

**EXEGEN LDLR MINISWINE- pldlr-neo not applicable**  
**Exemplar Genetics, LLC**

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**pLDLR-Neo in miniswine**

**ExeGen LDLR miniswine**

ExeGen LDLR miniswine are genetically engineered yucatan miniature swine containing the rDNA construct pLDLR-Neo which exhibit similar phenotypes to human patients in which the same LDLR gene is non-functional. Phenotypes include severely elevated serum cholesterol (total cholesterol and LDL) and atherosclerosis. These pigs are intended to be used as large animal models of human disease. We will not be requesting a food use authorization and the carcasses and all materials generated from these animals will be destroyed by incineration.

Product Definition: A specific line of Yucatan miniature pigs (*Sus scrofa domestica*), including both homozygous and heterozygous offspring resulting from a heterozygous founder, in which the LDLR (low-density lipoprotein receptor) gene has been disrupted by the homologous recombination of a single copy of a pLDLR-Neo construct in exon 4, for use in biomedical research.

Warning: this product is from a genetically engineered animal and may contain an investigational new animal drug. It is for research purposes only and not for use in humans or as food/feed unless authorization has been granted by the US Food and Drug Administration. In case of emergency or release contact Exemplar Genetics at 712-722-2767 or 712-441-3408.

***Caution. This is an investigational animal or a product derived from the animal that may contain an investigational new animal drug. This animal and any products derived from it are for research purposes only and not for use in humans or as human or animal food.***

***In Case of Emergency Contact:***

***712-722-2767 or***

***712-441-3408***

ENABLING DISCOVERY

## EXEGEN LDLR MINISWINE

pdlr-neo not applicable

### Product Information

Product Type	RECOMBINANT DEOXYRIBONUCLEIC ACID CONSTRUCT LABEL	Item Code (Source)	NDC:86093-1901
Route of Administration	NOT APPLICABLE		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
YUCATAN MINIATURE PIG LDLR GENE DISRUPTED BY A LDLR-NEO RDNA CONSTRUCT IN EXON 4 (UNII: D2J8 YIK6 U6) (pLDLR-Neo - UNII:D2J8 YIK6 U6)	YUCATAN MINIATURE PIG LDLR GENE DISRUPTED BY A LDLR-NEO RDNA CONSTRUCT IN EXON 4	1 [arb'U] in 1 [arb'U]

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86093-1901-1	1 [arb'U] in 1 PACKAGE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/05/2019	

**Labeler** - Exemplar Genetics, LLC (958331121)

**Registrant** - Exemplar Genetics, LLC (958331121)

## Establishment

Name	Address	ID/FEI	Business Operations
Exemplar Genetics, LLC		958331121	manufacture

Revised: 8/2019

Exemplar Genetics, LLC