

# FIP Treatment, from a death sentence to long-term survival: The story so far.

Thursday, May 30, 2024 | 5-6 p.m. ET

*Presented by*

- *Samantha Taylor BVetMed(Hons) CertSAM DipECVIM-CA MANZCVS FRCVS*
- *Sally Coggins, BVSc (Hons I) MANZCVS (Feline Medicine), PhD Candidate (Science)  
Sydney School of Veterinary Science*
- *Samantha Evans DVM, PhD, DACVP*



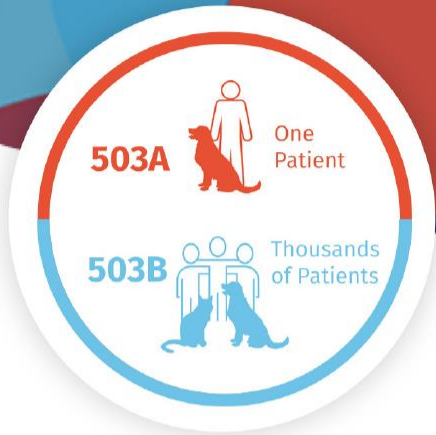
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- Having technical issues? Please send questions through the chat box to everyone.
- If you have questions related to the material being presented, please submit through the Q&A section. Upvote your favorite questions.
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- CE certificates and webinar slides will be sent out within 10 business days following the webinar and will come from Epicur Pharma.
- This webinar is being recorded and will be available to view on demand, however CE credits will only be issued if you are tuning in LIVE this evening.





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<b>Type of Facility</b>	Traditional Compounding Pharmacy	FDA Registered Outsourcing Facility
<b>Product Purpose</b>	Customized prescriptions for individual patients	Manufactured drugs in bulk quantities for hospitals
<b>Regulatory Oversight</b>	State Boards of Pharmacy	FDA
<b>Regulations</b>	USP (United States Pharmacopeia)	cGMP (current Good Manufacturing Practices)
<b>Product Dating</b>	Beyond-Use Date (limited)	Expiration Date (proven)

### Start Your Order!

For Office Orders: 888-508-5032

For Patient Prescriptions: 800-754-5222

# FIP Treatment Available in the U.S. Starting June 1st

NEW!

The only oral formula identical to the Bova formula used in clinical studies.

Stokes Pharmacy has formed an exclusive partnership with the Bova group to offer a U.S.-made oral treatment for FIP. This treatment is supported by Bova's unique drug formula, which has been utilized in clinical research studies across the globe and is currently in use in the UK and Australia.



**Stokes Pharmacy**<sup>®</sup>  
*Precision Compounding - Nationwide.*

**BOVA**



Scan the QR code to learn more!

# GS-441524

Formulation Available at Stokes Pharmacy

Strength: 50mg

Form: Quad Scored Tablet

Flavor: Tuna

Summary

Drug Class: Antiviral

Target Species: Cats



Tablet sizing compared to a U.S. dime

Diagnosis	GS-441524 PO Dosage Rate
Effusion(s) and <u>without</u> ocular or neurological signs	15 mg/kg q 24 hrs or split q 12 hrs
No effusion and without ocular or neurological signs	15 mg/kg q 24 hrs or split q 12 hrs
Ocular signs present ( $\pm$ effusion)	15-20 mg/kg q 24 hrs or split q 12 hrs
Neurological signs present ( $\pm$ effusion)	10 mg/kg q 12 hrs

## Prescription Pricing

10 tablets = \$195.00

20 tablets = \$325.00

40 tablets = \$546.00

Prices subject to change. These prices do not include shipping + tax when applicable. Our standard 1-2 day shipping is \$9.50. Overnight shipping is available upon request of pet owner.

