

OPTAFLEXX 45- ractopamine hydrochloride powder
Elanco US Inc.

Elanco™

AF0630

Optaflexx™ 45

(ractopamine hydrochloride Type A medicated article)

For use in Feeds For Cattle Fed in Confinement for Slaughter 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:

Complete Feed: For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

Top Dress Feed: For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

Note: Carcass leanness effects are not an approved indication for use when feeding ractopamine by Top Dress Feeding methods.

Complete Feed

Indications	Appropriate Concentration of Ractopamine in Type C Medicated Feed ^a	Ractopamine (mg/hd/d)
Increased Rate of Weight Gain, and Improved Feed Efficiency	8.2 to 24.6 g/ton (9 ppm to 27 ppm)	70-430
Increased Rate of Weight Gain, Improved Feed Efficiency, and Increased Carcass Leanness	9.8 to 24.6 g/ton (11 ppm to 27 ppm)	90-430

^a Based on 90% Dry Matter Basis

	Effect of Ractopamine ^a
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Carcass Measurements	8.2 grams/ton (9 ppm)	16.4 grams/ton (18 ppm)	24.6 grams/ton (27 ppm)
Hot Carcass Weight, lbs	↑	↑	↑
Dressing Percentage, %	NC	↑ ^b	↑ ^b
Carcass Percent Fat, %	NC	↓	↓
12th Rib Fat Thickness, in.	NC	NC	NC
Average Rib Eye Area, sq. in.	↑	↑	↑
USDA Yield Grade	NC	NC	↓ ^c
Marbling Score	NC	NC	NC
Rate of Carcass Lean Gain per Day	NC	↑	↑
Efficiency of Carcass Lean Gain per Day	NC	↑	↑

^a The effect of ractopamine on parameters listed in this table is supported by data generated at the doses tested in the clinical field efficacy trials.

NC = No Change, ↑ = Increased, ↓ = Decreased

^b Steers Only

^c Reduction indicates an improvement in USDA Yield Grade.

Top Dress Feed

Indications	Appropriate Concentration of Ractopamine in Type C Medicated Feed ^a	Ractopamine (mg/hd/d)
Increased Rate of Weight Gain and Improved Feed Efficiency	Appropriate Concentration of Ractopamine in a minimum of 1.0 lb Top Dressed Type C Medicated Feed ^a (maximum of 800 g/ton)	70-400

^a Based on 90% Dry Matter Basis

Inert Ingredients: Ground corn cobs.

Mixing Directions (Complete Feed):

Thoroughly mix Optaflexx 45 Type A Medicated Article in a ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type B Medicated Feed (maximum 4,920 g/ton). The following table gives examples of how some Type B Medicated Feed concentrations can be prepared:

Pounds of Optaflexx 45 ^a To Add Per Ton To Make a Type B Medicated Feed	Resulting Ractopamine Concentration in Type B Medicated Feed ^b	
	grams/ton	grams/pound
36.1	1,640	0.82
72.2	3,280	1.64
108.3	4,920	2.46

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

^b Based on 90% Dry Matter Basis

Thoroughly mix Optaflexx 45 Type A Medicated Article in a ton of complete cattle feed according to the table below to obtain the proper concentration in the Type C Medicated Feed. Prepare an 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 one ton of complete feed.

Pounds of Optaflexx 45 ^a Per Ton To Make a Type C Medicated Feed	Resulting Ractopamine Concentration in Type C Medicated Feed ^b
0.18	8.2 grams/ton (9 ppm)
0.36	16.4 grams/ton (18 ppm)
0.54	24.6 grams/ton (27 ppm)

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

^b Based on 90% Dry Matter Basis

Mixing Directions (Liquid Type B Feeds):

Thoroughly mix Optaflexx Type A Medicated Article in a ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type B Medicated Feed (maximum 2300 g/ton).

Maintain supplement pH at 4.5 to 7.5. For stored liquid Type B Medicated Feeds containing ractopamine, recirculate immediately prior to use for not less than 10 minutes, moving not less than 1% of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not in use.

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

Pounds of Optaflexx 45 ^a To Add Per Ton To Make a Liquid Type B Medicated Feed	Resulting Ractopamine Concentration in Liquid Type B Medicated Feed	
	grams/ton	grams/pound
36.1	1,640	0.82
44.1	2,000	1.00
50.7	2,300	1.15

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

Mixing Directions for Preparing Type C Medicated Top Dress Feed:

Thoroughly mix Optaflexx 45 Type A Medicated Article in a ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type C Medicated Feed (maximum 800 g/ton).

