PAYLEAN 45- ractopamine hydrochloride granule Elanco US Inc.

Elanco™

AF0610

Paylean™ 45

(ractopamine hydrochloride Type A medicated article)

For Use in Finishing Swine Feeds Only

Net Weight 25 lb

(11.34 Kg)

Do not feed undiluted.

Active Drug Ingredient:

ractopamine hydrochloride

- 45.4 g per lb (100 g per kg)

Important: Must be thoroughly mixed into feeds before use. Follow label directions.

Indication:

For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.

Appropriate Concentration of Ractopamine in Type C Medicated Feed 4.5 to 9.0 g/ton* (5 to 10 ppm)

* No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.5 g/ton (5 ppm).

Inert Ingredients: Ground corncobs.

Variable	Last 45 lbs of body w	Last 90 lbs of body weight gain		
vai lable	4.5 g/ton ractopamine	9.0 g/ton	4.5 g/ton	
		ractopamine	ractopamine	ractopamine
Carcass Fat	↓ a	↓a	↓	1
10th Rib Backfat (3/4 location)	NC	NC	NC	1

Last Rib Backfat (midline)	NC	NC	NC	NC
Loin Eye Area (10th Rib)	↑a	1	1	1
Rate of Lean Gain	1	1	1	1
Efficiency of Lean Gain	1	1	1	1
Dressing Percentage	NC	1	1	1

NC = No Change, $\uparrow = increased$, $\downarrow = decreased$,

Mixing Directions: Thoroughly mix Paylean 45 Type A Medicated Article into one ton of appropriate feed ingredients according to the table below to obtain the proper concentration in the Type B Medicated Feed (maximum 4920 g/ton).

The following table gives examples of how some Type B Medicated Feed concentrations can be prepared:

Pounds of Paylean 45 To Add Per Ton To Make a Type B Medicated			
Feed	Grams/ton	Grams/pound	
19.82	900	0.45	
39.65	1,800	0.90	
59.47	2,700	1.35	
79.30	3,600	1.80	

Thoroughly mix Paylean 45 Type A Medicated Article into one ton of complete swine feed according to the table below to obtain the proper concentration in the Type C Medicated Feed. Prepare at least one intermediate pre-blend of the premix prior to mixing in a complete feed. Thoroughly mix the required amount in a convenient quantity of feed ingredients then add to the remaining feed ingredients to make a ton of complete feed.

Pounds of Paylean 45 To Add Per Ton of Type C Medicated Feed	Resulting Ractopamine Concentration in Type C Medicated Feed
0.10	4.5 grams/ton (5 ppm)
0.20	9 grams/ton (10 ppm)

Feeding Directions: Feed continuously as the sole ration to finishing swine weighing not less than 150 lbs for the last 45 to 90 lbs (group average) of weight gain prior to slaughter.

CAUTION: Ractopamine may increase the number of injured and/or fatigued pigs during marketing. Not for use in breeding swine.

^a Improvement was observed only in pigs weighing less than 250 lbs.

WARNING: The active ingredient in Paylean, ractopamine hydrochloride, is a beta-adrenergic agonist. Individuals with cardiovascular disease should exercise special caution to avoid exposure. Not for use in humans. Keep out of the reach of children. The Paylean formulation (Type A Medicated Article) poses a low dust potential under usual conditions of handling and mixing. When mixing and handling Paylean, use protective clothing, impervious gloves, protective eye wear, and a NIOSH-approved dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse eyes thoroughly with water. If irritation persists, seek medical attention. The material safety data sheet contains more detailed occupational safety information. To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

Storage information: Store at less than or equal to 25°C (77°F).

Excursions to 40°C (104°F) are acceptable.

Avoid excessive moisture.

Expiration Date and Lot Number are printed on the bag.

Not to be used after the expiry date.

Restricted Drug (California)

- Use Only as Directed -

Approved by FDA under NADA # 140-863.

Paylean™ 45

TAKE TIME
OBSERVE LABEL
DIRECTIONS

Manufactured for:

Elanco US Inc Greenfield, IN 46140, USA

To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

Paylean, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

BG230547X

Principal Display Panel - Paylean 45 Bag Label

Elanco™

AF0610

Paylean™ 45

(ractopamine hydrochloride Type A medicated article)
For Use in Finishing Swine Feeds Only
Net Weight 25 lb
(11.34 Kg)



AF0610

Paylean™45

TM

(ractopamine hydrochloride Type A medicated article)

For Use in Finishing Swine Feeds Only

Net Weight **25 lb** (11.34 Kg)

Do not feed undiluted.

