Pulmotil® (tilmicosin) Veterinary Feed Directive (VFD) checklist for cattle

Pulmotil® is an innovative Bovine Respiratory Disease (BRD) treatment for groups of cattle in the early stages of a BRD outbreak that provides 14 days of sustained in-feed therapy, a practice that reduces stress associated with cattle handling.

Similar to the prescription requirement for injectable products, a veterinarian must issue an FDA-required Veterinary Feed Directive for Pulmotil. The VFD process requires a coordinated effort by the veterinarian, producer, feedmill and feed advisor. Here is a checklist to help you get started.

Preparation

- Ensure a Pulmotil use protocol is in place with the client
- Determine number of cattle to be included on the VFD
- Determine the average weight of the cattle when Pulmotil feeding will begin
- Determine the projected dry matter feed intake of the cattle during the Pulmotil feeding period
- Determine the specific feed supplier/distributor who will supply Pulmotil to the client

Completing the form

- Complete **Client and Veterinarian** information sections
- Fill in the **Cattle to be treated** (number and location) box
- Fill in the **Special Instructions** box
  - It is suggested that the Special Instructions include information such as:
    - Specific instructions you have for the client to use Pulmotil appropriately
    - Effective date of the VFD if different from the veterinarian's signature date
    - Pulmotil supplier for this VFD
- Complete the **Mix into Type C Medicated Feed to Provide** section **(100% DM Basis)**
  - Record the **total lbs of Type C complete feed and g/ton tilmicosin** level
    - Complete the additional line to adjust the amount of tilmicosin included in the Type C complete feed during the 14-day administration period based on projected changes in dry matter intake (DMI)
- Combination Approval
  - Intitial the box if you are approving tilmicosin on this VFD to be used in an approved combination
  - Indicate the approved drug, level or special instructions and initial
- Fill in **VFD Expiration Date**
  - The expiration date is 45 days from the signature date or the effective date if one is designated in the Special Instructions box. Whichever date is used is considered day zero.
- Fill in **Amount of final (Type C) feed**
  - This is the sum of the total pounds of Type C feed included in the **Mix into Type C Medicated Feed to Provide** section
- Sign the VFD form
  - Enter **date when the VFD is signed**
  - Enter **veterinarian license # and state**
    - A veterinarian must be licensed in the state where the cattle reside to complete a valid VFD
- Distribute the VFD form
  - Top white for supplier; canary for client; and pink for veterinarian
  - VFD forms can be hand delivered, mailed, faxed, or you can e-mail a scan of the completed VFD form
    - ***The original signed VFD (top white copy) must be received by the mill or distributor supplying the VFD feed to the client within five business days of sending a copy via fax or e-mailed scanned copy***
    - ***The mill or distributor cannot deliver Pulmotil medicated feed to the client until they have a copy (faxed, scanned e-mail or original) of the VFD for the client***
- Records
  - Retain your pink copy of the VFD for a period of two years
    - Client and Pulmotil feed supplier must also keep their copies of the VFD for two years

Pulmotil medicated feeds can only be delivered to distributors with a signed Acknowledgement of Distribution form on file or to a client's cattle with a valid VFD.

Pulmotil example guide for dry matter feed intake and grams/ton levels

Average Body Weight (BW), lbs	Dry Matter Intake (DMI), lbs					
100	1.50	1.60	1.70	1.80	1.90	2.00
150	2.25	2.40	2.55	2.70	2.85	3.00
200	3.00	3.20	3.40	3.60	3.80	4.00
250	3.75	4.00	4.25	4.50	4.75	5.00
300	4.50	4.80	5.10	5.40	5.70	6.00
350	5.25	5.60	5.95	6.30	6.65	7.00
400	6.00	6.40	6.80	7.20	7.60	8.00
450	6.75	7.20	7.65	8.10	8.55	9.00
500	7.50	8.00	8.50	9.00	9.50	10.00
550	8.25	8.80	9.35	9.90	10.45	11.00
600	9.00	9.60	10.20	10.80	11.40	12.00
650	9.75	10.40	11.05	11.70	12.35	13.00
700	10.50	11.20	11.90	12.60	13.30	14.00
750	11.25	12.00	12.75	13.50	14.25	15.00
800	12.00	12.80	13.60	14.40	15.20	16.00
850	12.75	13.60	14.45	15.30	16.15	17.00
900	13.50	14.40	15.30	16.20	17.10	18.00
950	14.25	15.20	16.15	17.10	18.05	19.00
1000	15.00	16.00	17.00	18.00	19.00	20.00
Pulmotil g/ton (100% DM Basis)	**757**	**710**	**668**	**631**	**598**	**568**

Pulmotil example calculations

The following calculations are based on Pulmotil's approved Type C dose range of 568 to 757 g/ton tilmicosin **(100% dry matter basis)** within the DMI range of 1.5 to 2% of body weight (BW).

Tilmicosin dose: 12.5 mg/kg of BW/hd/d = 5.68 mg/lb of BW/hd/d

Formulas:
BW x expected DMI as a % of BW = **DMI**
DMI x number of cattle x 14-day administration = **total lbs Type C complete feed**
[(BW x 5.68) ÷ DMI] x 2 = **g/ton tilmicosin in complete feed**

Example:
100 head of steers average BW 500 lbs, expected DMI 2% of BW

Expected DMI
500 lbs x 0.02 = 10 lbs/hd/d

Total lbs Type C complete feed
10 lbs/hd/d x 100 hd x 14 days = **14,000 total lbs Type C complete feed**

Tilmicosin g/ton level
[(500 lbs BW x 5.68 mg/lb BW/hd/d) ÷ 10 lbs DMI] x 2 = **568 g/ton tilmicosin in complete feed**

Pulmotil premix lbs/ton of complete feed (100% dry matter basis)

- Example using **Pulmotil 90***: (568 g/ton tilmicosin ÷ 90.7 g tilmicosin/lb) = 6.26 lbs Pulmotil 90/ton of complete feed
- Example using **Pulmotil 18**: (568 g/ton tilmicosin ÷ 18.1 g tilmicosin/lb) = 31.38 lbs Pulmotil 18/ton of complete feed

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

Feeds containing tilmicosin must be withdrawn 28 days prior to slaughter.