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

Pounds of Optaflexx 45 ^a To Add Per Ton To Make Type C Medicated Top Dress Feed	Resulting Ractopamine Concentration in Type C Top Dress Medicated Feed ^b		
	grams/ton	grams/pound	mg/pound
Top Dress			
2.20	100	0.05	50
4.41	200	0.10	100
6.61	300	0.15	150
8.81	400	0.20	200
17.62	800	0.40	400

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

^b Based on 90% Dry Matter Basis

Directions for Use (Complete Feed):

Feed continuously to cattle fed in confinement for slaughter as the sole ration for the last 28 to 42 days on feed.

Directions for Use (Type C Medicated Top Dress Feed):

Feed continuously to cattle fed in confinement for slaughter a Type C Medicated Feed containing up to a maximum of 800 g/ton ractopamine (see mixing direction table) to provide 70 to 400 mg/head/ day for the last 28 to 42 days on feed. Type C Medicated Top Dress Feed must be fed in a minimum of 1.0 lb per head per day to provide 70 to 400 mg/head/day.

CAUTION: Not for animals intended for breeding.

Warning

Withdrawal Period:

No withdrawal period is required when used according to labeling.

NOT FOR HUMAN USE

WARNING: The active ingredient in Optaflexx, 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 Optaflexx 45 formulation (Type A Medicated Article) poses a low dust potential under usual conditions of handling and mixing. When mixing and handling Optaflexx, 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.

Store at Room Temperature. Avoid 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 # 141-221

Optaflexx™ 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.

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BG230548X

Principal Display Panel - 25 lb Bag Label

Elanco™

AF0630

Optaflexx™ 45

(ractopamine hydrochloride Type A medicated article)

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for Slaughter Only**

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

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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: Complete Feed: For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

Top Dress Feed: For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

Note: Carcass leanness effects are not an approved indication for use when feeding ractopamine by Top Dress Feeding methods.

Complete Feed

Indications	Appropriate Concentration of Ractopamine in Type C Medicated Feed ^a	Ractopamine (mg/hd/d)
Increased Rate of Weight Gain, and Improved Feed Efficiency	8.2 to 24.6 g/ton (9 ppm to 27 ppm)	70-430
Increased Rate of Weight Gain, Improved Feed Efficiency, and Increased Carcass Leanness	9.8 to 24.6 g/ton (11 ppm to 27 ppm)	90-430

^a Based on 90% Dry Matter Basis

Carcass Measurements	Effect of Ractopamine ^a		
	8.2 grams/ton (9 ppm)	16.4 grams/ton (18 ppm)	24.6 grams/ton (27 ppm)
Hot Carcass Weight, lbs	↑	↑	↑
Dressing Percentage, %	NC	↑ ^b	↑ ^b
Carcass Percent Fat, %	NC	↓	↓
12th Rib Fat Thickness, in.	NC	NC	NC
Average Rib Eye Area, sq. in.	↑	↑	↑
USDA Yield Grade	NC	NC	↓ ^c
Marbling Score	NC	NC	NC
Rate of Carcass Lean Gain per Day	NC	↑	↑
Efficiency of Carcass Lean Gain per Day	NC	↑	↑

^a The effect of ractopamine on parameters listed in this table is supported by data generated at the doses tested in the clinical field efficacy trials.
NC = No Change, ↑ = Increased, ↓ = Decreased

^b Steers Only

^c Reduction indicates an improvement in USDA Yield Grade.

Top Dress Feed

Indications	Appropriate Concentration of Ractopamine in Type C Medicated Feed ^a	Ractopamine (mg/hd/d)
Increased Rate of Weight Gain and Improved Feed Efficiency	Appropriate Concentration of Ractopamine in a minimum of 1.0 lb Top Dressed Type C Medicated Feed ^a (maximum of 800 g/ton)	70-400

^a Based on 90% Dry Matter Basis

Inert Ingredients: Ground corn cobs.

Mixing Directions (Complete Feed): Thoroughly mix Optaflexx 45 Type A Medicated Article in a ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type B Medicated Feed (maximum 4,920 g/ton). The following table gives examples of how some Type B Medicated Feed concentrations can be prepared:

Pounds of Optaflexx 45 ^a	Resulting Ractopamine Concentration in Liquid Type B Medicated Feed
36.1	1,640
44.1	2,000
50.7	2,300

Mixing Directions (Liquid Type B Feeds): Thoroughly mix Optaflexx Type A Medicated Article in a ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type B Medicated Feed (maximum 2300 g/ton). Maintain supplement pH at 4.5 to 7.5. For stored liquid Type B Medicated Feeds containing ractopamine, recirculate immediately prior to use for not less than 10 minutes, moving not less than 1% of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not in use.

