

**OXYTOCIN- oxytocin injection, solution**  
**Bimeda Inc., Division of Cross Vetpharm Group**

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**Oxytocin**

**(purified oxytocic 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.**

**ANADA 200-328, Approved by FDA**

**DESCRIPTION:** Oxytocin injection is a sterile aqueous solution of highly purified oxytocic principle derived by synthesis or obtained from the posterior lobe of the pituitary gland of healthy domestic animals used for food by humans.

**EACH mL CONTAINS:** Oxytocin 20 USP Units, 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 prepartum 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 2.5mL.....30 to 50 USP Units

Cows, Horses:

5.0mL.....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 1.0mL.....10 to 20 USP Units

Sows:

0.25 to 1.0mL.....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 proper physiological state.

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

**HOW SUPPLIED:**

100mL multiple dose vials.

**Store at controlled room temperature.**

**Protect from freezing.**

**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:

<b>DOSAGE:</b>	<b>USP UNITS</b>
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.

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.

Manufactured by: Bimeda-MTC Animal Health Inc. Cambridge, ON Canada www.bimedamtc.com  
 Manufactured for: Bimeda, Inc. Le Sueur, MN 56058 www.bimeda.com

Product No. 10XY015 80XY021B Rev. 07/12



**OXYTOCIN**

oxytocin injection, solution

**Product Information**

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG LABEL	<b>Item Code (Source)</b>	NDC:6 1133-60 13
<b>Route of Administration</b>	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS	<b>DEA Schedule</b>	

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OXYTOCIN (OXYTOCIN)	OXYTOCIN	20 [USPU] in 1 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61133-6013-2	100 mL in 1 VIAL		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200328	05/24/2004	

**Labeler** - Bimeda Inc., Division of Cross Vetpharm Group (060492923)

**Registrant** - Bimeda Inc., Division of Cross Vetpharm Group (060492923)

**Establishment**

Name	Address	ID/FEI	Business Operations
Bimeda - MTC Animal Health, Division of Cross Vetpharm Group		256232216	manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
Hemmo Pharmaceutical Pvt. Ltd.		650515294	api manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
Aspen Oss B.V.		491013870	api manufacture

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Bimeda Inc., Division of Cross Vetpharm Group