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Treatment of Blastomycosis in Dogs and Cats

Summary

1. Generic FDA approved itraconazole is the treatment of choice, 5 mg/kg twice daily for 3 days and then once daily (do not combine with terbinafine, unnecessary). See dosing for cats, differs from dogs.
2. Itraconazole should be administered with food.
3. Serum should be obtained for trough (just before dosage) itraconazole blood levels 2 weeks after starting treatment (do not combine with terbinafine-falsely elevated itraconazole levels in bioassay).
4. Itraconazole dosage should be adjusted to achieve trough levels of 2-7 mcg/mL.
5. Treatment could be stopped if (a) at least 6 months treatment, (b) clinical findings resolved, (c) imaging abnormalities resolved, (d) antigen levels urine are negative (or serum if they are higher than urine).
6. If criteria for stopping treatment or not met continue treatment for another 3 months and reassess criteria for stopping treatment.
7. Antigen levels in urine (or serum if they are higher than urine) should be tested at 6 and 12 months after stopping or if suspect relapse.
8. Hepatic enzymes and bilirubin should be measured at baseline, periodically during treatment and if hepatotoxicity is suspected.
9. Obtain consultation if these criteria have not been met by 12 months or you have other questions.

Introduction. Several studies have evaluated fluconazole and itraconazole for treatment of blastomycosis in dogs and humans, but none have determined the best treatment or duration of treatment. Only two studies in dogs were prospective (Table 1). The itraconazole study evaluated 107 dogs that were treated for only two months and many of the dogs were severely ill, dying during the first week of treatment [1]. Among survivors, 39% relapsed. The prospective fluconazole study evaluated 21 dogs [2]. They were not severely ill and there were no deaths. However, 26% relapsed. In a retrospective study comparing itraconazole and fluconazole, 25% of dogs in the fluconazole group died within the first 2 weeks compared to 10% in the itraconazole group [3].

Treatment. FDA approved itraconazole is recommended for treatment of blastomycosis in dogs and humans [4,5]. Generic FDA approved itraconazole is less expensive than Sporanox® and achieves similar concentrations in the blood [6,7]. Itraconazole capsules should be administered with food to achieve maximum blood levels. Compounded itraconazole powder should not be used, as blood levels are undetectable or very low.[4,6] Guidance for use of itraconazole for treatment of dogs with blastomycosis is reviewed below.

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Life-Threatening Illness. Euthanasia may be avoided by an aggressive approach to life-threatening illness. Lipid or liposomal encapsulated (Abelcet® or Ambisome®) is recommended at a dosage of 1.0 mg/kg, three times weekly (or EOD) by intravenous infusion, over 4-6 hours for a cumulative dose up to 12 mg/kg (cat) or 24 mg/kg (dog) (Table 2). Low dose corticosteroids may reduce systemic toxicity caused by amphotericin B (fever, chills, malaise) and worsening of clinical signs related to inflammatory reaction to antigen released by dying fungal organisms. Renal function, electrolytes, and potassium levels should be monitored during treatment. Respiratory failure is the cause of death in most cases and supplemental oxygen is appropriate. Reasons that amphotericin B is more effective than itraconazole include immediate achievement of therapeutic blood levels and its fungicidal mode of action: itraconazole requires up to a week to reach therapeutic levels and is fungistatic.

Treatment Ocular Disease. The best treatment for ocular blastomycosis is uncertain. Some veterinary ophthalmologists prefer fluconazole because of higher penetration than itraconazole into ocular fluids and tissues [8]. However, studies in cats with ocular histoplasmosis reported response to itraconazole [9,10] In dogs voriconazole concentrations in aqueous humor are approximately 20% of that in blood, which due to the relative low MIC for blastomycosis might be effective. This study was performed in healthy dogs and it is possible that more drug enters the eye with inflammation.

Treatment CNS disease. Information on treatment of CNS blastomycosis is not available in veterinary patients. Initial treatment with a lipid or liposomal formulation of amphotericin B followed by fluconazole, itraconazole or voriconazole is recommended in humans [5]. In humans, voriconazole is preferred because of greater *in vitro* activity compared to fluconazole and good penetration into CSF.[11] In dogs CSF concentrations are approximately 20% of that in blood, although CSF concentrations might under estimate brain tissue concentrations. In a review of CNS blastomycosis, in humans, outcome was favorable in 9 of 10 patients that received voriconazole after initial treatment with amphotericin B [11].

