

**NADA Number: 141-302**

<b>Trade Name</b>	EAZI-BREED™ CIDR® Sheep Insert
<b>Sponsor</b>	Zoetis Inc.
<b>Ingredients</b>	PROGESTERONE
<b>Species</b>	<b>SHEEP (DOMESTIC)</b> (Sheep, breeding)
<b>Routes of Administration</b>	INTRAVAGINAL
<b>Dosage Form</b>	SOLID MATRIX
<b>Dispensing Status</b>	OTC
<b>Patent Number (Expiration Date)</b>	6,423,039 (06/22/2017) 6,663,608 (06/22/2017)
<b>Exclusivity</b>	Under section 573(c) of the Federal Food, Drug and Cosmetic Act (the act), this approval qualifies for SEVEN years exclusive marketing rights beginning on the date of approval because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act. (Exp. 10/01/2016)
<b>Specifications</b>	Each insert contains 0.3 gram progesterone in molded silicone over a flexible nylon spine.
<b>Dosage Amount, Indications &amp; Limitations</b>	Dosage: One insert per ewe for five days. Indications: For induction of estrus in ewes (sheep) during seasonal anestrus. Limitations: Do not use in ewes with abnormal, immature, or infected genital tracts or in ewes that have never lambed.
<b>Tolerances</b>	PROGESTERONE: No residues of progesterone are permitted in excess of the following increments above the concentrations of progesterone naturally present in untreated animals: (a) In uncooked edible tissues of steers and calves: (1) 3 parts per billion for muscle. (2) 12 parts per billion for fat. (3) 9 parts per billion for kidney. (4) 6 parts per billion for liver. (b) In uncooked edible tissues of lambs: (1) 3 parts per billion for muscle. (2) 15 parts per billion for fat, kidney, and liver. No residues of progesterone are permitted in excess of the following increments above the concentrations of progesterone naturally present in untreated animals: (a) In uncooked edible tissues of steers and calves: (1) 3 parts per billion for muscle. (2) 12 parts per billion for fat. (3) 9 parts per billion for kidney. (4) 6 parts per billion for liver. (b) In uncooked edible tissues of lambs: (1) 3 parts per billion for muscle. (2) 15 parts per billion for fat, kidney, and liver.