Active Drug Ingredient: ractopamine hydrochloride - 45.4 g per lb (100 g per kg)

Important: Must be thoroughly mixed into feeds before use.

Follow label directions.

Indication: For increased rate of weight gain, improved feed

efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain

prior to slaughter.

Appropriate Concentration of Ractopamine in Type C Medicated Feed

4.5 to 9.0 g/ton* (5 to 10 ppm)

* No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.5 g/ton (5 ppm).

Inert Ingredients: Ground corncobs.

Variable	Last 45 lbs of body weight gain		Last 90 lbs of body weight gain	
	4.5 g/ton ractopamine	9.0 g/ton ractopamine	4.5 g/ton ractopamine	9.0 g/ton ractopamine
Carcass Fat	4.	↓ a	4	4
10th Rib Backfat (3/4 location)	NC	NC	NC	4
Last Rib Backfat (midline)	NC	NC	NC	NC
Loin Eye Area (10th Rib)	↑ °	1	1	1
Rate of Lean Gain	1	1	1	1
Efficiency of Lean Gain	•	^	1	•
Dressing Percentage	NC	•	1	1

NC = No Change, \spadesuit = increased, \clubsuit = decreased, a Improvement was observed only in pigs weighing less than 250 lbs.

Mixing Directions: Thoroughly mix Paylean 45 Type A Medicated Article into one ton of appropriate feed ingredients according to the table below to obtain the proper concentration in the Type B Medicated Feed (maximum 4920 g/ton).

The following table gives examples of how some

Thoroughly mix Paylean 45 Type A Medicated Article into one ton of complete swine feed according to the table below to obtain the proper concentration in the Type C Medicated Feed. Prepare at least one intermediate pre-blend of the premix prior to mixing in a complete feed. Thoroughly mix the required amount in a convenient quantity of feed ingredients then add to the remaining feed ingredients to make a ton of complete feed.

Pounds of Paylean 45 To Add Per Ton of Type C Medicated Feed	Resulting Ractopamine Concentration in Type C Medicated Feed	
0.10	4.5 grams/ton (5 ppm)	
0.20	9 grams/ton (10 ppm)	

Feeding Directions: Feed continuously as the sole ration to finishing swine weighing not less than 150 lbs for the last 45 to 90 lbs (group average) of weight gain prior to slaughter.

CAUTION: Ractopamine may increase the number of injured and/or fatigued pigs during marketing. Not for use in breeding swine.

WARNING: The active ingredient in Paylean, ractopamine hydrochloride, is a beta-adrenergic agonist. Individuals with cardiovascular disease should exercise special caution to avoid exposure. Not for use in humans. Keep out of the reach of children. The Paylean formulation (Type A Medicated Article) poses a low dust potential under usual conditions of handling and mixing. When mixing and handling Paylean, use protective clothing, impervious gloves, protective eye wear, and a NIOSHapproved dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse eyes thoroughly with water. If irritation persists, seek medical attention. The material safety data sheet contains more detailed occupational safety information. To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

Type B Medicated Feed concentrations can be prepared:

Pounds of Paylean 45 To Add Per Ton To Make a Type B	Resulting Ractopamine Concentration in Type B Medicated Feed		
Medicated Feed	Grams/ton	Grams/pound	
19.82	900	0.45	
39.65	1,800	0.90	
59.47	2,700	1.35	
79.30	3,600	1.80	

Storage information: Store at less than or equal to 25° C (77°F). Excursions to 40° C (104° F) are acceptable.

Avoid excessive moisture.

Expiration Date and Lot Number are printed on the bag.

Not to be used after the expiry date.

Restricted Drug (California) -

Approved by FDA under NADA # 140-863.

Restricted Drug (California) -Use Only as Directed -

OBSERVE LABE

TAKE TIME

DIRECTIONS

Paylean™ 45

Manufactured for: Elanco US Inc

Greenfield, IN 46140, USA

To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

Paylean, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

BG230547X



Paylean 45

TM

(ractopamine hydrochloride Type A medicated article)

For Use in Finishing Swine Feeds Only Net Weight 25 lb (11.34 Kg)

Do not feed undiluted.

Active Drug Ingredient: ractopamine hydrochloride -

45.4 g per lb (100 g per kg)

Important: Must be thoroughly mixed into feeds

before use. Follow label directions.

