EXPERIOR 10- lubabegron granule Elanco US Inc.

 $Elanco^{TM}$

ExperiorTM10

(lubabegron Type A medicated article)

For Use in Feeds for Beef Steers and Heifers Fed in Confinement for Slaughter

Important:

For further manufacturing only. Experior 10 must be thoroughly mixed into feeds before use. Follow label directions.

Active Drug Ingredient:

Lubabegron (as lubabegron fumarate) - 10 g per kg (4.54 g per lb)

Inert Ingredients: Corn cob grits, mineral oil, citric acid.

Indications for Use:

For reduction of ammonia gas emissions per pound of live weight and hot carcass weight in beef steers and heifers fed in confinement for slaughter during the last 14 to 91 days on feed.

Effectiveness has not been demonstrated when fed for less than 14 days. Ammonia gas emissions were measured for individual animals or small groups of animals held in environmentally controlled facilities. Based on existing information, reliable predictions of the reduction of ammonia gas emissions cannot be made on a herd, farm, or larger scale.

Increased rate of weight gain, improved feed efficiency, and increased carcass leanness have not been demonstrated with this product.

Mixing Directions: Thoroughly mix Experior 10 Type A medicated article in a ton of appropriate feed ingredients according to the table below to obtain the proper concentration in the Type B medicated feed (maximum 720 g/ton). The following table gives examples of how some Type B medicated feed concentrations can be prepared:

Pounds of Experior 10 Type A ^a To	Resulting lubabegron Conce	ntration in Type B Medicated
Add Per Ton To Make a Type B	Fee	ed ^b
Medicated Feed	grams/ton	grams/pound
9.9	45	0.02
77.1	350	0.17
158.6	720	0.36

^a Experior 10 contains 4.54 grams of lubabegron per pound

Thoroughly mix Experior 10 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. You must prepare an intermediate pre-blend by thoroughly mixing the required amount of Experior 10 Type A medicated article in a convenient quantity of feed ingredients, and then add the pre-blend to the remaining feed ingredients to make a complete feed.

^b Based on 90% Dry Matter Basis

Pounds of Experior 10 Type A ^a To Add Per Ton	Resulting lubabegron Concentration (g/ton) in Type
To Make a Type C Medicated Feed	C Medicated Feed ^b
0.28 ^c	1.25
0.55	2.50
1.00	4.54

^a Experior 10 contains 4.54 grams of lubabegron per pound

Feeding Directions: Feed 1.25 to 4.54 g/ton (1.39 to 5 ppm) of complete feed (90% dry matter basis) to provide 13-90 mg lubabegron/head/day continuously to beef steers and heifers fed in confinement for slaughter as the sole ration during the last 14 to 91 days on feed.

Caution: Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing Experior 10. A decrease in dry matter intake may be noticed in some animals.

Warnings:

No withdrawal period is required when used according to labeling.

User Safety Warning: The active ingredient in Experior 10, lubabegron, is a beta-adrenergic agonist/antagonist. Individuals with cardiovascular disease should exercise special caution to avoid exposure. Not for human use. Keep out of reach of children. When mixing and handling Experior 10, 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 thoroughly with water; if wearing contact lenses, rinse eyes first, then remove contact lenses and continue to rinse for 5-20 minutes. If irritation persists, seek medical attention. The safety data sheet contains more detailed occupational safety information. To report adverse drug events, access medical information, or obtain additional product information, call Elanco US Inc. at 1-800-428-4441. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

Lot No:

Expiry Date:

Storage Information: Store at or below 25°C (77°F). Excursions permitted to 30°C (86°F).

Not to be used after the date printed on the bag.

Restricted Drug (California) – Use Only as Directed

Approved by FDA under NADA #141-508

Manufactured For: Elanco US Inc.

- 2500 Innovation Way
- Greenfield, IN 46140, U.S.A.

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

Net Weight 10 kg

(22.04 lb)

TAKE TIME

^b Based on 90% Dry Matter Basis

^c Rounded value



OBSERVE LABEL DIRECTIONS

YL102499X

Principal Display Panel – Experior 10kg Bag Label

ElancoTM

ExperiorTM10

(lubabegron Type A medicated article)



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c Rounded value

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YL102499X

b Based on 90% Dry Matter Basis

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EXPERIOR 10

lubabegron granule

D	J4	TC	4
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Product Type OTC ANIMAL DRUG Item Code (Source) NDC:58198-1567

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

Lubabegron (UNII: 8501207BZX) (Lubabegron - UNII:8501207BZX) Lubabegron
10 g in 1 kg

Inactive Ingredients

CORN GRAIN (UNII: C1Z9U7094Z)

Mineral oil (UNII: T5L8T28FGP)

CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)

Packaging

ı				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:58198-1567-1	10 kg in 1 BAG		

Marketing Information

NADA NADA141500	nd Date	Marketing End	Marketing Start Date	Application Number or Monograph Citation	Marketing Category
NADA NADA141508 11/06/2018			11/06/2018	NADA141508	NADA

Labeler - Elanco US Inc. (966985624)

Establishment			
Name	Address	ID/FEI	Business Operations
Elanco Clinton Laboratories		039138631	API MANUFACTURE, MANUFACTURE, PACK, LABEL

Revised: 4/2020 Elanco US Inc.