with this product will initiate strong, regular and purposeful contractions of the uterine muscle especially in the later stages of pregnancy and post-partum. It also evokes the 'let-down' of milk although it has no action on the smooth muscles of the gut or urinary bladder, nor is it effective in the treatment of diabetes insipidus. The absence of vasopressor and antidiuretic effects make it particularly suitable for obstetric use (stimulation of parturition, promotion of uterine involution and control of post-partum haemorrhage) and the treatment of agalactia.

The product is indicated for:
- stimulation of uterine contraction to facilitate parturition in the presence of a fully dilated cervix
- to promote involution of the post-parturient uterus and thus aid the passage of retained placenta
- to aid in control of post-partum haemorrhage
- promotion of milk 'let-down' in cases of agalactia and to facilitate ‘stripping out’ of infected quarters in the treatment of mastitis in cows.

5. CONTRAINDICATIONS

1. When the product is used as an aid to parturition, cervical dilation must be confirmed prior to administration to prevent the risk of foetal death and possible uterine rupture.
2. The product is contra-indicated in any form of obstructive dystocia.
3. Excessive doses of the product may delay parturition by producing incoordinated uterine contractions which interfere with the progress of the foetus especially in multiple pregnancies.
4. The effects of daily dosages of 100 iu or more (to facilitate 'stripping out' of infected quarters in the treatment of mastitis in cows) on the oestrous cycle have not been fully investigated and the cycle length may be altered.
5. 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.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Cattle, horses, pigs, sheep, goats, cats and dogs

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

The product should normally be given by deep intramuscular injection.

Species	*Dosage*	
Queen	2-5 iu	0.2 -0.5 ml
Bitch	2-10 iu	0.2 -1 ml
Ewe, goat, sow	2-10 iu	0.2 -1 ml
Mare	10-40 iu	1- 4 ml
Cow	10-40 iu	1- 4 ml
Other indications	10-40 iu	1- 4 ml

Adjunct to mastitis treatment
A single dose of up to 80 iu (8 ml) prior to stripping out before first mastitis treatment followed by repeated doses of 20 iu (2 ml) prior to each stripping out 2 or 3 times daily while mastitis treatment continues.

Where the intravenous route is used, these doses should be reduced to one-quarter of the intramuscular dose and the injection given slowly at a dilution of 1 in 10 Water for Injections. Where speed of onset is not a priority, the product may be

given by the subcutaneous route.

A low initial dosage is recommended by any route as repeat administration is permissible.
Large doses may be employed in post-parturient animals.

9. ADVICE ON CORRECT ADMINISTRATION

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10. WITHDRAWAL PERIOD(s)

Cattle, sheep, pigs, horses and goats: Meat – Zero days
Cattle, sheep and goats: Milk – Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (between +2°C and +8°C). Protect from light.
Shelf life of veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days.
When the container is broached for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf life of the product is given on the packaging insert. This discard date should be written in the space provided on the label.
Keep container in outer carton.
Should any apparent growth or discoloration occur, the product should be discarded
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

12. SPECIAL WARNING(S)

i. Special precautions for use in animals

Use aseptic precautions.

ii. Special precautions to be taken by the person administering the medicinal product to the animals

Care should be taken to avoid accidental self-injection. Should self-injection occur, medical advice should be sought immediately. Women, particular during lactation or the later stages of pregnancy should avoid handling the product as it could cause smooth muscle (e.g. uterine) contraction.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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Detailed information on this product is available on the VMD website www.gov.uk/vmd

15. OTHER INFORMATION

Multi-dose vial of 25 ml.

For animal treatment only

Keep out of reach and sight of children

Adverse events should be reported to the MAPI holder. To report an adverse event, ring +44 7905 759121.

To be supplied only on veterinary prescription.

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Vm 43877/4012

Approved 27 April 2023