# How to Order

## 3 Ways to Order:

- Online via iFill.com  
If you're a new user, registration is required  
\*Registration takes up to 48 hours
- E-form for patient prescriptions (Coming 6/1/24)
- Call (800) 754-5222



# Register for parts 2 & 3

Scan the QR codes provided or go to [epicurpharma.com/webinars](https://epicurpharma.com/webinars)



## **FIP Diagnosis: Now we can treat it, how sure do we need to be?**

*Dr. Samantha Taylor, BVetMed(Hons), CertSAM, DipECVIM-CA, MANZCVS, FRCVS*

**June 20, 2024 | 5-6 pm ET**

**RACE-Approved CE Credit Hours: 1**



## **Legal FIP Treatment in the USA: Learn how to start treating FIP cases in your practice.**

*Dr. Sally Coggins, BVSc (Hons I) MANZCVS (Feline Medicine), PhD Candidate (Science)*

**June 27, 2024 | 8-9 pm ET**

**RACE-Approved CE Credit Hours: 1**



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# FIP Veterinary Resources

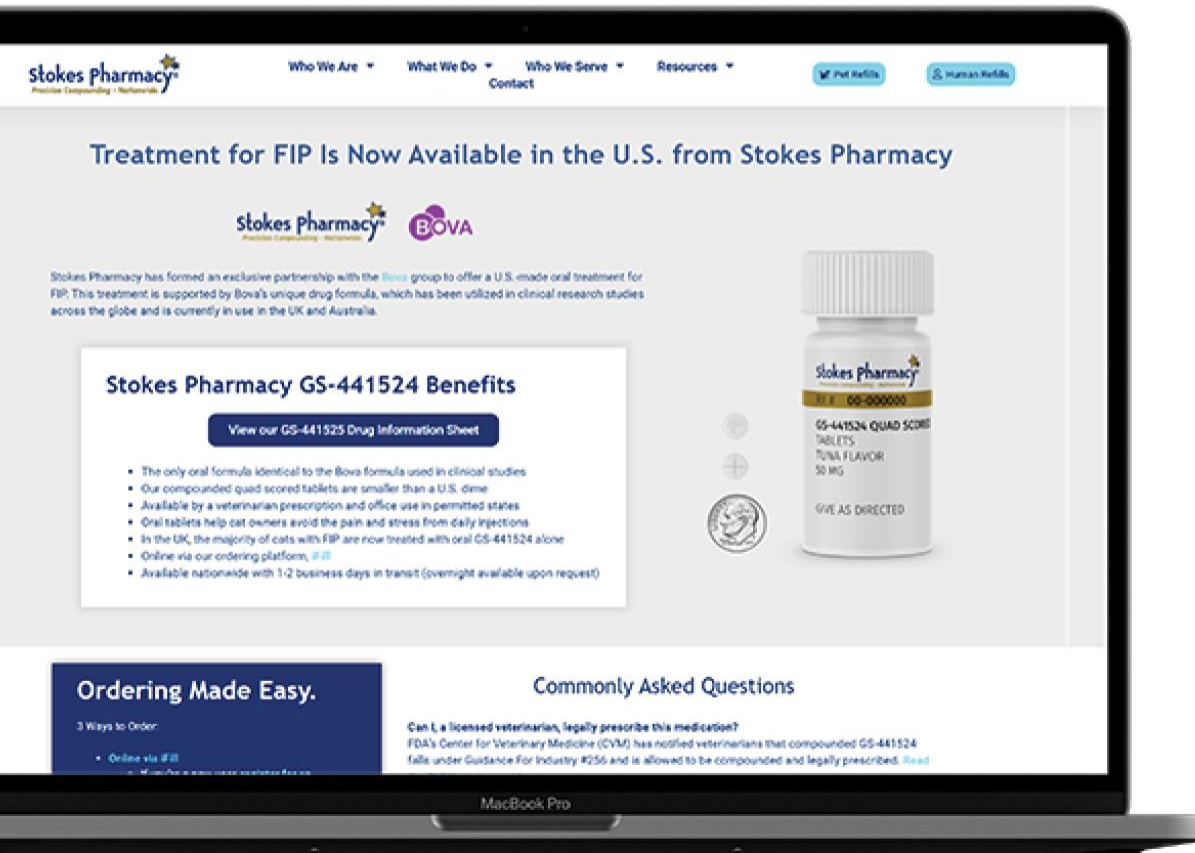
Veterinary FIP specialists have also provided educational materials that veterinarians need when it comes to diagnosing and treating FIP.