Itraconazole penetrates CSF poorly but achieves good concentration in brain tissue [8]. But CSF penetration may not be important for treatment of meningitis. Itraconazole was equally as effective as amphotericin B and more effective than fluconazole in an experimental model of *Histoplasma* meningitis and is recommended for treatment of meningitis in humans.12,13 Itraconazole and fluconazole were equally effective in a rabbit model of Coccidioides meningitis and itraconazole was effective as salvage treatment in patients who failed standard therapy for *Coccidioides* meningitis [14,15]

Combined Treatment with Terbinafine. Some veterinarians recommend terbinafine in combination with other antifungal agents in dogs failing treatment. *In vitro* activity has been demonstrated with MICs below 0.39 µg/ml in 90% of strains [16]. Pharmacokinetic studies demonstrate that blood levels exceed MICs of *Blastomyces dermatitidis*, *Histoplasma capsulatum* and *Coccidioides immitis* [17]. *In vivo* animal studies suggest terbinafine may be effective in treating histoplasmosis [18].

Role of anti-inflammatory treatment. A retrospective study reported that administration of steroids did not improve survival [19]. Of 139 dogs with pulmonary blastomycosis treated with corticosteroids and itraconazole, 61% survived at least 30 days. Of non-survivors, 27% were euthanized and the median time to death was 3 days (range 1-15 days). Studies in humans with acute respiratory distress syndrome (ARDS) showed no benefit from use of corticosteroids [20]. Anti-inflammatory treatment (low dose corticosteroid) is commonly used in veterinary medicine to reduce fever, malaise, and lethargy, hastening clinical improvement.

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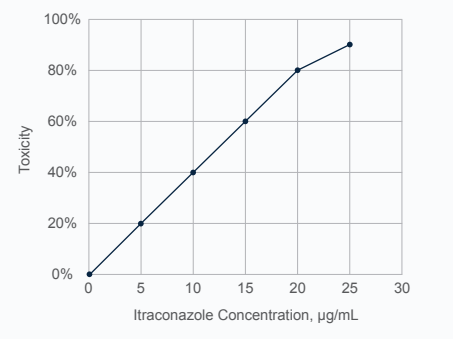
Formulation. Generic FDA approved itraconazole, compounded FDA approved itraconazole capsules (see below), and brand name Sporanox capsules contain “pelletized” drug coated onto spheres and polyethylene glycol, which improves oral bioavailability. Itraconazole capsules should be administered with food for better absorption (see Sporanox capsule package insert). Sporanox® and Itrafungol® oral solutions contains cyclodextrin which improves bioavailability. Blood levels of itraconazole are similar with FDA approved brand name Sporanox® and generic FDA approved itraconazole [6]. Compounded itraconazole powder should not be used as blood levels are undetectable or very low [6].

Dosage. Itraconazole should be administered 5 mg/kg twice daily for 3 days and then once daily in dogs [1]. In cats, the starting dose for itraconazole capsules is 10 mg/kg/day and for solution is 7.5 mg/kg/day. Itraconazole blood levels should be measured after 2 weeks in dogs and 3 weeks in cats to verify that levels are in the therapeutic range (2-7 mcg/mL). Dosage may need to be increased in puppies/kittens and adult dogs or cats that have lost considerable weight caused by the illness and regain weight during treatment: consider repeating blood levels 1-2 months intervals until weight stabilizes.

Small dogs pose challenges for use of 100 mg capsules. Alternatives include Sporanox solution (more expensive than generic itraconazole) and compounded pelletized itraconazole capsules. At least two veterinary pharmacies provide that service: (http://www.pethealthpharmacy.com (623-214-2791); https://petapothecary.com/ (414-247-8633). Prices for FDA approved itraconazole are presented in Table 4 but should be verified for your location (GoodRx.com). Alternatively, some veterinarians prescribe 100 mg generic FDA approved capsules and instruct the pet owners to empty the capsules onto a hard surface and divide the pellets into roughly equal size piles in dosages appropriate for the weight of the dog. They instruct the owners to coat the pellets onto peanut butter for administration. Finally, findings of a pharmacokinetic study support the use of 100 mg itraconazole capsules once every other day in cats [21].

Therapeutic drug level monitoring. It’s important to obtain serum for trough (just before next dose) itraconazole blood level at the end of 2 weeks in dogs and 3 weeks in cats to verify than concentrations are between 2-7 mcg/mL. A dosage change is recommended if concentrations are outside that range. Blood levels should be determined again following a dosage change to verify levels between 2-7 mcg/mL. Itraconazole blood level testing measured by bioassay is offered at MiraVista Diagnostics.

Duration. At least 6 months of itraconazole is recommended in humans [5]. Although 3-6 months is recommended in dogs, 39% of dogs treated for 2 months relapsed, supporting treatment for at least 6 months, Table 3 [4]. Many cases require a year or more of treatment, especially those with bone, ocular, central nervous system involvement or widespread disseminated disease.



