

MULTIMIN[®] 90

(zinc, copper, manganese, and selenium injection)

A sterile solution for subcutaneous injection containing 60 mg/mL zinc, 15 mg/mL copper, 10 mg/mL manganese, and 5 mg/mL selenium.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

An injectable blue aqueous sterile solution for subcutaneous injection.

Active Ingredients:

Zinc	60 mg/mL (as zinc oxide)
Copper	15 mg/mL (as copper carbonate)
Manganese	10 mg/mL (as manganese carbonate)
Selenium	5 mg/mL (as sodium selenite)

Inactive Ingredients:

Edetic acid	399.74 mg/mL
Sodium hydroxide	106.9 mg/mL
Benzyl alcohol	10.4 mg/mL (as preservative)

INDICATIONS FOR USE

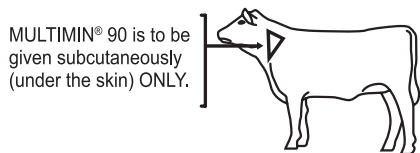
To provide a supplemental source of zinc, copper, manganese, and selenium in cattle. Not for use in pregnant cows and heifers during their first trimester because reproductive safety testing has not been done in these animals. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety has not been established.

DOSAGE AND ADMINISTRATION

Determine accurate body weights prior to treatment. Administer subcutaneously under the loose skin of the middle of the side of the neck per the following dosages depending on age and bodyweight of the cattle:

Cattle up to 1 year, 1 mL/100 lb bodyweight
Cattle from 1-2 years, 1 mL/150 lb bodyweight
Cattle over 2 years, 1 mL/200 lb bodyweight

To be administered as a single dose.



The maximum volume per injection site is 7 mL. Use standard aseptic procedures during administration to reduce the risk of injection site abscesses or lesions. Ensure there are at least 4 inches between injection sites for MULTIMIN[®] 90 and other injection sites.

MULTIMIN[®] 90 is intended as a single dose product. Allow a minimum of 30 days before considering repeat dosing. Additional zinc, copper, manganese, or selenium products should not be administered at the same time.

Use within 28 days of first puncture of the vial and puncture a maximum of 15 times. If more than 15 punctures

are anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16 gauge, discard any product remaining in the vial immediately after use.

CONTRAINDICATIONS

Do not use MULTIMIN[®] 90 concurrently with other injectable selenium and copper products.

Do not use MULTIMIN[®] 90 concurrently with selenium or copper boluses.

WARNINGS AND PRECAUTIONS

Withdrawal Periods and Residue Warnings

Cattle must not be slaughtered for human consumption within 14 days of the last treatment. No milk discard time is required when used according to labeling. A withdrawal period has not been established in pre-ruminating calves.

User Safety Warnings

Not for use in humans. Keep out of reach of children. Do not allow children access to used or empty syringes. Wash hands after use.

This product is highly concentrated in zinc, copper, manganese, and selenium. Due to a potential risk of zinc, copper, manganese, and selenium toxicity, care should be taken when handling the product to avoid accidental self-injection. Symptoms of exposure to zinc, copper, manganese, and selenium include aches, chills, nausea, vomiting, diarrhea, tachycardia, epigastric pain, tremors, and irritability.

In case of accidental self-injection or ingestion, SEEK IMMEDIATE MEDICAL ATTENTION and take the vial with you.

To obtain a Safety Data Sheet, contact Multimin North America, Inc. at +1-877-907-5315.

Animal Safety Warnings and Precautions

Selenium and copper are toxic if administered in excess. MULTIMIN[®] 90 may cause clinical signs associated with copper toxicity or selenium toxicity, including death, if overdosed or used in conjunction with excessive dietary levels of copper and selenium or other selenium or copper products. Additional zinc, copper, manganese, or selenium products should not be administered at the same time. Do not use concurrently with other injectable selenium and copper products. Do not use concurrently with selenium or copper boluses.

MULTIMIN[®] 90 may cause injection site swelling that appears on the day of injection and resolves by 2 days later. MULTIMIN[®] 90 may cause induration at the injection site that appears the day of injection and may persist for at least 14 days post-injection. These reactions may result in trim loss of edible tissue at slaughter.

Do not use in cases of known hypersensitivity to the active ingredients or to any of the excipients. Do not use in emaciated cattle with a body condition score of 1 on a 5-point scale in dairy or 1-3 on a 9-point scale in beef.

Do not use during the first trimester of pregnancy because safety has not been evaluated. Do not use in pre-ruminant calves because safety has not been evaluated.

ADVERSE REACTIONS

Accidental overdose of copper or selenium through misdosing or the use of multiple sources, including the use of injectable products in addition to high dietary levels, can result in adverse events, including death, depression, weakness, ataxia, salivation, and drooling.