Scan to view



Resources include:

- Disease information
- Treatment
- Tablet dosage guide chart
- How to order GS-441524 in the U.S.
- FAQs
- Clinical studies and downloads





Nick Bova  
CEO- Bova Group





Bova Aus was founded nearly 60 years ago. The veterinary compounding facility has been running for 16 years.



The UK business was established as a specials manufacturer in 2017. Bova UK follows current Good Manufacturing Practices (cGMP), similar to 503B.

Bova Aus developed the FIP products. FIP products launched in October 2021 in Aus and shortly after in the UK.

Units sold since launch (as 50mg units):  
 Bova Aus: 141,060  
 Bova UK: 397,135

Clinical trials that have taken place and due to be published using Bova formulations:

- 3 Published studies using Bova formulations from Australia and the UK (a total of 360 cats studied)
- 3 European studies due to be published
- 1 Australian study due to be published





# FIP Treatment

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*From a death sentence to long-term survival*



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# Disclosure

## **FINANCIAL DISCLOSURES:**

Coggins: I have delivered many webinars and lectures with honorarium on the topic of FIP treatment developments, including sponsored lectures and providing FIP treatment advice to vets by BOVA (Aus & UK)

Evans: I have delivered many webinars and lectures with honorarium on the topic of FIP diagnosis and treatment, including unlicensed ("black market") therapy for FIP

Taylor: I have delivered many webinars and lectures with honorarium on the topic of FIP treatment developments, including sponsored lectures and providing FIP treatment advice to vets by BOVA (FIP advice email – international)

## **UNLABELED/UNAPPROVED USES DISCLOSURE:**

We will discuss the off-label use of remdesivir and the non-FDA approved use of GS-441524 for use in cats in the USA



# Webinar Outline – The Story So Far

Dr Coggins

- Introduction to nucleoside and nucleotide analogues and where their use in cats began
- How Australia gained legal veterinary access with BOVA Aus in 2020
- What we know about how cats metabolise these drugs and initial survival rates

Dr Taylor

- How the UK then gained legal veterinary access with BOVA UK in 2021
- UK based studies assessing treatment response

Dr Evans

- Use of unlicensed antivirals for FIP treatment in the USA
- Where compounded GS-441524 sits in the USA context
- Q & A



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## FIP Diagnosis: Now we can treat it, how sure do we need to be?