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

Pounds of Optaflexx 45 ^a To Add Per Ton To Make a Liquid Type B Medicated Feed	Resulting Ractopamine Concentration in Liquid Type B Medicated Feed	
	grams/ton	grams/pound
36.1	1,640	0.82
44.1	2,000	1.00
50.7	2,300	1.15

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

Mixing Directions for Preparing Type C Medicated Top Dress Feed: Thoroughly mix Optaflexx 45 Type A Medicated Article in a ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type C Medicated Feed (maximum 800 g/ton).

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

Pounds of Optaflexx 45 ^a To Add Per Ton To Make Type C Medicated Top Dress Feed	Resulting Ractopamine Concentration in Type C Top Dress Medicated Feed ^b		
	Top Dress	grams/ton	grams/pound
2.20	100	0.05	50
4.41	200	0.10	100
6.61	300	0.15	150
8.81	400	0.20	200
17.62	800	0.40	400

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

^b Based on 90% Dry Matter Basis

Directions for Use (Complete Feed): Feed continuously to cattle fed in confinement for slaughter as the sole ration for the last 28 to 42 days on feed.

Directions for Use (Type C Medicated Top Dress Feed): Feed continuously to cattle fed in confinement for slaughter a Type C Medicated Feed containing up to a maximum of 800 g/ton ractopamine (see mixing direction table) to provide 70 to 400 mg/head/day for the last 28 to 42 days on feed. Type C Medicated Top Dress Feed must be fed in a minimum of 1.0 lb per head per day to provide 70 to 400 mg/head/day.

CAUTION: Not for animals intended for breeding.

Warning

Withdrawal Period:

No withdrawal period is required when used according to labeling.

NOT FOR HUMAN USE

WARNING: The active ingredient in Optaflexx, 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 Optaflexx 45 formulation (Type A Medicated Article) poses a low dust potential under usual conditions of handling and mixing. When mixing and handling Optaflexx.

To Add Per Ton To Make a Type B Medicated Feed	Type B Medicated Feed ^a	
	grams/ton	grams/pound
36.1	1,640	0.82
72.2	3,280	1.64
108.3	4,920	2.46

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

^b Based on 90% Dry Matter Basis

Thoroughly mix Optaflexx 45 Type A Medicated Article in a ton of complete cattle feed according to the table below to obtain the proper concentration in the Type C Medicated Feed. Prepare an 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 one ton of complete feed.

Pounds of Optaflexx 45 ^a Per Ton To Make a Type C Medicated Feed	Resulting Ractopamine Concentration in Type C Medicated Feed ^b
0.18	8.2 grams/ton (9 ppm)
0.36	16.4 grams/ton (18 ppm)
0.54	24.6 grams/ton (27 ppm)

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

^b Based on 90% Dry Matter Basis

When using Optaflexx 45, 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.

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

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Note: Carcass leanness effects are not an approved indication for use when feeding ractopamine by Top Dress Feeding methods.

Complete Feed

Indications	Appropriate Concentration of Ractopamine in Type C Medicated Feed ^a	Ractopamine (mg/hd/d)
Increased Rate of Weight Gain, and Improved Feed Efficiency	8.2 to 24.6 g/ton (9 ppm to 27 ppm)	70-430
Increased Rate of Weight Gain, Improved Feed Efficiency, and Increased Carcass Leanness	9.8 to 24.6 g/ton (11 ppm to 27 ppm)	90-430

^a Based on 90% Dry Matter Basis

Carcass Measurements	Effect of Ractopamine ^a		
	8.2 grams/ton (9 ppm)	16.4 grams/ton (18 ppm)	24.6 grams/ton (27 ppm)
Hot Carcass Weight, lbs	↑	↑	↑
Dressing Percentage, %	NC	↑ ^b	↑ ^b
Carcass Percent Fat, %	NC	↓	↓
12th Rib Fat Thickness, in.	NC	NC	NC
Average Rib Eye Area, sq. in.	↑	↑	↑
USDA Yield Grade	NC	NC	↓ ^c
Marbling Score	NC	NC	NC
Rate of Carcass Lean Gain per Day	NC	↑	↑
Efficiency of Carcass Lean Gain per Day	NC	↑	↑

^a The effect of ractopamine on parameters listed in this table is supported by data generated at the doses tested in the clinical field efficacy trials.