CAUTION: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.

For the control of Bovine Respiratory Disease (BRD) in groups of beef and non-lactating dairy cattle, where active BRD has been diagnosed in at least 10% of the animals in the group: Feed continuously for a single, 14-day period at 568 to 757 g/ton of tilmicosin (100% DM basis) in a Type C medicated feed as the sole ration to provide 12.5 mg/kg of body weight/hd/d.

*Inventory and use of Pulmotil 90 requires a Medicated Feed Mill License.

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Elanco™

Elanco Pulmotil®

Pulmotil® (tilmicosin) Veterinary Feed Directive for use in Cattle

Sequential VFD ID Number

Client: _____ Veterinarian: _____
Address: _____ Address: _____
_____ _____
_____ _____
Phone #: _____ Phone #: _____
Fax #: _____ Fax #: _____

Cattle to be treated (number and location):	**Special Instructions:**

Mix into Type C Medicated Feed to Provide:

_____total lbs Type C Complete feed at _____ g/ton
Type C complete feed range of 568 to 757 g/ton (100% Dry Matter Basis)

Complete this additional line to adjust the amount of tilmicosin included in Type C Complete feed during the 14 day administration period

_____total lbs Type C Complete feed at _____g/ton
Type C complete feed range of 568 to 757 g/ton (100% Dry Matter Basis)

VFD Expiration Date: _____
Month/Day/Year (not to exceed 45 days)

Amount of final (Type C) feed: _____

Veterinarian's signature: _____

Date:_____ License # and State _____

☐ Initial this box if you would like to use this VFD order to authorize the feeding of this tilmicosin medicated animal feed in an FDA approved combination of tilmicosin with other drug(s). If so, you are required to provide the information on the other drug(s) in such drug combination in the following table.

Drug (Ingredient)	**Drug Level or Any Special Instructions**	**Initial**

CAUTION: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. Extra-label use, (i.e., use of this VFD feed in a manner other than as provided for in the VFD drug approval) is strictly prohibited.

Active Drug Ingredient: tilmicosin (as tilmicosin phosphate) 90.7 g per lb (200 g per kg)
Inert ingredients: ground corncobs.

Description: Pulmotil is a formulation of the antibiotic tilmicosin. Tilmicosin is produced semi-synthetically and is in the macrolide class of antibiotics. Each kilogram of Type A Medicated Article contains 200 grams (0.44 lbs) of tilmicosin adsorbed onto ground corncobs.

Indications:
Cattle: For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in groups of beef and non-lactating dairy cattle, where active BRD has been diagnosed in at least 10% of the animals in the group.

Feeding Instructions:
Cattle (Complete Feed): This tilmicosin feed is to be fed continuously for a single, 14-day period at 568 grams to 757 grams (626 ppm to 834 ppm) per ton on a 100% dry matter basis of Type C medicated feed as the sole ration to provide 12.5 mg tilmicosin/kg/head/day.

IMPORTANT: Must be thoroughly mixed in feeds before use.

Mixing Instructions:
For incorporation into Cattle Feeds (Complete Feed): Thoroughly mix Pulmotil Type A medicated article with feed to provide a complete Type C medicated feed containing 568 to 757 grams tilmicosin per ton on a 100% dry matter basis. Complete Type C medicated feeds should not be pelleted.

Starting concentration of Pulmotil Type A Medicated Article	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type C Medicated Feed*
grams per pound	pounds	grams per ton
90.7	8.35	757
	6.26	568

*100% Dry Matter Basis

CAUTION:

Use only in cattle fed in confinement for slaughter.

Do not allow horses or other equines access to feeds containing tilmicosin. The safety of tilmicosin has not been established in cattle intended for breeding purposes.

To assure both food safety and responsible use in cattle, the treatment of cattle with this medicated feed is required to be initiated within the first 45 days of the production period. The treatment should not occur concurrent with or following administration of an injectable macrolide, or within 3 days following administration of a non-macrolide injectable BRD therapy

Tilmicosin medicated feed treatment has not been evaluated in cattle with severe clinical disease. Cattle with severe clinical illness should be evaluated for individual treatment with an alternative non-macrolide therapy.

Complete Type C medicated feeds containing tilmicosin should not be pelleted. Do not use in any feeds containing bentonite, cottonseed meal, or cottonseed hulls. Bentonite, cottonseed meal, or cottonseed hulls in feeds may affect the efficacy of tilmicosin.

The expiration date for a tilmicosin Veterinary Feed Directive (VFD) for cattle must not exceed 45 days from the time of issuance. VFDs for tilmicosin phosphate shall not be refilled.

WARNINGS:

RESIDUE WARNING: Cattle: Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product.

This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk.
This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves.

User Safety Warnings: Avoid inhalation, oral exposure, and direct contact with skin or eyes. Operators mixing and handling PULMOTIL 90 should use protective clothing, impervious gloves, goggles, and a NIOSH-approved dusk mask. Wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. If irritation persists, seek medical attention. Not for human consumption. Keep out of reach of children. The Material Safety Data Sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain a Material Safety Data Sheet, call 1-800-428-4441.

For technical service call: 1-800-428-4441
Store at less than or equal to 25°C (77°F). Excursions to 40°C (104°F) are acceptable. Avoid excessive moisture.
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