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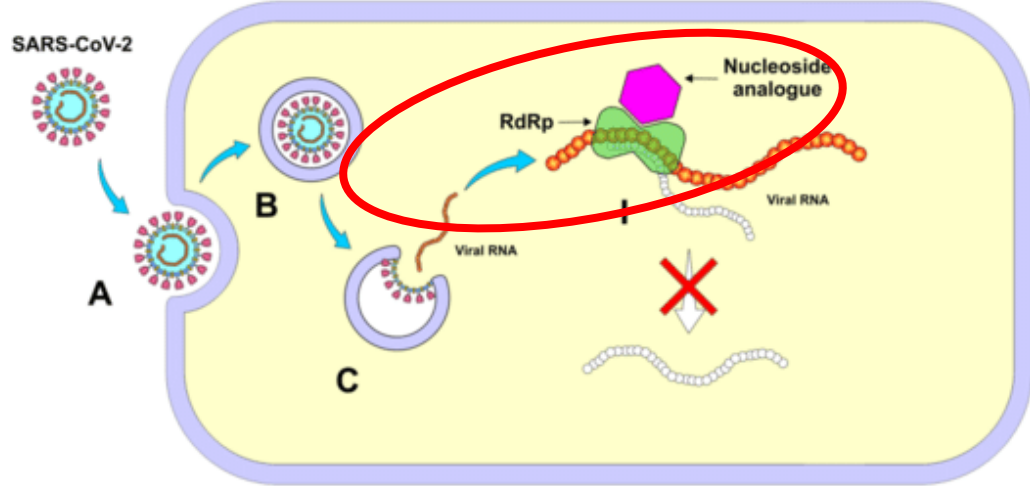
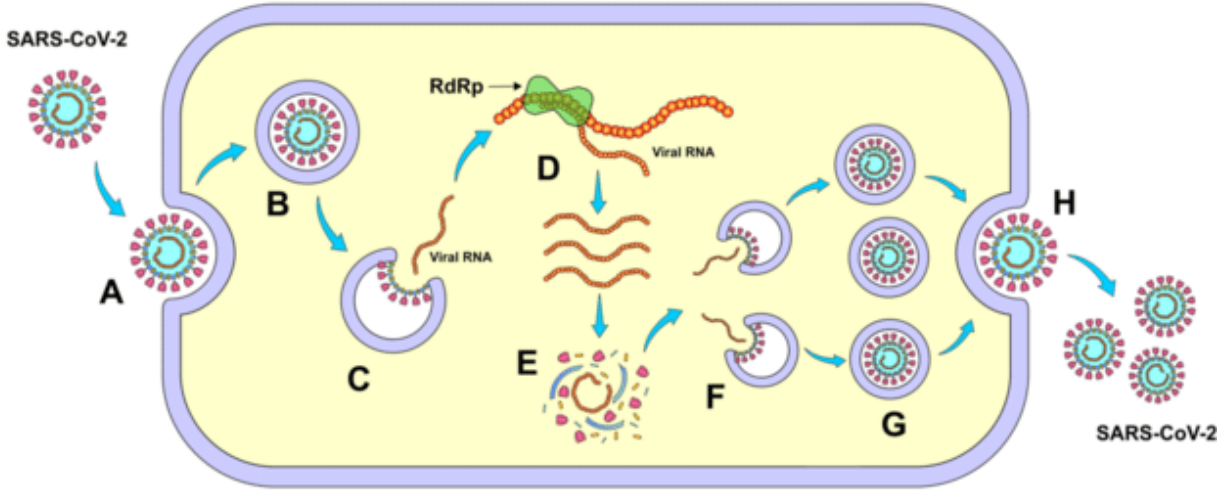
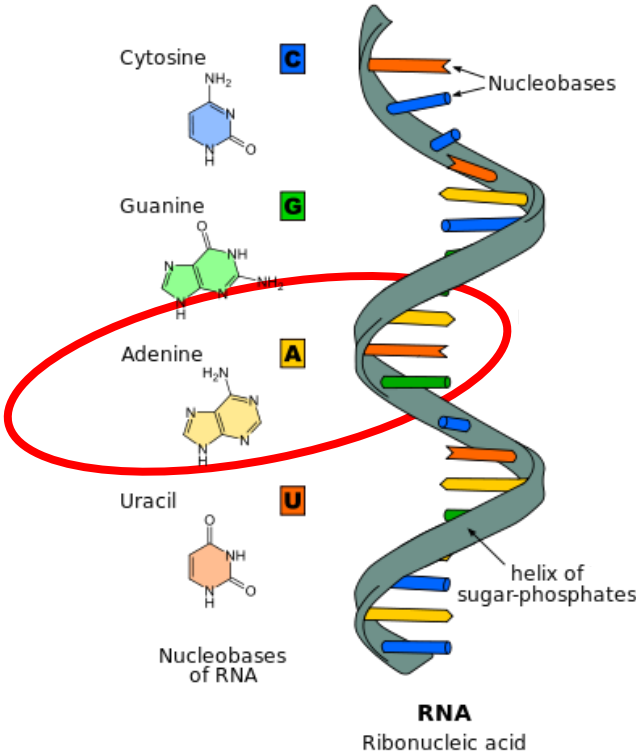
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# Nucleoside & Nucleotide Analogues