Indication: For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to

slaughter.

Appropriate Concentration of Ractopamine in Type C Medicated Feed

4.5 to 9.0 g/ton* (5 to 10 ppm)

* No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.5 g/ton (5 ppm).

Inert Ingredients: Ground corncobs.

Variable	Last 45 lbs of body weight gain		Last 90 lbs of body weight gain	
Turidolo	4.5 g/ton ractopamine	9.0 g/ton ractopamine	4.5 g/ton ractopamine	9.0 g/ton ractopamine
Carcass Fat	↓ a	↓ a	4	4
10th Rib Backfat (3/4 location)	NC	NC	NC	¥
Last Rib Backfat (midline)	NC	NC	NC	NC
Loin Eye Area (10th Rib)	♠ª	^	^	^

Thoroughly mix Paylean 45 Type A Medicated Article into one ton of complete swine feed according to the table below to obtain the proper concentration in the Type C Medicated Feed. Prepare at least one intermediate pre-blend of the premix prior to mixing in a complete feed. Thoroughly mix the required amount in a convenient quantity of feed ingredients then add to the remaining feed ingredients to make a ton of complete feed.

Pounds of Paylean 45 To Add Per Ton of Type C Medicated Feed	Resulting Ractopamine Concentration in Type C Medicated Feed
0.10	4.5 grams/ton (5 ppm)
0.20	9 grams/ton (10 ppm)

Feeding Directions: Feed continuously as the sole ration to finishing swine weighing not less than 150 lbs for the last 45 to 90 lbs (group average) of weight gain prior to slaughter.

CAUTION: Ractopamine may increase the number of injured and/or fatigued pigs during marketing. Not for use in breeding swine.

WARNING: The active ingredient in Paylean, ractopamine hydrochloride, is a beta-adrenergic agonist. Individuals with cardiovascular disease should exercise special caution to avoid exposure. Not for use in humans. Keep out of the reach of children. The Paylean formulation (Type A Medicated Article) poses a low dust potential under usual conditions of handling and mixing. When mixing and handling Paylean, use protective clothing, impervious gloves, protective eye wear, and a

	65	100		9/50
Rate of Lean Gain	1	1	1	1
Efficiency of Lean Gain	^	^	1	^
Dressing Percentage	NC	^	^	^

NC = No Change, ↑ = increased, ↓ = decreased, a Improvement was observed only in pigs weighing less than 250 lbs.

Mixing Directions: Thoroughly mix Paylean 45
Type A Medicated Article into one ton of
appropriate feed ingredients according to the table
below to obtain the proper concentration in the
Type B Medicated Feed (maximum 4920 g/ton).

The following table gives examples of how some Type B Medicated Feed concentrations can be prepared:

Pounds of Paylean 45 To Add Per Ton To Make a Type B	Resulting Ractopamine Concentration in Type B Medicated Feed		
Medicated Feed	Grams/ton	Grams/pound	
19.82	900	0.45	
39.65	1,800	0.90	
59.47	2,700	1.35	
79.30	3,600	1.80	

NIOSH-approved dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse eyes thoroughly with water. If irritation persists, seek medical attention. The material safety data sheet contains more detailed occupational safety information. To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

Storage information: Store at less than or equal to 25°C (77°F).

Excursions to 40°C (104°F) are acceptable.

Avoid excessive moisture.

Expiration Date and Lot Number are printed on the bag.

Not to be used after the expiry date.

Restricted Drug (California) -Use Only as Directed -

Approved by FDA under NADA # 140-863.

Paylean™ 45

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140, USA

To report adverse effects,

access medical information, or obtain additional product information, call 1-800-428-4441.

Paylean, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates. YL230547X

PAYLEAN 45

ractopamine hydrochloride granule

Product Information					
Product Type	OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:58198- 0610		
Route of Administration	ORAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ractopamine hydrochloride (UNII: 309G9J93TP) (ractopamine - UNII:573700Z3P1)	ractopamine hydrochloride	45.5 g in 0.45 kg	

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:58198-0610-9	11.34 kg in 1 BAG		

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

NADA NADA140863 06/06/2008

Labeler - Elanco US Inc. (966985624)

Establishment			
Name	Address	ID/FEI	Business Operations
Evonik Corporation		130890994	API MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
TriRx Speke Limited		228138655	MANUFACTURE, PACK, LABEL

Revised: 7/2022 Elanco US Inc.