

TDM

Therapeutic Drug
Monitoring

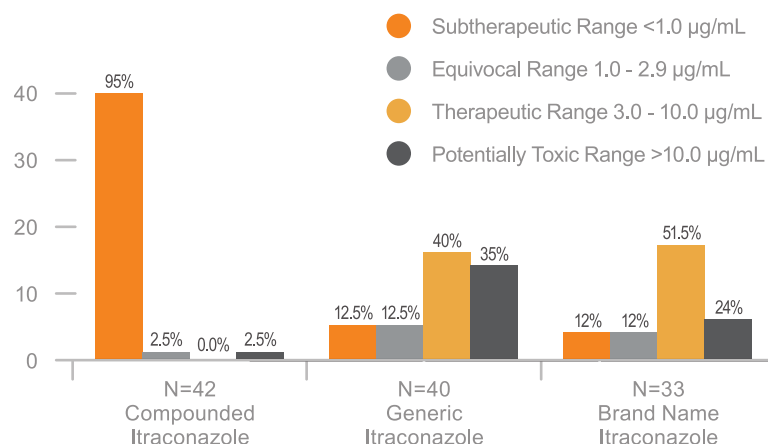
Clinical Recommendations for Animals Receiving Itraconazole Treatment for Serious Fungal Infections

Veterinary Itraconazole Bioassay by MiraVista Diagnostics

Avoid Itraconazole Compounded from Bulk Powder:

A recent clinical study performed at MiraVista Diagnostics (published in JAAHA) revealed that 95% of dogs and cats receiving itraconazole compounded from bulk powder had a subtherapeutic blood concentration of itraconazole.

Generic pelletized itraconazole (both FDA approved and non-FDA approved) produced similar blood concentration levels in dogs and cats as compared to brand name itraconazole (Sporanox by Janssen Pharmaceuticals) capsules or oral solution. Some animals in the generic and the brand name groups demonstrated subtherapeutic levels or potentially toxic levels.



ISSUES WITH COMPOUNDED ITRACONAZOLE

- Low Solubility
- Questionable Stability
- Low Blood Levels in Patients

Leverage Itraconazole Bioassays to Achieve Therapeutic Levels and Mitigate Common Risks Associated with Antifungal Drug Treatment

SUBTHERAPEUTIC CONCENTRATIONS

- 95% subtherapeutic with compounded itraconazole
- 12.5% subtherapeutic with generic itraconazole
- 12.1% subtherapeutic with brand name itraconazole

POTENTIALLY TOXIC BLOOD LEVELS

- 35% toxic levels with generic itraconazole
- 24% toxic levels with brand name itraconazole

INAPPROPRIATE DOSING & DURATION

- Subtherapeutic levels can extend treatment time & necessitate repeat treatment
- Dosage, duration & frequency impact treatment costs

REFERENCES

(1) J.S. Renschler, A.J. Albers, H.R. Sinclair-Mackling and L.J. Wheat. 2015. Comparison of compounded, generic and innovator-formulated itraconazole in dogs and cats. J Am Anim Hosp Assoc 2018; 54(4): 195-200.

(2) J.A. Smith, M.G. Papich, G. Russell and M.A. Mitchell. Effects of compounding on pharmacokinetics of itraconazole in black-footed penguins (Spheniscus demersus). J Zoo Wildlife Med 2010; 41(3): 487-495.

Antifungal Therapeutic Drug Monitoring Improves Veterinary Itraconazole Treatment Outcomes

Confirm
THERAPEUTIC LEVELS

Lower
TREATMENT COST



Limit
TREATMENT TIME

Improve
DOSE ACCURACY

VETERINARY ITRACONAZOLE BIOASSAY by MiraVista Diagnostics

TEST CODE: 312

METHODOLOGY: Bioassay

TURNAROUND: Testing is performed on Wednesdays. Results are released the next morning.

LIMITATIONS: Results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

- The bioassay is not accurate if the patient has taken another antifungal agent concurrently or within the prior week.
- Concentration determined on a single specimen may not reflect future concentrations because of changes in adherence, drug dosage, route of administration, absorption, or receipt of other medication affecting absorption or metabolism of the azole.
- Follow-up testing may be necessary if there are changes in treatment, including starting or stopping interacting medications, or suspicion of treatment failure.
- Drug levels should be measured after treatment, of at least 2 weeks in dogs and 3 weeks in cats, to reach a steady state.

INTERPRETIVE INFORMATION:

- **None Detected:** Reported when there is no zone of inhibition.
- **<0.3 µg/mL:** Reported when the zone of inhibition is smaller than that of the lowest calibrator.
- **Positive:** 0.3 - 20.0 µg/ml
- **>20.0 µg/mL:** Reported when the zone of inhibition is greater than the highest calibrator.

CLINICAL SIGNIFICANCE: Monitors blood itraconazole concentrations in animals during antifungal drug treatment to determine therapeutic levels.

SPECIMEN REQUIREMENTS: Serum or Plasma ONLY. Any other type of specimen will be rejected.

SPECIMEN MINIMUM: 0.25 ml Serum/ Plasma

COLLECTION INSTRUCTIONS: Refrigerated/Frozen

- Preferable to collect blood sample at trough time.
- **SERUM:** Collect serum specimens in serum separator or red top tube. Allow blood to clot for 30 minutes, then centrifuge. Pipette serum into a plastic screw cap vial.
- **PLASMA:** Collect plasma specimens in an EDTA or heparin tube. Centrifuge for 15 minutes and pipette plasma into a screw cap vial.

SPECIMEN STABILITY: 7 Days

Room Temperature/Refrigerated/Frozen

TRANSPORT TEMPERATURE: Refrigerated/Frozen

SHIPPING INSTRUCTIONS: Ship refrigerated/frozen specimen on dry ice or frozen cool pack for Next Day Delivery Monday - Friday.