Toxicity and Drug Interactions. Toxicities are usually caused by high blood levels. A human study reported 31% of patients with levels below 17 µg/mL experienced toxicity compared to 86% with levels above 17.1 mcg/mL. Toxicity occurred in 20 to 40% of patients with levels between 5 and 10 mcg/mL and may occur with levels between 2-7 mcg/mL. Levels above 7 mcg/mL are unnecessary and dose reduction decreases toxicity and cost.

The most common toxicities observed in humans were fluid retention (21%) and gastrointestinal intolerance (21%) [22]. Central nervous system toxicity occurred in 19%. Diffuse nonpruritic maculopapular rash (7%) resolved after stopping treatment and may be caused by hypersensitivity rather than high blood levels. Hepatic toxicity with a bilirubin greater than

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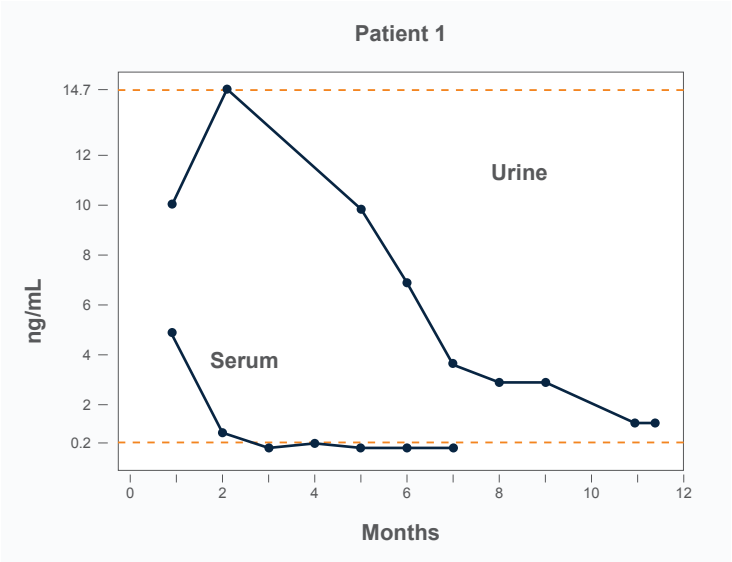
3 times the reference limit occurred in 2% of humans. Congestive heart failure occurred in 1%. Itraconazole also can cause hypertension and hypokalemia, although these have not been reported in dogs and cats (see Sporanox® and Itrafungol® package inserts).

Toxicities in dogs resemble those in humans. Median ALT levels were higher in dogs receiving 5 mg/kg twice daily (84 IU/L) than once daily (35 IU/L). ALT and ALP elevation in the absence of clinical findings of hepatotoxicity can be managed by dose reduction or discontinuation until they have resolved, after which itraconazole could be resumed at a lower dosage [1]. Ulcerative skin lesions (a sign of cutaneous vasculitis) also occurred in approximately 7% dogs receiving 10 mg/kg/d [1]. Itraconazole is a negative inotrope and should be used with caution in dogs and cats with significant heart disease.

Most toxicities resolve within a week or two after stopping or reducing the dose of itraconazole. Drug levels should be rechecked 2 weeks after resuming itraconazole to verify the level is therapeutic but nontoxic. Itraconazole can be resumed at a lower dose in dogs with clinical evidence of hepatotoxicity once clinical findings have resolved and ALT and ALP levels declined [1,23]. ALT, ALP, bilirubin, and itraconazole blood levels should be monitored closely if itraconazole is resumed.

Itraconazole inhibits cytochrome P450 3A4 isoenzymes and may increase levels of drugs cleared by that mechanism. Serious drug interactions, including death may occur when itraconazole is used with certain drugs that are cleared by P450 CYP3A4 [24]. Drugs that might be affected include amitriptyline, amlodipine, benzodiazepines, cisapride, corticosteroids, cyclosporine, ivermectin, and macrolides, to name a few.

Inducers of CYP3A4, such as phenobarbital, accelerate metabolism of itraconazole and may cause treatment failure because of subtherapeutic blood levels. Drugs that decrease gastric acid secretion reduce itraconazole blood levels. Review potential drug interactions in patients receiving medications that affect or are affected by hepatic metabolism.



Antigen monitoring. A prospective study assessed antigen clearance during treatment with fluconazole [2]. The Antigen concentrations decreased during treatment but there was no correlation between residual antigen concentration at discontinuation of treatment and the occurrence of relapse. The authors proposed criteria for stopping treatment: normal physical exam including fundic evaluation, normal or static chest radiographic findings, and to be conservative, a negative urine antigen. Obtain consultation if antigen levels are not declining after 3 months of treatment or if treatment must be extended beyond 12 months based on the above criteria.

