

OXYTOCIN- oxytocin injection, solution
Bimeda, Inc.

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:

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.

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:
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Manufactured for:
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Product No. 10XY015 80XY021B Rev. 07/12



OXYTOCIN

oxytocin injection, solution

Product Information

Product Type

PRESCRIPTION ANIMAL DRUG

Item Code (Source)

NDC:6 1133-6013

Route of Administration

INTRAVENOUS, INTRAMUSCULAR,
SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYTOCIN (UNII: 1JQS135EYN) (OXYTOCIN - UNII:1JQS135EYN)	OXYTOCIN	20 [USP'U] 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. (060492923)**Registrant** - Bimeda, Inc. (060492923)**Establishment**

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

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Bimeda, Inc.