The chemical names of the isomers are (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-\[\beta\text{-diamino}] of DRAXXIN contains 100 mg of tulathromycin as the free base in a 50% propylene glycol/Water (40:1) mixture. Each mL of DRAXXIN Injectable Solution contains 100 mg of tulathromycin/mL. The free base has a base pair melting point of 167 °C. Its phosphate salt has a base pair melting point of 168 °C. It is soluble in chloroform. Its solubility at 25 °C is 1 mg/mL in water and 10 mg/mL in dimethyl sulfoxide. The solubility of the salt is 1 mg/mL in water and 10 mg/mL in dimethyl sulfoxide.

Beef and Non-lactating Dairy Cattle

For subcutaneous injection in beef and non-lactating dairy cattle and swine:

**INDICATIONS**

For the treatment of respiratory disease associated with:

- Mannheimia haemolytica
- Pasteurella multocida
- Histophilus somni
- Mycoplasma bovis

**CONTRAINDICATIONS**

The use of DRAXXIN Injectable Solution is contraindicated in animals previously known to be hypersensitive to the drug.

**WARNINGS FOR USE IN ANIMALS ONLY. NOT FOR USE IN HUMANS.**

**KEEP OUT OF REACH OF CHILDREN.**

No known USE IN CHICKENS OR TURKEYS.

**RESIDUE WARNINGS**

Cattle

- No specific data are available for human consumption. However, it is recommended that no drug be administered to cattle during the last 14 days before slaughter as a precautionary measure.

Swine

- No specific data are available for human consumption. However, it is recommended that no drug be administered to swine during the last 14 days before slaughter as a precautionary measure.

**PRECAUTIONS**

**Cattle**

The effects of DRAXXIN on bovine reproductive performance, pregnancy, and lactation, have not been determined. Subcutaneous injection can cause a transient local tissue reaction that may result in thinning of subcutaneous tissue at the injection site.

Swine

The effects of DRAXXIN on porcine reproductive performance, pregnancy, and lactation, have not been determined. Intramuscular injection can cause a transient local tissue reaction that may result in thinning of subcutaneous tissue at the injection site.

**ADVERSE REACTIONS**

**Cattle**

In one field study, two calves treated with DRAXXIN at 2.5 mg/kg BW exhibited transient hypoesthesia. One of these calves also exhibited transient dyspnea, which may have been related to pulmonary edema.

**Swine**

In one field study, one out of 40 pigs treated with DRAXXIN at 2.5 mg/kg BW exhibited mild clinical signs within 24 hours of treatment. Clinical signs resolved in less than four hours.

**CLINICAL PHARMACOLOGY**

At physiological pH, tulathromycin is a weak base (pKa is approximately 6.5) and is therefore unionized and not ionized in blood and the tissues. It is transported across species and animal barriers. Tulathromycin is present in the plasma primarily as the unionized form, and its active concentration is higher in the plasma than in the tissues. It is bound to plasma proteins (1-2%) and is only partially metabolized in the liver. It is then eliminated by the kidneys. Tulathromycin is not metabolized in the body and is only slightly adsorbed. Tulathromycin is stable in blood and plasma for up to 24 hours at room temperature.

**CONTRAINDICATIONS**

The use of DRAXXIN Injectable Solution is contraindicated in animals previously known to be allergic to the drug.

**WARNINGS FOR USE IN ANIMALS ONLY. NOT FOR USE IN HUMANS.**

**KEEP OUT OF REACH OF CHILDREN.**

No known USE IN CHICKENS OR TURKEYS.

**RESIDUE WARNINGS**

Cattle

The treatment of bovine respiratory disease (BRD) associated with Pasteurella multocida, Histophilus somni, and Mycoplasma bovis and for the control of respiratory disease in cattle at high risk of developing respiratory disease associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni, and Mycoplasma bovis.

**INDICATIONS**

Beef and Non-lactating Dairy Cattle

**DOSAGE AND ADMINISTRATION**

**Cattle**

- The drug is administered as a single dose in the neck at a dosage of 2.5 mg/kg BW. The drug is not injected more than 25 mL per injection site.

**Swine**

- The drug is administered as a single dose in the neck at a dosage of 2.5 mg/kg BW. The drug is not injected more than 25 mL per injection site.

**Swine**

**Contraindications**

The use of DRAXXIN Injectable Solution is contraindicated in animals previously known to be allergic to the drug.

**WARNINGS FOR USE IN ANIMALS ONLY. NOT FOR USE IN HUMANS.**

**KEEP OUT OF REACH OF CHILDREN.**

No known USE IN CHICKENS OR TURKEYS.

**RESIDUE WARNINGS**

Cattle

- No specific data are available for human consumption. However, it is recommended that no drug be administered to cattle during the last 14 days before slaughter as a precautionary measure.

Swine

- No specific data are available for human consumption. However, it is recommended that no drug be administered to swine during the last 14 days before slaughter as a precautionary measure.

**PRECAUTIONS**

**Cattle**

The effects of DRAXXIN on bovine reproductive performance, pregnancy, and lactation, have not been determined. Subcutaneous injection can cause a transient local tissue reaction that may result in thinning of subcutaneous tissue at the injection site.

Swine

The effects of DRAXXIN on porcine reproductive performance, pregnancy, and lactation, have not been determined. Intramuscular injection can cause a transient local tissue reaction that may result in thinning of subcutaneous tissue at the injection site.

**ADVERSE REACTIONS**

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**CLINICAL PHARMACOLOGY**

At physiological pH, tulathromycin is a weak base (pKa is approximately 6.5) and is therefore unionized and not ionized in blood and the tissues. It is transported across species and animal barriers. Tulathromycin is present in the plasma primarily as the unionized form, and its active concentration is higher in the plasma than in the tissues. It is bound to plasma proteins (1-2%) and is only partially metabolized in the liver. It is then eliminated by the kidneys. Tulathromycin is not metabolized in the body and is only slightly adsorbed. Tulathromycin is stable in blood and plasma for up to 24 hours at room temperature.

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