Experior[™]

(lubabegron Type A medicated article)

A TOOL TO SUPPORT BEEF ENVIRONMENTAL STEWARDSHIP EFFORTS



EXPERIOR™ AT-A-GLANCE

Every day, feedlot operators must balance increasing **environmental stewardship demands** with delivering business results.

Experior (lubabegron Type A medicated article) creates the **freedom** and **flexibility** to support environmental sustainability without hindering animal performance measures (average daily gain, feed efficiency, or carcass characteristics)*.

* Animal performance measures (average daily gain, feed efficiency, or carcass characteristics) were not negatively affected by Experior at any dose, compared to animals not fed Experior.

Experior is approved for the 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.

Experior is the 1st United States Food and Drug Administration (FDA) approved product labeled to reduce gas emissions from an animal or its waste.

Ammonia gases impact the environment and are known to come from many sources.¹

"The reduction of ammonia gases reasonably may be expected to provide some benefit to the environment."²

Based on existing information, reliable prediction of the reduction of ammonia gas emissions cannot be made on a herd, farm or larger scale.

GENERAL INFORMATION

Experior (lubabegron Type A medicated article)

Beta-adrenergic agonist/antagonist

Type A contains 10 g per kg (4.54 g per lb)

How Supplied: 10 kg bag

Directions for Use: Feed 1.25 to 4.54 g/ton (1.39 to 5 ppm) of complete feed (90% Dry Matter (DM) 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.

IMPORTANT SAFETY INFORMATION

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. A decrease in dry matter intake may be noticed in some animals.

The label contains complete use information, including cautions and warnings. Always read, understand, and follow the label, and use directions.



WHY REDUCING AMMONIA GAS EMISSIONS IS IMPORTANT



Air quality and addressing air emissions is a shared responsibility, including for feedyard owners and operators.³



Feedyards should be aware of the environmental concerns and management strategies associated with air emissions, including ammonia.³



Agricultural sources (which include livestock) are the largest known source of ammonia gas emissions in the U.S.^{4,5}



Ammonia gas is thought to be a significant contributor to the eutrophication of waterways and the formation of atmospheric haze and noxious odors.⁴



Experior is thought to act by increasing nitrogen (amino acid) uptake and the amount of nitrogen retained in the carcass as muscle protein, thereby reducing the amount of urea excreted in manure (manure is considered the urine and feces combined).^{4,6}



The urea in manure is rapidly converted by an enzyme, urease, to ammonia and ammonium. Subsequently, this ammonia is volatilized (i.e., released as a gas) to the atmosphere.

Thus, the reduction in excreted urea from the animal results in a reduction in ammonia gas emissions to the environment.

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.

EXTENSIVELY EVALUATED, EXPERIOR CAN BE USED WITH CONFIDENCE.

Through several studies conducted for approval, Experior was deemed safe when used according to its label. Animal and human safety analysis showed no negative impact on animal health or food safety.

- Animal safety information was evaluated in 4,240 animals across 15 studies.⁷ These studies demonstrated that, when fed according to its label, use of Experior did not affect animal lameness.⁷
 - Lameness issues in the studies appear to be related to nutritional management and pen conditions.⁷ Lameness incidence for animals fed Experior was similar to commercial feedlot incidence.⁸
 - Most cases resolved while the animals were still receiving Experior, indicating that lameness is not related to the product.
- Experior has also been evaluated in post approval research involving 2,160 animals, results of which support Experior's safety profile.⁹
- Experior was found to be safe to the target animal when administered for the reduction of NH₃ gas emissions per lb of LW and HCW in beef steers and heifers fed in confinement during the last 14- to 91-days on feed.
- A caution statement is included on the label: "A decrease in dry matter intake may be noticed in some animals."
- Human food safety analysis supports a zero-day pre-slaughter withdrawal period for Experior doses up to 5 g/ton (4.54 g/ton on a 90% DM basis)⁷
 - The no-observed-effect-level (NOEL) for lubabegron, the main ingredient in Experior, is 0.16 mg/kg BW/day for humans.
 - The Acceptable Daily Intake (ADI) of lubabegron is 3 μg/kw BW/day for humans, which includes a 50X safety factor.

FREQUENTLY ASKED QUESTIONS

1. What is Experior?

Experior (lubabegron Type A medicated article) is an important new tool that enables beef producers to care for the environment and their cattle. This is increasingly important as beef producers manage a complex business while trying to meet customer expectations. Experior is approved for the 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.

2. What does Experior do?

Experior helps support the beef industry's environmental stewardship efforts. Every day, feedlot operators must balance expectations of increasing environmental stewardship, while managing a complex business. Experior creates the freedom and flexibility to do both through the reduction of ammonia gas emissions from cattle. Clinical studies suggest that cattle fed Experior at 5 g/ton for 91 days emit approximately 16% less ammonia per pound of hot carcass weight compared to animals not fed Experior.⁷

3. How does Experior work?

Experior is a beta-adrenergic agonist/antagonist that is thought to act by increasing nitrogen (amino acid) uptake and the amount of nitrogen retained in the carcass as muscle protein, thereby reducing the amount of urea excreted in manure (manure is considered the urine and feces combined). The reduction in excreted urea from the animal results a reduction in ammonia gas emissions to the environment.

4. Is Experior safe for my cattle?

Through several studies conducted for approval, Experior was deemed safe when used according to its label. Animal safety analysis showed no negative impact on animal health.

5. Does Experior have a pre-slaughter withdrawal time?

Human food safety analysis supports a zero-day pre-slaughter withdrawal period for Experior doses up to 5 g/ton (4.54 g/ton on a 90% DM basis).⁷ 6. Do packers in the United States accept cattle fed Experior?

Elanco is working with packers to ensure acceptance of this FDA-approved technology.

7. Is beef from Experior-fed cattle accepted in major export markets? Maximum Residue Limits (MRL's) are in the process of being established in key export markets.

REFERENCES

- ¹ChemicalSafetyFacts.org Ammonia. https://www.chemicalsafetyfacts.org/ammonia/. May 2020.
- ² FDA Announcement Press Release: FDA Approves Experior for Reduction of Ammonia Gas Released from Beef Cattle Waste. https://www.fda.gov/animal-veterinary/cvmupdates/fda-approves-experior-reduction-ammonia-gas-released-beef-cattlewaste. Nov. 6, 2018.
- ³ U.S. Roundtable on Sustainable Beef. https://www.beefsustainability.us/highpriority-indicators/air-greenhouse-gas. May 2020.
- ⁴ Experior FONSI, summarized from page 3, https://animaldrugsatfda.fda.gov/adafda/ app/search/public/document/downloadFonsi/1271.
- ⁵ USEPA. 2014. 2014 National Emissions Inventory (NEI) Data.
- ⁶ Environmental Assessment for the use of Experior™ (lubabegron Type A medicated article) 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. https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadEA/1311. June 2018.
- ⁷ Experior FOI, Summarized from pages 4-32. https://animaldrugsatfda.fda.gov/ adafda/app/search/public/document/downloadFoi/5005. Accessed May 2020.
- ⁸ USDA APHIS NAHMS. Feedlot 2011 Part IV: Health and Management on U.S. Feedlots with a Capacity of 1,000 or More Head. https://www.aphis.usda.gov/animal_health/nahms/feedlot/downloads/feedlot2011/Feed11_dr_PartIV_1.pdf. Accessed June 2020.

⁹ Elanco Animal Health. Data on file.

If you have any questions regarding Experior,

please contact your Elanco representative or our Product and Veterinary Support Team at **1-800-428-4441**.



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