

**OXYTOCIN- oxytocin injection, solution**  
**Bimeda, Inc.**

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**Oxytocin**

**(purified oxytocic principle)**  
**INJECTION FOR HORSES, COWS, SOWS, & EWES**

20 USP Units per mL

**HAZARDOUS**

**Not for Use in Humans**

**KEEP OUT OF REACH OF CHILDREN**

**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 oxytocic 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 know 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.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae).

**HOW SUPPLIED:** 100mL multiple dose vials.

Approved by FDA under ANADA # 200-328

**Store at controlled room temperature. Protect from freezing.**

OXYTOCIN				
oxytocin injection, solution				
Product Information				
<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG		<b>Item Code (Source)</b>	NDC:61133-6013
<b>Route of Administration</b>	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS			
Active Ingredient/Active Moiety				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	OXYTOCIN (UNII: 1JQS135EYN) (OXYTOCIN - UNII: 1JQS135EYN)	OXYTOCIN	20 [USP'U] in 1 mL	
Packaging				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:61133-6013-2	100 mL in 1 VIAL		
Marketing Information				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANADA	ANADA200328	05/24/2004		

**Labeler** - Bimeda, Inc. (060492923)

**Registrant** - Bimeda, Inc. (060492923)

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

Revised: 12/2023

Bimeda, Inc.