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^b Steers Only

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Mixing Directions (Liquid Type B Feeds): Thoroughly mix Optaflexx Type A Medicated Article in a ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type B Medicated Feed (maximum 2300 g/ton).

Maintain supplement pH at 4.5 to 7.5. For stored liquid Type B Medicated Feeds containing ractopamine, recirculate immediately prior to use for not less than 10 minutes, moving not less than 1% of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not in use.

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

Pounds of Optaflexx 45 ^a To Add Per Ton To Make a Liquid Type B Medicated Feed	Resulting Ractopamine Concentration in Liquid Type B Medicated Feed	
	grams/ton	grams/pound
36.1	1,640	0.82
44.1	2,000	1.00
50.7	2,300	1.15

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

Mixing Directions for Preparing Type C Medicated Top Dress Feed: Thoroughly mix Optaflexx 45 Type A Medicated Article in a ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type C Medicated Feed (maximum 800 g/ton).

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

Pounds of Optaflexx 45 ^a To Add Per Ton To Make Type C Medicated Top Dress Feed	Resulting Ractopamine Concentration in Type C Top Dress Medicated Feed ^b		
	grams/ton	grams/pound	mg/pound
Top Dress			
2.20	100	0.05	50
4.41	200	0.10	100
6.61	300	0.15	150
8.81	400	0.20	200
17.62	800	0.40	400

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

^b Based on 90% Dry Matter Basis

Directions for Use (Complete Feed): Feed continuously to cattle fed in confinement for slaughter as the sole ration for the last 28 to 42 days on feed.

Directions for Use (Type C Medicated Top Dress Feed):

Reduction indicates an improvement in USDA Yield Grade.

Top Dress Feed

Indications	Appropriate Concentration of Ractopamine in Type C Medicated Feed ^a	Ractopamine (mg/hd/d)
Increased Rate of Weight Gain and Improved Feed Efficiency	Appropriate Concentration of Ractopamine in a minimum of 1.0 lb Top Dressed Type C Medicated Feed ^a (maximum of 800 g/ton)	70-400

^a Based on 90% Dry Matter Basis

Inert Ingredients: Ground corn cobs.

Mixing Directions (Complete Feed): Thoroughly mix Optaflexx 45 Type A Medicated Article in a ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type B Medicated Feed (maximum 4,920 g/ton). The following table gives examples of how some Type B Medicated Feed concentrations can be prepared:

Pounds of Optaflexx 45 ^a To Add Per Ton To Make a Type B Medicated Feed	Resulting Ractopamine Concentration in Type B Medicated Feed ^b	
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^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

^b Based on 90% Dry Matter Basis

Thoroughly mix Optaflexx 45 Type A Medicated Article in a ton of complete cattle feed according to the table below to obtain the proper concentration in the Type C Medicated Feed. Prepare an 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 one ton of complete feed.

Pounds of Optaflexx 45 ^a Per Ton To Make a Type C Medicated Feed	Resulting Ractopamine Concentration in Type C Medicated Feed ^b
0.18	8.2 grams/ton (9 ppm)
0.36	16.4 grams/ton (18 ppm)
0.54	24.6 grams/ton (27 ppm)

^a Optaflexx 45 contains 45.4 g ractopamine hydrochloride per pound

^b Based on 90% Dry Matter Basis

Directions for Use (Type C Medicated Top Dress Feed):

Feed continuously to cattle fed in confinement for slaughter a Type C Medicated Feed containing up to a maximum of 800 g/ton ractopamine (see mixing direction table) to provide 70 to 400 mg/head/day for the last 28 to 42 days on feed. Type C Medicated Top Dress Feed must be fed in a minimum of 1.0 lb per head per day to provide 70 to 400 mg/head/day.

CAUTION: Not for animals intended for breeding.

Warning

Withdrawal Period:

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Expiration Date and Lot Number are printed on the bag.

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Restricted Drug (California) -

Use Only as Directed -

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Optaflexx™ 45

Manufactured for: Elanco US, Inc

Greenfield, IN 46140, USA

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TAKE TIME



OBSERVE LABEL DIRECTIONS

YL230548X

OPTAFLEXX 45

ractopamine hydrochloride powder

Product Information

Product Type	OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:58198-0630
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ractopamine hydrochloride (UNII: 309G9J93TP) (ractopamine - UNII:57370OZ3P1)	ractopamine hydrochloride	45.4 g in 0.45 kg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-0630-9	11.34 kg in 1 BAG		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
NADA	NADA141221	06/03/2010	

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.