

## Frequently Heard Statements about Metacam for Cats

This article discusses six frequently heard statements regarding the use of Metacam in cats. Taken as a set, these statements paint a very positive picture. However, when each statement is individually scrutinized, many interesting truths emerge.

### “Metacam is approved for cats”

Metacam is marketed worldwide in three forms (injectable solution, oral suspension, and chewable tablets) and for five target species (dogs, cats, horses, cattle, and pigs). So any general statements about its approval status must be accompanied by the country issuing the approvals and the forms and target species covered by those approvals. The following table shows the approval dates for dogs and cats in the United States.

FDA Approval Dates Drug Form	Target Species	
	dogs	cats
Injectable (NADA 141-219)	12 Nov 2003	28 Nov 2004
Oral susp (NADA 141-213)	15 Apr 2003	Not approved

Note that the FDA approval for cats is limited to *one-time use* of the injectable form; subsequent oral dosing is specifically contraindicated.<sup>[1]</sup>

The FDA grants a five-year marketing exclusivity period for new animal drugs; Metacam Oral's exclusivity expires on 15 April 2008, at which time generic versions will become available in the USA.

### “Metacam has been used for 10 years in Europe”

Again, we need to disambiguate this statement with more specific information from the European Medicines Agency.<sup>[2]</sup>

EMA Approval Dates Drug Form	Target Species	
	dogs	cats
Injectable EU/2/97/004/006	10 Nov 1999	09 Aug 2002
Oral susp EU/2/97/004/003	07 Jan 1998	Not approved

Now we see that European approval in cats (again, for one-time injection only) is much more recent. Note also that Novopharm UK has recently (April 2006) received EMA approval for the generic version Flexicam Oral.<sup>[3]</sup>

### “35 million doses of Metacam have been sold”

This may indeed be true, but this is likely a worldwide aggregate figure and the vast majority of these doses have been for use in dogs and farm animals. It's better to ask more specific and relevant questions such as “How many doses of *Metacam Injection for Cats* have been sold in the USA?” or “How many doses of Metacam Oral have been sold for cats in this country?”

### “Metacam has an unparalleled safety record”

This may indeed be true *for dogs*; the target animal safety studies<sup>[4]</sup> filed with the FDA show that dogs can tolerate single 120X doses (where 1X = 0.1 mg/ml) and repeated daily 5X doses for six months with no deaths. However, when four cats were given repeated daily 3X doses for eight days, one died and another was moribund.<sup>[5]</sup> It is therefore clear that Metacam's safety in dogs cannot be extrapolated to cats.

The FDA's Adverse Drug Experience summaries<sup>[6]</sup> raise additional concerns about the safety of Metacam in cats. The following table summarizes the top reported adverse effects of Metacam (both oral and injected) in cats.

Meloxicam in cats, route:	Oral	Parenteral
No. of animals evaluated:	328	71
Clinical Sign	Reacted	
Anorexia	152	34
BUN high (blood)	145	38
Creatinine high (blood)	143	37
Depression/lethargy	135	31
<b>Kidney failure</b>	<b>105</b>	<b>17</b>
Vomiting	102	25
Azotemia	55	15
<b>Death</b>	<b>52</b>	<b>16</b>
Phosphorous high (blood)	51	15
<b>Death (euthanized)</b>	<b>37</b>	<b>9</b>
Dehydration	33	8
Weight loss	29	4
Diarrhea	25	1

### “Deaths in cats are idiosyncratic”

*Idiosyncratic* refers to an unusual drug reaction that is particular to an individual or group. Since there are no adequate field trials for Metacam in cats, there is no data to define “usual” reactions. It is therefore impossible to determine whether the death of any particular cat is idiosyncratic or not.

### “There's nothing wrong with off-label use”

Off-label drug use is a widespread practice in both human and veterinary medicine; however, prescribing directly against label directions (i.e. *do not use in cats*) is not common. Recent jurisprudence (*Richardson vs. Miller*<sup>[7]</sup>) in the field of human medicine shows that the practitioner is exposed to significant legal liability when ignoring label contraindications, and particularly so when informed consent is not given. Off-label prescription of Metacam for cats is especially problematic in Canada, where other NSAIDs (ketoprofen and tolfenamic acid) have approved labeling for short-term repeated use in cats. This makes Metacam difficult to justify.

## References

- [1] **Product sheet: Metacam Solution for Injection for Cats**  
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[http://www.bi-vetmedica.com/.../Metacam\\_Cat\\_RP.pdf](http://www.bi-vetmedica.com/.../Metacam_Cat_RP.pdf)
- [2] **Metacam European Public Assessment Report**  
<http://www.emea.eu.int/vetdocs/vets/Epar/metacam/metacamM.htm>
- [3] **Flexicam European Public Assessment Report**  
<http://www.emea.eu.int/vetdocs/vets/Epar/flexicam/flexicam.htm>
- [4] **Freedom of Information Summary for NADA 141-213** (Metacam Oral)  
<http://www.fda.gov/cvm/FOI/141-213.pdf>
- [5] **Freedom of Information Summary for Supplemental NADA 141-219** (Metacam 5 mg/ml Solution for Injection for Cats (28 October 2004))  
<http://www.fda.gov/cvm/FOI/141-219s102804.pdf>
- [6] **FDA Adverse Drug Experiences Report (10 July 2006)**  
[http://www.fda.gov/cvm/Documents/ade\\_web\\_rpts\\_MN.pdf](http://www.fda.gov/cvm/Documents/ade_web_rpts_MN.pdf)
- [7] **Off-Label Prescribing**, Maxwell J. Mehlman, J.D.  
[http://www.thedoctorwillseeyounow.com/articles/bioethics/offlabel\\_11/](http://www.thedoctorwillseeyounow.com/articles/bioethics/offlabel_11/)

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