Antigen should be tested in urine at least every 3 months during treatment, at 6 and 12 months after stopping treatment, and any time the clinical findings suggest recurrence. And if the urine antigen is “Above Limit of Quantification, ALQ” serum should be used for treatment monitoring instead. When the serum antigen is negative resume monitoring urine antigen until negative.

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Alternatives to Itraconazole. Fluconazole is not recommended as a first-line treatment because *in vitro* activity against *Blastomyces* is inferior to that of itraconazole (Table 3). It should be noted that a retrospective study failed to detect a significant difference in survival or relapse rates between dogs with blastomycosis treated with itraconazole or fluconazole [3]. This suggests that fluconazole could be considered if itraconazole is not a viable option. Several new triazoles are available for treatment of patients unable to take itraconazole, but they are several-fold more expensive. Posaconazole is highly active against *Blastomyces* (Table 4) [25]. Posaconazole was more effective than itraconazole and equally as effective as amphotericin B in a murine model of blastomycosis [25]. Posaconazole was more effective than itraconazole in experimental models of histoplasmosis in immunocompetent and immunocompromised mice [26,27]. Four case reports in humans describe successful treatment with posaconazole in patients who could not take itraconazole because of adverse effects or insurance restrictions [28-30]. Itraconazole is the treatment of choice, and posaconazole may be the best alternative based on MICs and limited clinical experience. [4].

Cost for itraconazole treatment. Prices for FDA approved itraconazole are presented in Table 4 but should be verified for your location (GoodRx.com).

When to Stop Treatment. Treat for at least 6 months and until (1) clinical findings have resolved, (2) radiographic findings have resolved or improved significantly and are thought to represent residual scarring, and (3) antigen test is negative. If these criteria are not met, continue treatment for another 3 months and reevaluate. Obtain a consultation if the antigen concentration has not decreased after 3 months of treatment or remains positive after 12 months of treatment.

Table 1. Outcome of treatment of blastomycosis in dogs

Drug	Dose	Duration	Death	Relapse	Reference
Itraconazole Prospective (n=91)[1]	5 or 10 mg/kg/d	2 months	25% (most occurred in the first week)	39%	1
Itraconazole Retrospective (n=31)[3]	4.6-10.8 mg/kg/d	Median 138 days	10%	18%	3
Fluconazole Prospective (n= 21)[2]	10 mg/kg/d	Most received 6 months	0%*	26%	2
Fluconazole Retrospective (n=36)[3]	2.9-19 mg/kg/d	Median 183 days	25%	22%	3
*Only the survivors were enrolled in the study					

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Table 2. Treatment recommendations for dogs and cats with blastomycosis

Category	Dose	Duration
Mild-Moderate	Itraconazole: 10 mg/kg/day for 3 days then 5 mg/kg/day (dog) 10 mg/kg/day (capsule cat) 7.5 mg/kg/day (solution cat)	6-12 months
Severe disease*	Amphotericin B#: 0.5 mg/kg (cat) or 1.0 mg/kg (dog) IV 3 times a week or EOD	Up to 12 mg/kg (cat or 24 mg/kg (dog) cumulative dose
	Itraconazole as above	6-12 months

* Anti-inflammatory doses of corticosteroids may reduce amphotericin B toxicity and inflammatory response to antigens released from dying *Histoplasma* yeast.
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Table 3 MICs (µg/mL) of *Blastomyces* to triazoles

Itra	Flu	Vori	Posa		References
0.125	*28.2*	0.250	0.06		25,31-33
	Italics = median or geometric mean MIC, others are MIC_{90}				

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Table 4. Example drug costs for treatment of blastomycosis in dogs and cats

	20 kg dog	20 kg dog	5 kg cat	20 kg dog	5 kg cat	5 kg cat	5 kg cat
Medication	Generic, Itraconazole tablet 100 mg	Sporanox, Itraconazole tablet 100 mg	Sporanox, solution 10 mg/ml	Generic, Fluconazole tablet 200 mg	Generic, Fluconazole solution 40 mg/ml	ItraFungol, solution 10 mg/ml	Compounded Itraconazole Capsule 25 mg
Costco	$39.36	$841.30	$259.87	$66.88	$45.41		
CVS	$89.84	$891.54	$277.37	$142.02	$77.78		
Walmart	$53.13	$889.84	$274.60	$82.46	$60.97		
Chewy	Pricing unique to Chewy or veterinary compounding pharmacies					$114.72	
Compounding Pharmacy							$72.00 - $260.00
Dose	5 mg/kg/d	5 mg/kg/d	7.5 mg/kg/d	20 mg/kg/d	20 mg/kg/ d	7.5 mg/kg/d	10 mg/kg/d
Lowest cost	$39.36 Costco	$841.30 Costco	$259.87 Costco	$82.46 Costco	$45.41 Costco	$114.72 Chewy	$72.00 compounding pharmacy

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