## Mimic endogenous nucleotides



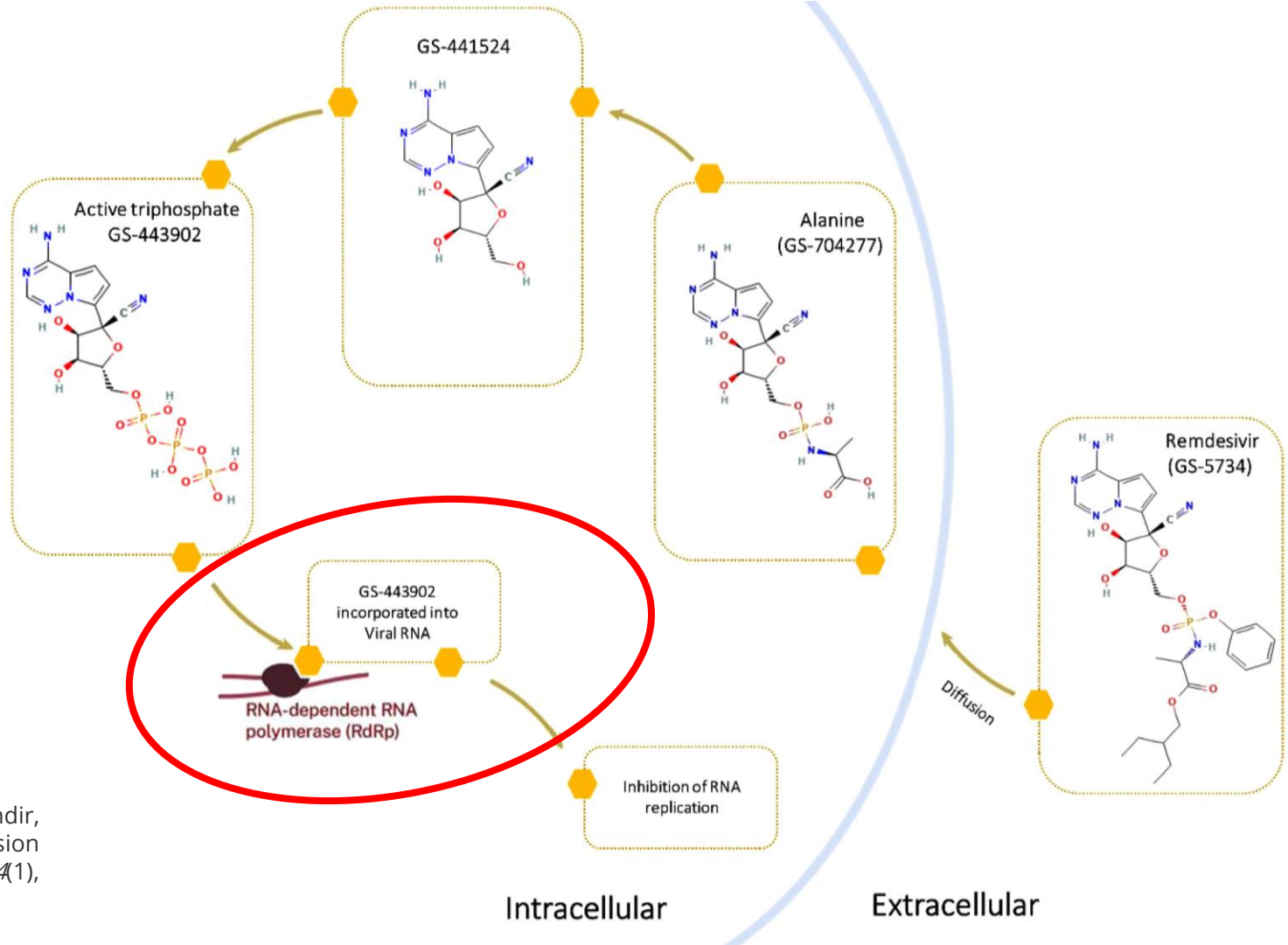
- A – Cell Entry
- B – Endosome formation
- C – Release of viral RNA
- D – Self-replication (RdRp)

