

EXEGEN CLN3 MINISWINE- pcln3-neo excised not applicable
Exemplar Genetics LLC (dba Precigen Exemplar)

pCLN3 in miniswine

ExeGen CLN3 miniswine

ExeGen CLN3 miniswine are genetically engineered yucatan miniature swine containing the rDNA construct pCLN3-Neo Excised which exhibit similar phenotypes to human patients with CLN3 disease. 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 homozygous offspring resulting from a heterozygous founder, in which the CLN3 gene has been disrupted by the homologous recombination of a single copy of a mutated CLN3-PGK construct for use in biomedical research. The desirable animal will be a homozygote CLN3 Ex7-8del Neo Excised/Ex7-8del Neo Excised miniswine.

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 CLN3 MINISWINE

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Product Information

Product Type	RECOMBINANT DEOXYRIBONUCLEIC ACID CONSTRUCT LABEL	Item Code (Source)	NDC:86093- 2001
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLN3 RDNA CONSTRUCT DISRUPTING EXON 7 AND EXON 8 OF CLN3 GENE IN YUCATAN MINIATURE SWINE (UNII: E3SP91Q3EF) (CLN3 RDNA CONSTRUCT DISRUPTING EXON 7 AND EXON 8 OF CLN3 GENE IN YUCATAN MINIATURE SWINE - UNII:E3SP91Q3EF)	CLN3 RDNA CONSTRUCT DISRUPTING EXON 7 AND EXON 8 OF CLN3 GENE IN YUCATAN MINIATURE SWINE	1 [arb'U] in 1 [arb'U]

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86093-2001-1	1 [arb'U] in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/15/2020	

Labeler - Exemplar Genetics LLC (dba Precigen Exemplar) (958331121)

Registrant - Exemplar Genetics LLC (dba Precigen Exemplar) (958331121)

Establishment

Name	Address	ID/FEI	Business Operations
Exemplar Genetics LLC (dba Precigen Exemplar)		958331121	manufacture

Revised: 1/2020

Exemplar Genetics LLC (dba Precigen Exemplar)