

Merck Animal Health Announces Update to ZILMAX® Label in Canada

VDD approval of updates to ZILMAX® label, includes new feed delivery method.

Merck Animal Health (known outside the United States and Canada as MSD Animal Health) today announced it has obtained approval from the Veterinary Drugs Directorate (VDD) to update the ZILMAX® label to include Component Feeding, which is an alternative method of administering ZILMAX using a targeted lower dose. Component Feeding provides cattle feeders with an alternative option to deliver the appropriate dose of ZILMAX to cattle every day. The new convenient feed delivery method allows cattle feeders to mix ZILMAX in feed to deliver a lower targeted dose of 60 mg zilpaterol hydrochloride/head/day in one of multiple daily feedings.

In addition to Component Feeding, the VDD has approved a revision to the existing Complete Feed information in the label. The current Complete Feed label dose for zilpaterol hydrochloride is 8.3 grams/tonne (100% dry matter basis) to provide 60 to 90 mg zilpaterol hydrochloride/head/day. The label will now include an updated caution statement that notes cattle should not be fed ZILMAX in excess of 90 mg/head/day. If pen consumption of complete feed exceeds 10.8 kg/head/day (on a 100% dry matter basis), ZILMAX should not be fed in complete feed.

With insights from the company's advisory board, an extensive assessment and analysis of existing as well as new product data, was conducted. Additionally, Merck Animal Health obtained the input of industry experts, business partners and customers about the product and its use. The totality of the comprehensive review supported that ZILMAX(zilpaterol hydrochloride) is safe when used according to the product label and in conjunction with sound animal husbandry practices.

Please see attached for updated ZILMAX label.

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Net Weight: 10 kg

For Veterinary Use Only

Zilmax[®]

Zilpaterol Hydrochloride

4.8% w/w

DIN 02324121

Medicated Premix

TO BE USED ONLY IN CATTLE WEIGHING AT LEAST 450 KG AND FED IN CONFINEMENT FOR SLAUGHTER

WARNINGS: Treated animals must not be slaughtered for use in food for at least four (4) days after the latest treatment with this drug. Do not use in lactating dairy cattle. Do not use in calves to be processed for veal. Not for use in humans. Keep out of reach of children.

HANDLER SAFETY WARNINGS: The active ingredient in Zilmax[®], is zilpaterol hydrochloride a beta₂-adrenergic agonist. Not for use in humans. Individuals with cardiovascular disease should exercise special caution to avoid exposure to this medicated feed. An anti-dust process has been applied in order to greatly reduce inhalation risk. Extended handling tasks with the potential for dust generation requires respiratory protection. Wear appropriate skin protection (e.g., impervious gloves, apron, overalls) if there is potential for extended skin contact. Wear protective eye wear, if there is a potential for eye contact. If accidental eye contact occurs, immediately rinse with water and consult a physician. Operators should wash thoroughly with soap and water after handling.

ACTIVE INGREDIENT: Contains zilpaterol hydrochloride, 48 grams per kilogram.

INDICATIONS: For increased carcass leanness, increased dressing percent, improved rate of body weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.

In clinical trials performed at various locations in North America, the following effects were demonstrated:

Carcass Effects	Effect of Zilpaterol ^a	
	Complete Feed 8.3 g/tonne (8.3 ppm)	Component Feed ^d 60 mg/head/day
Dressing Percentage, %	↑	↑
Hot Carcass Weight, (kg)	↑	↑
Ribeye Area, (cm ²)	↑	↑
Yield Grade	↓ ^b	↓ ^b
12th Rib Fat Thickness, (cm)	NC	NC
Marbling Score	NC when fed for 20 days ^c	↓

^a The effect of zilpaterol on parameters listed in this table is supported by data generated at the dose tested in the clinical efficacy trials. NC = No Change, ↑ = increased, ↓ = decreased

^b Reduction indicates an improvement in Yield Grade

^c Zilpaterol has been shown to decrease marbling score when fed for 40 days

^d A feed that provides a daily dose of active ingredient(s) in a portion of the daily ration, for example in the morning or evening feeding

DOSAGE AND ADMINISTRATION: For use in Manufactured Feeds Only. Do not feed undiluted. Zilmax[®] must be thoroughly mixed into feeds before use. Do not feed as top dressing.