Modified from: Fernandes ACL, Vale AJM, Guzen FP, Pinheiro FI, Cobucci RN and de Azevedo EP (2020) Therapeutic Options Against the New Coronavirus: Updated Clinical and Laboratory Evidences. *Front. Med.* 7:546. doi: 10.3389/fmed.2020.00546

# Nucleoside & Nucleotide Analogues

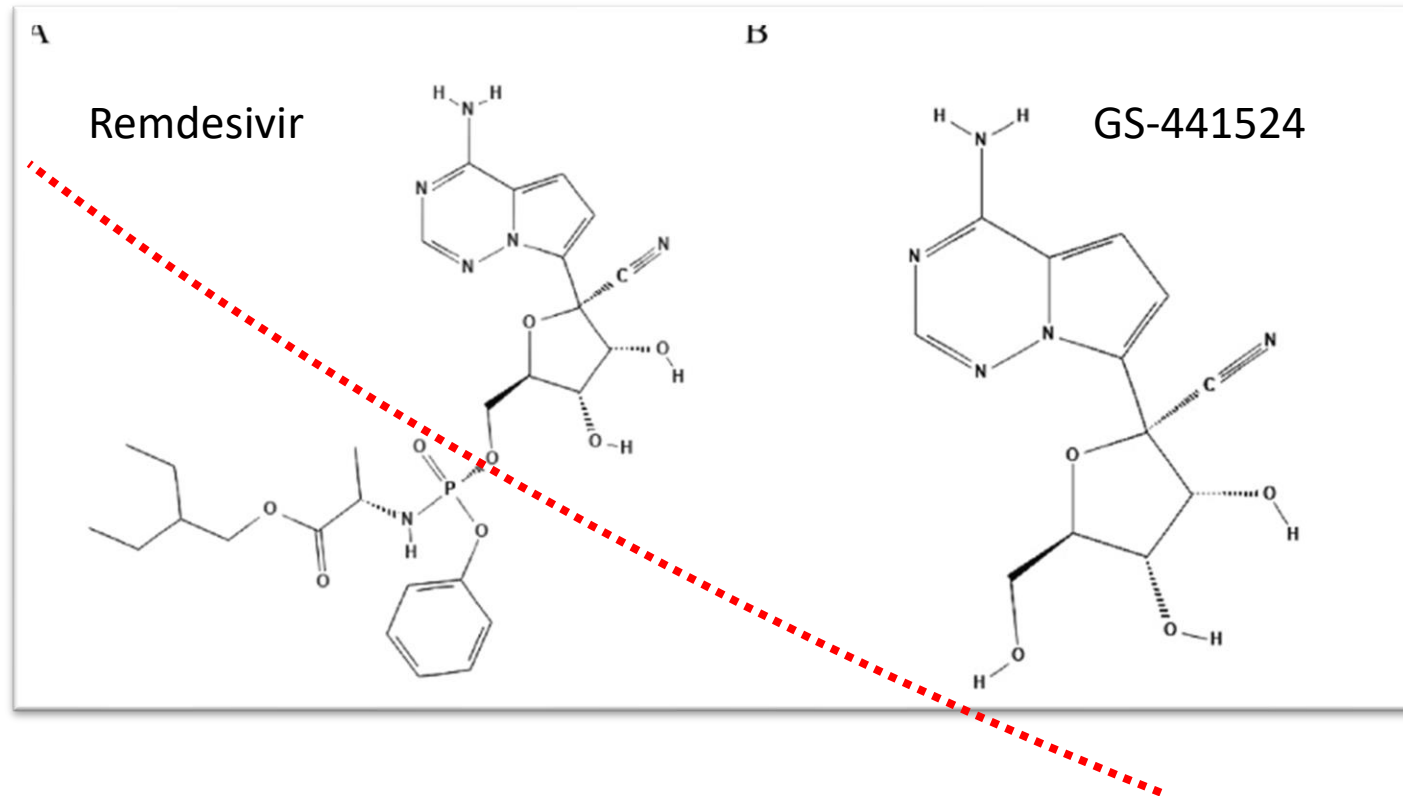


Become incorporated into viral RNA via RNA-dependent RNA Polymerase (RdRp) and prevents viral replication



Coggins, S. J., Kimble, B., Malik, R., Thompson, M. F., Norris, J. M., & Govendir, M. (2024). Assessing *in vitro* stability of remdesivir (GS-5734) and conversion to GS-441524 in feline plasma and whole blood. *Veterinary Quarterly*, 44(1), 1-9. <https://doi.org/10.1080/01652176.2024.2305731>

# Remdesivir (GS-5734) & GS-441524



# GS-441524 - Pharmacokinetics & FCoV antiviral activity

2018

Veterinary Microbiology 219 (2018) 226–233

Contents lists available at ScienceDirect

Veterinary Microbiology

journal homepage: [www.elsevier.com/locate/vetmic](http://www.elsevier.com/locate/vetmic)



The nucleoside analog GS-441524 strongly inhibits feline infectious peritonitis (FIP) virus in tissue culture and experimental cat infection studies

B.G. Murphy<sup>a</sup>, M. Perron<sup>c</sup>, E. Murakami<sup>c</sup>, K. Bauer<sup>a</sup>, Y. Park<sup>c</sup>, C. Eckstrand<sup>a</sup>, M. Liepnieks<sup>a</sup>, N.C. Pedersen<sup>b,\*</sup>

<sup>a</sup> Department of Pathology, Microbiology, and Immunology, School of Veterinary Medicine, University of California, Davis, CA, USA

