

List of statistically different non-neoplastic effects (increased compared with controls, unless indicated; p < 0.05):

Males (1.3 mg/kg):

- Chronic sialadenitis (salivary gland)
- Perivascular mono. infil. (lung)^a
- Interstitial pneumonia (lung)^a
- Hemosiderosis (spleen)^a

Males (14.2 mg/kg):

- Cystoid degeneration (liver)
- Megalocytosis (liver)
- Portal mononuclear cell infiltration (liver)
- Alveolar macrophages (lung)
- Hemorrhage (lung)
- Vascular mineralization (testis/epididymis)
- Chronic sialadenitis (salivary gland)
- Perivascular mono. infil. (lung)^a

Females (1.6 mg/kg):

- Vascular mineralization (lung)
- Tubular hyperplasia (ovary)
- Chronic myocarditis^a
- Perivascular mono. infil. (lung)^a
- Hemosiderosis (spleen)^a

Females (16.1 mg/kg):

- Megalocytosis (liver)
- Tubular hyperplasia (ovary)
- Hemosiderosis (spleen)^a

^aDecreased incidence relative to controls

Genetic toxicity studies (study type and results):

None

Remarks:

-Dose-related decreased in mean body weights in excess of 10% was observed in high-dose males and females.

-Mean feed consumption (as grams diet/kg bw) was increased in all of the FC-143 treated males throughout the study when compared to male control feed consumption. Overall, the variations were related to the variation in body weight among groups. Actual mean feed consumption was decreased in high-dose males relative to controls for the first year of the study.

-Dose-related occurrence of ataxia in females was the only clinical sign observed.

-A statistically significant (p<0.05) decrease in red blood cell parameters was noted in the high-dose males as compared to the controls.

-A statistically significant (p<0.05) increase in relative liver and kidney weights was found in high-dose males and an increase in relative kidney weights was found in high-dose females.