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**pSCN5A-Neo in miniswine**

**ExeGen SCN5A miniswine**

ExeGen SCN5A miniswine are genetically engineered yucatan miniature swine containing the rDNA construct pSCN5A-Neo which exhibit similar phenotypes to human patients with sudden arrhythmia death syndromes (SADS). These pigs are intended to be used as large animal models of the 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 domesticus*), including heterozygous offspring resulting from a heterozygous founder in which the SCN5A gene has been disrupted by the homologous recombination of a single copy of a pSCN5A-Neo construct in exon 11, 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.



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***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 SCN5A MINISWINE

pscn5a-neo not applicable

## Product Information

<b>Product Type</b>	RECOMBINANT DEOXYRIBONUCLEIC ACID CONSTRUCT LABEL	<b>Item Code (Source)</b>	NDC:86093- 1902
<b>Route of Administration</b>	NOT APPLICABLE		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HETERZYGIOUS YUCATAN MINIATURE PIG SCN5A MUTATED GENE DISRUPTED BY A SCN5A-NEO RDNA CONSTRUCT IN EXON 11 (UNII: 08X2W5664O) (pSCN5A-Neo - UNII:08X2W5664O)	HETERZYGIOUS YUCATAN MINIATURE PIG SCN5A MUTATED GENE DISRUPTED BY A SCN5A-NEO RDNA CONSTRUCT IN EXON 11	1 [arb'U] in 1 [arb'U]

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86093-1902-1	1 [arb'U] in 1 PACKAGE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/2019	

**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