EXEGEN ATM MINISWINE- patm-neo not applicable Exemplar Genetics LLC (dba Precigen Exemplar)

pATM-Neo in miniswine.

ExeGen ATM miniswine

ExeGen ATM miniswine are genetically engineered yucatan miniature swine containing the rDNA construct pATM-Neo which exibit similar phenotypes to human patients with Ataxia Telangiectasia (AT). These pigs are intended to be used as large animal models of the human disease. We will not be requesting a food use authorizaiton 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 both homozygous and heterozygous offspring resulting from a heterozygous founder in which the ATM (ataxia telangiectasia mutated) gene has been disrupted by the homologous recombination of a single copy of a pATM-Neo construct in exon 57, 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.

See image of warning label "FDA statement 2020.jpg"



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 ATM MINISWINE

patm-neo not applicable

Product Information						
Product Type	RECOMBINANT DEOXYRIBONUCLEIC ACID CONSTRUCT LABEL	Item Code (Source)	NDC:86093- 1801			
Route of Administration	NOT APPLICABLE					

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
HOMOZYGOUS YUCATAN MINIATURE PIG ATAXIA TELANGIECTASIA MUTATED (ATM) GENE DISRUPTED BY A ATM-NEO RDNA CONSTRUCT IN EXON 57 (UNII: 2U7SBS8LTK) (HOMOZYGOUS YUCATAN MINIATURE PIG ATAXIA TELANGIECTASIA MUTATED (ATM) GENE DISRUPTED BY A ATM-NEO RDNA CONSTRUCT IN EXON 57 - UNII:2U7SBS8LTK)	HOMOZYGOUS YUCATAN MINIATURE PIG ATAXIA TELANGIECTASIA MUTATED (ATM) GENE DISRUPTED BY A ATM-NEO RDNA CONSTRUCT IN EXON 57	1 [arb'U] in 1 [arb'U]			

]	Packaging						
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:86093-1801-1	1 [arb'U] in 1 NOT APPLICABLE					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
unapproved drug other		04/09/2018				

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

Revised: 4/2019 Exemplar Genetics LLC (dba Precigen Exemplar)