

OXYTOCIN- oxytocin solution
Aspen Veterinary Resources

ANADA 200-328, Approved by FDA

OXYTOCIN INJECTION

Purified Oxytotic Principle

INJECTION FOR HORSES, COWS, SOWS, & EWES

20 USP Units per mL

Sterile Aqueous Solution

HAZARDOUS

NOT FOR USE IN HUMANS

KEEP OUT OF REACH OF CHILDREN

Restricted Drug (California) - Use Only as Directed.

CAUTION:Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Oxytocin injection is a sterile aqueous solution of highly purified oxytotic principle derived by synthesis or obtained from the posterior lobe of the pituitary gland of healthy domestic animals used for food by humans. Oxytocin injection contains 20 USP Units of oxytocin and less than 0.4 units of presser activity per mL. Each mL of sterile solution also contains 0.9% w/v sodium chloride, 0.5% w/v chlorobutanol (as a preservative), with water for injection q.s. and pH adjusted to 3.0 to 5.0 with acetic acid.

ACTIONS: Oxytocin acts directly on the smooth musculature of the uterus in all species to induce rhythmic contractions, although in some species the uterine cervix does not respond to oxytocin. The responsiveness of the uterine musculature to oxytocin varies greatly with the stage of the reproductive cycle. During the early phases of pregnancy the uterus is relatively insensitive to the effects of oxytocin, while in the late phases the sensitivity is markedly increased. Most authorities attribute this varying response to the varying levels of estrogen and progesterone during the course of pregnancy.

Oxytocin also has been shown to exert a milk ejecting effect, occasionally referred to as the galactogogic effect. The actual mechanism by which oxytocin stimulates the release of milk from the mammary glands is not known with certainty, but oxytocin is presumed to act on certain smooth muscle elements in the gland.

INDICATIONS: Because of the specific action of oxytocin upon the uterine musculature, it is recommended as an aid in the management of the following conditions:

1. To precipitate labor.
2. To accelerate normal parturition.
3. Postpartum evacuation of uterine debris.
4. Postoperative contraction of the uterus following a cesarean section and control of uterine hemorrhage.

Oxytocin will contract the smooth muscle cells of the mammary gland to induce milk let-down if the udder is in a proper physiological state.

CONTRAINDICATION: Do not use in dystocia due to abnormal presentation of the fetus until correction is accomplished.

PRECAUTIONS: Oxytocin is a potent preparation, accordingly, it should be administered with due caution. For parturition usage full dilation of the cervix should be accomplished either naturally or through the administration of estrogen prior to oxytocin therapy.

DOSAGE AND ADMINISTRATION:

Obstetrical Use:

Inject aseptically by the intravenous, intramuscular or subcutaneous route as follows:

EWES, SOWS:

1.5 to 2.5 mL.....30 TO 50 USP Units

COWS, HORSES:

5.0 mL.....100 USP Units

These dosages are recommended, and may be repeated as indicated.

Milk Let-down:

Inject aseptically by the intravenous, intramuscular or subcutaneous route.

COWS:

0.5 to 1.0 mL.....10 to 20 USP Units

SOWS:

0.25 to 1.0 mL.....5 to 20 USP Units

These dosages are recommended and may be repeated as necessary.

Note: Oxytocin will not induce milk let-down unless the udder is in the proper physiological state.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

HOW SUPPLIED:

100 mL multiple dose vials.

STORAGE:

Store at controlled room temperature.

Protect from freezing.

For use in inducing rhythmic contractions of the smooth musculature of the uterus and/or milk letdown. For complete use directions and precautions see insert.

Restricted Drug (California) - Use Only as Directed.
80XY045B



Manufactured for:
Aspen Veterinary Resources, Ltd.
Liberty, MO 64068, USA
www.aspenveterinaryresources.com
A236B Rev. 12/15

Manufactured by:
Bimeda-MTC Animal Health Inc.
Cambridge, ON Canada N3C 2W4



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Purified Oxytocic Principle
INJECTION FOR HORSES, COWS, SOWS, & EWES
Sterile Aqueous Solution

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Not for Use in Humans

Keep Out of Reach of Children

NET
CONTENTS:
100 mL (3.4 fl. oz)

EACH mL CONTAINS: Oxytocin 20 USP Units, sodium chloride 0.9% w/v, chlorobutanol 0.5% w/v, water for injection q.s. and pH adjusted to 3.0 to 5.0 with acetic acid.

ROUTE OF ADMINISTRATION: Intravenous, intramuscular, or subcutaneous route as follows:

DOSAGE: **USP Units**
For Obstetrical Use:
Horses & Cows.....100
Sows & Ewes.....30 to 50
Milk Let-down:
Cows..... 10 to 20
Sows.....5 to 20

Store at controlled room temperature.
Protect from freezing.

PULL

OXYTOCIN

oxytocin solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:46066-506
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYTOCIN (UNII: 1JQS135EYN) (OXYTOCIN - UNII:1JQS135EYN)	OXYTOCIN	20 [USPU] in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46066-506-02	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200328	09/01/2009	

Labeler - Aspen Veterinary Resources (627265361)

Registrant - Bimeda Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda-MTC		256232216	manufacture

