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 (VFD) 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.

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: 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/day.

Preparation

- Ensure a Pulmotil use protocol is in place with the client
- Determine approximate number of cattle to be included on the VFD
- Determine the average weight of the cattle when Pulmotil feeding will begin
- 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** (approximate 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
    - Additional information to identify the cattle that are covered in the VFD
    - Pulmotil supplier for this VFD
- Record the **Dosage**
  - Pulmotil in cattle should be included at a rate of 568 to 757 grams per ton
- Combination Approval
  - Indicate whether the VFD drug is (1) not intended to be used with a combination drug; (2) intended to be used with a specific combination (name approved combination); or (3) can be used with any FDA-approved combination
- Fill in **VFD Issuance Date**
  - The issuance date is the date that the veterinarian provides the VFD
- Fill in **VFD Expiration Date**
  - For Pulmotil, the expiration date is 45 days from the issuance date
  - Cattle must complete their 14-day therapy before the VFD expires; plan accordingly
- Sign the VFD form
- Distribute the VFD form
  - White copy for veterinarian; canary for client; and pink for distributor
  - VFD forms can be hand delivered, mailed or faxed; or you can e-mail a scan of the completed VFD form
    - ***The mill or distributor cannot deliver Pulmotil Type C medicated feed to the client until it has a copy (faxed or scanned e-mail) of the VFD for the client***
- Records
  - You are required to keep the VFD in its original format. The distributor and client copies may be kept as an electronic copy or hardcopy
  - Retain your white copy of the VFD for two years
  - Client and Pulmotil feed supplier must also keep their copies of the VFD for two years

Pulmotil Type A medicated feeds (Pulmotil 90) or Type B premixes (Pulmotil 18, 5.68) can be delivered only to distributors with a signed Acknowledgement of Distribution form on file or a Type C medicated feed to a client's cattle with a valid VFD. Distributors must also send a one-time notice to the FDA of intent to distribute VFD feeds.

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

IMPORTANT SAFETY INFORMATION

- CAUTION: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.
- Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment.
- To assure both food safety and responsible use, treatment must 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 inject able BRD therapy.
- VFD expiration date must not exceed 45 days from the time of issuance. VFDs shall not be refilled.
- Use only in cattle fed in confinement for slaughter.
- Cattle with severe clinical illness should be evaluated for individual treatment with an alternative non-macrolide therapy.
- Do not use in female dairy cattle 20 months of age or older or in veal calves.
- Safety has not been established for cattle intended for breeding.
- Do not allow horses or other equines access to feeds containing tilmicosin.
- Feeds containing tilmicosin must be withdrawn 28 days prior to slaughter.

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

Elanco Pulmotil®

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

Sequential VFD ID Number

Client: _____
Business or Home Address: _____
_____
Phone #: _____

Veterinarian: _____
Address: _____
_____
_____
Phone #: _____

Approximate number of cattle: _____ **Location of animals:** _____	**Special instructions and/or other animal identification (optional):**

Indication: 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.

Dosage: _____ g/ton (568 to 757g/ton)

Duration: 14 Days

Use of feed containing this Veterinary Feed Directive (VFD) drug in a manner other than as directed on the labeling (extra-label use) is not permitted.

Caution: 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.

Use only in cattle fed in confinement for slaughter. 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.

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.

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.

RESIDUE WARNING: 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.

Combination Feeding with Other Drugs (select one):

❑ This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.

❑ This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

_____ (list approved combination)

❑ This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

VFD Issuance Date: _____

VFD Expiration Date: _____
Month/Day/Year
(Not to exceed 45 days from issuance date)

Veterinarian's signature: _____

For technical service call: 1-800-428-4441

NADA 141 - 064, Approved by the FDA.

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

White Copy (Original) – Veterinarian **Canary Copy – Client** **Pink Copy – Distributor**