PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin-S 10 iu/ml Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCE

Oxytocin 10 iu/ml (equivalent to 0.018 mg/ml)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

25 ml

5. TARGET SPECIES

For use in cattle, sheep, horses, pigs, goats, dogs and cats.

6. INDICATION(S)

Not applicable.

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.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle, horses, pigs, sheep and goats:

Meat - Zero days

Cattle, sheep and goats:

Milk - Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Avoid accidental self-injection and pregnant or lactating women should avoid handling the product as it could cause smooth muscle (e.g. uterine) contraction (see package leaflet).

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Once broached use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (+2°C and +8°C).

Protect from light.

Keep container in outer carton.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

FOR ANIMAL TREATMENT ONLY

POM-V

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

MA Holder:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

Distributor in Northern Ireland:

INTERVET IRELAND Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4314

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin-S 10 iu/ml Solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE

Oxytocin 10 iu/ml (equivalent to 0.018 mg/ml)

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

25 ml

4. ROUTES OF ADMINISTRATION

IM, SC, and IV

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Cattle, sheep, pigs, horses, goats:

Meat - Zero days.

Cattle, sheep, goats: Milk - Zero hours.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

Once broached use within 28 days.

Use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

POM-V

To be supplied only on veterinary prescription.

Keep out of the sight and reach of children

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

MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

Walton Manor

Walton

Buckinghamshire

Milton Keynes

MK7 7AJ

MANUFACTURER RESPONSIBLE FOR BATCH RELEASE:

Intervet International GmbH

Unterschleissheim, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin-S, 10 iu/ml solution for injection

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

Each ml of clear aqueous solution contains:

Active substance

Oxytocin 10 iu (equivalent to 0.018 mg)

Excipients

Chlorbutanol 5 mg (as a preservative)

4. INDICATION(S)

Injections of Oxytocin-S will initiate strong, regular and purposeful contractions of the uterine muscle especially in the later stages of pregnancy and post-partum. Oxytocin-S 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 Oxytocin-S particularly suitable for obstetric use (stimulation of parturition, promotion of uterine involution and control of post-partum haemorrhage) and the treatment of agalactia.

Oxytocin-S 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 Oxytocin-S 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. Oxytocin-S is contraindicated 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

None known.

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.

7. TARGET SPECIES

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

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

Oxytocin-S should normally be given by deep intramuscular injection.

Species	**Dosage**	**mls**
Queen	2-5 iu	0.2-0.5 ml
Bitch	2-10 iu	0.2-1.0 ml
Ewe, goat, sow	2-10 iu	0.2-1.0 ml
Mare	10-40 iu	1.0-4.0 ml
Cow *Indications other than mastitis as listed in section 4. For mastitis treatment see below.*	10-40 iu	1.0-4.0 ml

Adjunct to mastitis treatment in cows:

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, Oxytocin-S 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

See section 8.

Avoid the introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

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

Cattle, sheep and goats: Milk - Zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (+2°C and +8°C).

Protect from light.

Following withdrawal of the first dose, use the product within 28 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

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

12. SPECIAL WARNING(S)

Following text included in "Contra-indications, Warnings etc" section of mock-up

Special precautions for use in animals:

Use aseptic precautions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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 and lactation:

Promotes parturition and milk let-down. Not to be used in late pregnancy unless the intention is to promote parturition.

Interaction with other medicinal products and other forms of interaction:

Stimulation of beta-adrenergic receptors may reduce the effect of oxytocin on the uterus or mammary gland.

Overdose (symptoms, emergency procedures, antidotes):

Excessive doses might cause uncoordinated uterine contractions.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

FOR ANIMAL TREATMENT ONLY.

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

Medicines should not be disposed of via wastewater.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DATE OF PREPARATION

December 2020

15. OTHER INFORMATION

LEGAL CATEGORY

POM-V

To be supplied only on veterinary prescription.

16. PACKAGE QUANTITIES

25 ml

17. FURTHER INFORMATION

18. MARKETING AUTHORISATION NUMBER

Vm 01708/4314

DISTRIBUTOR IN NORTHERN IRELAND:

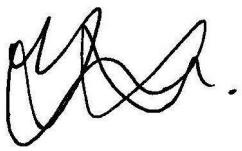
INTERVET IRELAND Ltd.

Magna Drive

Magna Business Park

Citywest road

DUBLIN 24



Approved: 30 December 2020