CONTACT INFORMATION

Contact Multimin North America, Inc. at +1-877-907-5315 or <http://www.axiota.com>. To report suspected adverse drug experiences, contact Multimin North America, Inc. at +1-877-907-5315. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS (1-888-332-8387) or <http://www.fda.gov/reportanimalae>

CLINICAL PHARMACOLOGY

As essential minerals, zinc, copper, manganese, and selenium, contribute to homeostasis by participating as cofactors of a wide range of enzymes in multiple biochemical processes in the body. In a laboratory margin of safety study in 32 growing cattle less than 1 year of age, after daily subcutaneous administration of MULTIMIN[®] 90 (zinc, copper, manganese, and selenium injection) for 3 days (see Target Animal Safety section), a dose-related increase in plasma concentrations of zinc, copper, manganese, and selenium was observed for treated animals when compared with untreated controls.

TARGET ANIMAL SAFETY

MULTIMIN[®] 90 or saline was injected subcutaneously over 3 consecutive days to 32 English and/or Continental pure or mixed beef breed cattle (16 non-pregnant females and 16 intact males, 4 animals per sex per treatment group) ranging in weight from 289-387 kg and less than 10 months of age. Treatment groups were 1x [1 mL MULTIMIN[®] 90/100 lb (45 kg) body weight (BW)], 3x [3 mL MULTIMIN[®] 90/100 lb (45 kg) BW], 5x [5 mL MULTIMIN[®] 90/100 lb (45 kg) BW], or control group [5 mL saline/100 lb (45 kg) BW]. All animals were euthanized and necropsied 1 to 2 days after the last treatment. The only treatment-associated findings from the 1x dose group included injection site swelling and a minor, clinically insignificant, dose and time dependent decrease in cholesterol. The treatment-associated findings from the 3x dose group were injection site swelling, a decrease in feed consumption, and a decrease in cholesterol. In the 5x dose group, treatment-associated findings included injection site swelling, a decrease in feed consumption, a decrease in cholesterol, an increase in creatinine kinase, a decrease in calcium, and signs of acute copper toxicity (2 out of 8 animals), including sudden death, depression, weakness, ataxia, salivation, and drooling. Animals in the 5x dose group also had hepatic centrilobular necrosis on necropsy and an increase in serum chemistries associated with liver damage.

Sixteen animals were each injected with MULTIMIN[®] 90 and saline subcutaneously on opposite sides of the neck. Eleven animals were administered 1 mL/50 kg body weight and the other 5 animals received the maximum dose per injection site of 7 mL. Injection of MULTIMIN[®] 90 resulted in pain upon injection (1 of 16 animals); injection site swelling that appeared on the day of injection and resolved 2 days later; and induration that appeared on the day of injection and persisted for at least 14 days. Subcutaneous injection of MULTIMIN[®] 90 in cattle can cause a local tissue reaction. These reactions may result in trim loss of edible tissue at slaughter.

EFFECTIVENESS

To provide a supplemental source of zinc, copper, manganese, and selenium was demonstrated in a single multisite study. A total of 90 Holstein replacement dairy heifers, approximately 9 months of age, were administered either a single subcutaneous injection of MULTIMIN[®] 90 or saline at a dose of 1 mL/100 lb (45 kg) BW on Day 0. Blood samples were obtained for plasma zinc, copper, manganese, and selenium analysis within 1 to 2 hours prior to dosing, and 0.5 hours (\pm 10 minutes), 1 hour (\pm 10 minutes), 3 hours (\pm 15 minutes), 6 hours (\pm 15 minutes), and 8 hours (\pm 15 minutes) post-treatment. Treatment was considered successful if the partial area under the plasma concentration curve from dosing to 8 hours (AUC_{0-8}) of zinc, copper, manganese, and selenium was significantly different and higher in the MULTIMIN[®] 90 treated group versus the saline treated group. For all four minerals the AUC_{0-8} was different and higher in the MULTIMIN[®] 90 treated group versus the saline treated group. The mean AUC_{0-8} for zinc plasma concentration was significantly different and higher (P-value=0.0031) in the MULTIMIN[®] 90 treated group (16.36 hour*mg/L) compared to the saline treated group (7.74 hour*mg/L). The mean AUC_{0-8} for copper plasma concentration was significantly different and higher (P-value=0.0041) in the MULTIMIN[®] 90 treated group (8.34 hour*mg/L) compared to the saline treated group (7.05 hour*mg/L). The mean AUC_{0-8} for manganese plasma concentration was significantly different and higher (P-value=0.0023) in the MULTIMIN[®] 90 treated group (253.79 hour* μ g/L) compared to the saline treated group (10.89 hour* μ g/L). The mean AUC_{0-8} for selenium plasma concentration was significantly different and higher (P-value=0.0042) in the MULTIMIN[®] 90 treated group (2734.03 hour* μ g/L) compared to the saline treated group (790.25 hour* μ g/L).

HOW SUPPLIED

MULTIMIN[®] 90 is available in the following package sizes:
100 mL vial
500 mL vial

NDC# 49920-006-01
NDC# 49920-006-05

STORAGE, HANDLING, AND DISPOSAL

Store between 15°C and 30°C (59°F and 86°F).

Approved by FDA under NADA # 141-582

NAME AND PLACE OF BUSINESS

Manufactured for: Multimin North America, Inc.,
1300 Kaw Valley Rd, Suite A, Wamego, KS 66547

U.S. Patent: www.axiota.com/patent

Made in Ireland

REVISION DATE
April 2026

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