

Expert.ai Life Sciences & Pharmaceutical Solutions

In a 14 day repeat dose oral toxicity study, CAB (sodium salt) was administered to CD-1 mice (10 / sex /group) at doses of 0 (control), 10, 75 and 1000 mg/kg/day [Report RD2009/00692, m4.2.3.2]. CAB was formulated with 0.5% HPMC and 0.1% Tween 80. Parameters that were evaluated during the study were clinical observations, toxicokinetics, body weights, food consumption, hematology and clinical chemistry, ophthalmoscopic observations, organ weights, macroscopic observations and microscopic pathology (including stage dependent evaluation of spermatogenesis). A tabulated summary of this study is presented in m2.6.7, Table 6.2.

The systemic exposure (plasma Cmax and AUC0-24 values) of CAB increased less than proportionally with the increase in dose in each sex on both Days 1 and 14. Although the systemic exposure was slightly higher (about 10% to 70%) on Day 14 compared to Day 1, there were no marked differences in exposure. There were no gender differences in systemic exposure.

Minimal to moderate increases in serum enzymes alanine aminotransferase (ALT), glutamate dehydrogenase (GLDH), and aspartate aminotransferase (AST) were noted in one male and female mouse each given 1000 mg/kg/day. No hepatic histological correlates were observed in the male, and it could not be determined if the minimal hepatocellular necrosis in the female was responsible for the minimal to mild elevated serum enzymes, as a control male had comparable hepatocellular necrosis, but with no enzyme elevations. Although likely test article-related, a definitive relationship could not be established because there were no histologic correlates or similar changes in other mice. These findings were considered non-adverse.

Other clinical or anatomic pathology changes were within the range of biological variation and were not considered related to treatment with CAB. There were no changes considered related to CAB administration in the stage-dependent evaluation of spermatogenesis.

The NOAEL was 1000 mg/kg/day (mean AUC0-24 2587 µg.h/mL; mean Cmax 142 µg/mL (gender-averaged based on Day 14 values)).

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In a 14 day repeat dose oral toxicity study, CAB (sodium salt) was administered to CD-1 mice (5 / sex /group) at doses of 0 (control), 10, 75 and 100 mg/kg/day [Report RD2009/00692, m4.2.3.2]. CAB was formulated with 0.5% HPMC and 0.1% Tween 80. Parameters that were evaluated during the study were clinical observations, toxicokinetics, body weights, food consumption, hematology and clinical chemistry, ophthalmoscopic observations, organ weights, macroscopic observations and microscopic pathology (including stage dependent evaluation of spermatogenesis). A tabulated summary of this study is presented in m2.6.7, Table 6.2.

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The NOAEL was 1000 mg/kg/dose (mean AUC0-24 2,586.5 µg.h/mL; mean Cmax 142 µg/mL (gender-averaged based on Day 14 values)).

Having timely access to relevant data accelerates decision making, reduces regulatory review cycles and helps bring better medical treatments to market faster.

Leveraging artificial intelligence helps biomedical researchers monitor trends, discover new drugs and track key experts as they collaborate using the most current knowledge about diagnosis, treatment and prevention.

During analysis, research teams must be able to distill the most accurate, up-to-date information by disambiguating across mountains of content from diverse sources that may be repetitive, dated or worse, false. This is especially important considering the escalating costs of failed AI projects that overpromise, underdeliver and end up distracting rather than empowering, research teams.

Expert.ai's Life Science and Pharmaceutical solutions provides medical, research, regulatory and knowledge management teams with the highest quality, standards-based and most consistent Life Sciences Knowledge Model available.



Leading global research teams rely on expert.ai to:

- Automatically extract connections between biomedical entities in literature for in-depth causality analysis to support researchers.
- Monitor clinical trials and social media sources filtered by any combination of indication, drug, mechanism of action, sponsor or geography to gain insight for clinical trials.
- Accelerate the quality control process of preclinical reports prior to their submission to regulatory bodies.
- Identify experts and influencers beyond your network so you can drive therapeutic awareness with both established leaders and rising stars.
- Scan the latest scientific and biopharma news on drug approvals, trials, conferences and more to ensure users get instant updates for their topics of interest.
- Analyze safety signals on adverse events in medical cases and comparisons with known side effects as reported to regulatory authorities.

Key Capabilities:

- Extract scientific data and related concepts based on technical language understanding that is explainable and easily fine-tuned by subject matter experts.
- Customizable solutions and endpoints designed for specific roles (i.e., Regulatory Review with comparative analytics to identify conflicts and inconsistencies that would likely result in FDA rejection).
- Scalable to support multiple publication sources, multiple disease areas and multiple types of medical data sources (i.e., regulatory reports, EHR medical notes, etc.).
- Bring complex and hidden relationships between biomedical entities to light, thanks to deep semantic enrichment.
- Stay up to date with the latest information through continuous review and data mining of biomedical content from Medline Publications, Clinical Trials, NIH-funded research, U.S. Patents, world news, social media and more.
- Visualize key relationships, launch dates, timeline information and other data with executive summaries, bulls-eye charts and other graphics in real time to support decision making.
- Customizable, fine-tunable and reusable knowledge models to meet specific business needs.

