Tulathromycin is eliminated from the body primarily unchanged via biliary excretion. In animals, drug concentration tends to be the most powerful determinant of the duration of PAE. Of the two variables, concentration and exposure time, drug concentration tends to be the most powerful determinant of the duration of PAE. For skin infections, the PAE will increase to some maximal duration. Of the two variables, concentration and exposure time, drug concentration tends to be the most powerful determinant of the duration of PAE. For skin infections, the PAE will increase to some maximal duration. 

**INDICATIONS**

**Beef and Non-Lactating Dairy Cattle**

- BRD – Beef and non-lactating dairy cattle is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni, and Mycoplasma bovis and, for the control of respiratory disease in cattle at risk of developing BRD associated with Mycoplasma hyopneumoniae, Pasteurella multocida, Histophilus somni, and Mycoplasma haemolytica.

**Swine**

- IBK – Indicated for the treatment of a mixed respiratory disease syndrome (IBK) caused by Porphyromonas levii, Fusobacterium necrophorum, and Actinobacillus lignieresii. For the control of IBK associated with Porphyromonas levii, Fusobacterium necrophorum, and Actinobacillus lignieresii.

**Use in Livestock**

- Intramuscular injection can cause a transient local tissue reaction that may result in a local swelling and warmth. Although the relationship between these reactions and the characteristics of the administered effects has not been characterized, as a class, macrocyclic lactones tend to be primarily cutaneous, but may be occasionally systemic. This is partially related to the rate of bacterial deactivation. When intramuscular injection is used to control an ongoing infection, the rate of bacterial deactivation does not play a significant role.

**CAUTION:**

- Beef and non-lactating dairy cattle

  **WARNINGS**

- **Residue Warnings**

  - Swine: Safety studies were conducted in pigs receiving a single oral dose of 25 mg/kg BW or 75 mg/kg BW of oral solution. Sixty-seven percent of these pigs were cured or showed clinical improvement and negative gross and histological lung findings. In both studies, the treatment success percentage for pigs treated with 25 mg/kg BW was statistically significantly higher than those treated with saline solution. In both studies, the treatment success percentage for pigs treated with 25 mg/kg BW was statistically significantly higher than those treated with saline solution.

- **Animal Safety**

  - Swine: Safety studies were conducted in calves receiving a single subcutaneous dose of 25 mg/kg BW or 75 mg/kg BW of oral solution. Sixty-seven percent of these pigs were cured or showed clinical improvement and negative gross and histological lung findings. In both studies, the treatment success percentage for pigs treated with 25 mg/kg BW was statistically significantly higher than those treated with saline solution. In both studies, the treatment success percentage for pigs treated with 25 mg/kg BW was statistically significantly higher than those treated with saline solution.

- **Effects of Food on Drug Utilization**

  - BRD – Drug levels were undetermined in BRD after the first treatment but were undetermined in BRD after the second treatment. There were no BRD-related deaths in the BRD-treated group compared with the saline-treated group. The cure rate was significantly higher (P < 0.05) in the DRAXXIN-treated calves compared with saline-treated calves. Additionally, time to treatment success was significantly prolonged for calves treated with saline compared with those treated with DRAXXIN.

- **Safety**

  - **Residue Warnings**

    - Draxxin Injectable Solution is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni, and Mycoplasma haemolytica. **WARNINGS**

      - Swine

        - **Residue Warnings**

          - Safety studies were conducted in pigs receiving a single oral dose of 25 mg/kg BW or 75 mg/kg BW of oral solution. Sixty-seven percent of these pigs were cured or showed clinical improvement and negative gross and histological lung findings. In both studies, the treatment success percentage for pigs treated with 25 mg/kg BW was statistically significantly higher than those treated with saline solution. In both studies, the treatment success percentage for pigs treated with 25 mg/kg BW was statistically significantly higher than those treated with saline solution.

- **Anesthetic Considerations**

  - The use of DRAXXIN Injectable Solution is contraindicated in animals previously branded to be treated with such solutions.

  - **WARNINGS**

    - USE IN LIVESTOCK ONLY

      - NEGLIGEABLE FOR HUMAN USE

    - USE FOR USE ON COWS OR BULLS

      - RESTRICTED USE IN CATTLE

    - Swine

      - Intended for human consumption must not be slaughtered within 16 days from the last treatment. Do not use on dairy calves 30 days or younger or with an estrus cycle.

    - Swine

      - Intended for human consumption must not be slaughtered within 16 days from the last treatment.

  - **PRECAUTIONS**

    - Cattle

      - The use of DRAXXIN Injectable Solution in bovine respiratory reactivity, performance, and lactation and have not been determined. Subclinical infection can cause a transient local tissue reaction that may result in a local swelling and warmth. Although the relationship between these reactions and the characteristics of the administered effects has not been characterized, as a class, macrocyclic lactones tend to be primarily cutaneous, but may be occasionally systemic. This is partially related to the rate of bacterial deactivation. When intramuscular injection is used to control an ongoing infection, the rate of bacterial deactivation does not play a significant role.

    - Swine

      - The use of DRAXXIN Injectable Solution in bovine respiratory reactivity, performance, and lactation and have not been determined. Subclinical infection can cause a transient local tissue reaction that may result in a local swelling and warmth. Although the relationship between these reactions and the characteristics of the administered effects has not been characterized, as a class, macrocyclic lactones tend to be primarily cutaneous, but may be occasionally systemic. This is partially related to the rate of bacterial deactivation. When intramuscular injection is used to control an ongoing infection, the rate of bacterial deactivation does not play a significant role.