

EXEGEN PKD MINISWINE- ppkd-blast excised not applicable
Exemplar Genetics, Llc

pPKD-Blast in miniswine

ExeGen PKD miniswine

ExeGen PKD miniswine are genetically engineered yucatan miniature swine containing the rDNA construct pPKD-Blast which exhibit similar phenotypes to human patients with PKD. 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 PKD1 gene has been disrupted by the homologous recombination of a single copy of a mutated PKD1-PGK construct resulting in a point mutation for use in biomedical research. The desirable animal will be a heterozygote PKD1 +/-R3277C Blast 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 PKD MINISWINE

ppkd-blast excised not applicable

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | | Item Code (Source) | NDC:86093-2002 |
| Route of Administration | NOT APPLICABLE | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|---------------------------|
| PKD1 +/R3278C-BLAST RDNA CONSTRUCT AT EXON 29 IN YUCATAN MINIATURE SWINE (UNII: H02ZF3289J) (PKD1 +/R3278C-BLAST RDNA CONSTRUCT AT EXON 29 IN YUCATAN MINIATURE SWINE - UNII:H02ZF3289J) | PKD1 +/R3278C-BLAST RDNA CONSTRUCT AT EXON 29 IN YUCATAN MINIATURE SWINE | 1 [arb'U] in 1 [arb'U] |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------|----------------------|--------------------|
| 1 | NDC:86093-2002-1 | 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 (958331121)

Registrant - Exemplar Genetics, Llc (958331121)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|---------------------|
| Exemplar Genetics, Llc | | 958331121 | manufacture |

Revised: 6/2025

Exemplar Genetics, Llc