A. MEDICATED COMPLETE FEEDS

The recommended inclusion rate in complete feed for cattle fed in confinement is 8.3 g zilpaterol hydrochloride per tonne (8.3 ppm) on a 100% dry matter basis. The amount of zilpaterol hydrochloride consumed daily by cattle fed in confinement for slaughter will depend upon the consumption rate of the medicated feed. Zilpaterol hydrochloride consumption will range between 60 and 90 mg per head per day based on the consumption rates. Examples are provided in the table below:

Cattle Weight (kg)	Average Feed Consumption ¹ /Head/Day, 100% Dry Matter (kg)	Zilpaterol Hydrochloride Consumed Daily by Each Animal (mg)
450	8.10	67.23
500	9.00	74.70
550	9.90	82.17
600	10.8	89.64

¹ assumes ad libitum intake

Mixing Directions: It is recommended that Zilmax[®] be diluted in a suitable carrier before addition to the final feed. A dilution of 1 part Zilmax and 9 parts carrier is the suggested working premix. No medicated feed should be manufactured with less than 8.3 grams zilpaterol hydrochloride/tonne on a 100% dry matter basis. Zilmax and working premix addition rates for complete feeds of varying dry matter are in the following table:

Complete Feed % Dry Matter	Zilpaterol Hydrochloride Level (g/tonne)	kg to Be Added Per Tonne of Feed	
		Zilmax [®]	1-9 Working Premix
60	5.0	0.104	1.04
70	5.8	0.121	1.21
80	6.7	0.140	1.40
90	7.5	0.156	1.56
100	8.3	0.173	1.73

Thoroughly mix both working premix and finished feed to ensure complete and uniform distribution of the Zilmax.

Feeding Directions: Complete feed containing zilpaterol hydrochloride at a rate of 8.3 g /tonne on a 100% dry matter basis must be fed continuously to cattle fed in confinement for slaughter for a period of not less than 20 consecutive days nor more than 40 consecutive days at the end of the feeding period.

B. MEDICATED COMPONENT FEED

Medicated component feeds are intended to deliver the recommended daily dose of 60 mg zilpaterol hydrochloride per head per day in one of multiple daily feedings, for example in the morning or evening feeding.

Mixing Directions:

Thoroughly mix Zilmax[®] into appropriate feed ingredients to make one tonne (1000 kg) of Working Premix. The following table gives examples of how the Working Premix can be prepared with Zilmax and how the Working Premix can be used to prepare Component Feeds ranging from 8.3 to 29.4 g/tonne (100% dry matter basis) to provide 60 mg zilpaterol hydrochloride per head per day.

Amount of Zilmax to be Added to 1000 kg of Feed Ingredients ¹	Zilpaterol Hydrochloride Concentration in Working Premix (g/tonne)	Amount of Working Premix to be Added to 1000 kg of Component Feed ¹	Zilpaterol Hydrochloride Concentration in Component Feed (g/tonne)	Component Feed Consumption (kg/head/day ¹)	mg Zilpaterol Hydrochloride/head/day
8.3 kg	400	20.75 kg	8.3	7.23 ²	60
8.3 kg	400	22.50 kg	9.0	6.67	60
16.67 kg	800	22.50 kg	18	3.33	60
16.67 kg	800	32.50 kg	26	2.31	60

¹Based on 100% dry matter basis

² A daily feeding must not exceed 7.23 kg

Feeding Directions:

Component feed containing no less than 8.3 g zilpaterol hydrochloride/tonne (100% dry matter basis) must be fed continuously in one daily feeding to cattle fed in confinement for slaughter, at an appropriate rate to provide 60 mg zilpaterol hydrochloride per head per day for a period of not less than 20 consecutive days nor more than 40 consecutive days at the end of the feeding period.

C. LIQUID SUPPLEMENTS INTENDED FOR ADDITION TO DRY FEEDS FOR CONFINEMENT CATTLE

- Liquid Supplements should be in a pH range of 3.8 to 7.5
- Liquid Supplements should be recirculated or agitated daily and prior to use for 10 to 20 minutes
- Liquid Supplements can be manufactured containing 83 to 830 g zilpaterol hydrochloride/tonne.

Before feeding, the medicated Liquid supplement must be thoroughly mixed with other feed materials to make a complete feed. Examples of addition rates to complete feeds are shown in the following table:

Zilpaterol Hydrochloride in Liquid	Addition Rate of Liquid Supplement to Complete Feed,	Zilpaterol Hydrochloride in Final Complete Feed,
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BAG FRONT PANEL (ENGLISH)

Supplements (g/tonne)	100% Dry Matter (kg/tonne)	100% Dry Matter (g/tonne)*
83	100	8.3
415	20	8.3
830	10	8.3

* The dry matter content of the complete feed will be reduced proportional to the amount of liquid supplement added to the feed.

CAUTIONS: Not for animals intended for breeding. Do not allow horses or other equines access to feed containing Zilmax[®]. Not to be fed to cattle in excess of 90 mg/head/day in complete feed. If pen consumption of complete feed exceeds 10.8 kg/head/day (100% dry matter basis), zilpaterol should not be fed in complete feed. Animals receiving Zilmax may exhibit an increased respiratory rate as well as elevated levels of creatine phosphokinase (CPK) and creatinine.

STORAGE : Store between 15 to 25°C.

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