<sup>b</sup> Center for Companion Animal Health, School of Veterinary Medicine, University of California, One Shields Ave., Davis, CA, USA

<sup>c</sup> Gilead Sciences, Foster City, CA, USA

- Inhibits viral replication *in vitro*
- Non-cytotoxic
- The pharmacokinetic following IV and SQ administration have been described
- Active intracellular triphosphate levels achieved (PBMC's) exceeded EC50 for 72h
- Lower concentrations of GS-441524 in CSF and aqueous humour

# GS-441524 – Treatment outcomes (experimental FIP)

2018

Veterinary Microbiology 219 (2018) 226–233



ELSEVIER

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- $n = 10$  cats with experimentally induced FIP
  - 2mg/kg OR 5mg/kg SID x 2 weeks
- ALL showed rapid resolution of signs
- Two had recurrence at 4 & 6 weeks and were retreated
- **All survived to time of publish**  
(8mths post treatment)

# GS-441524 – Treatment outcomes (Natural FIP)

2019

Original Article



**jfms**  
Journal of Feline  
Medicine and Surgery

## Efficacy and safety of the nucleoside analog GS-441524 for treatment of cats with naturally occurring feline infectious peritonitis

Niels C Pedersen<sup>1</sup> , Michel Perron<sup>2</sup>, Michael Bannasch<sup>1</sup>, Elizabeth Montgomery<sup>1</sup>, Eisuke Murakami<sup>2</sup>, Molly Liepnieks<sup>3</sup> and Honqwei Liu<sup>3</sup>

Journal of Feline Medicine and Surgery  
1–11

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 SAGE

n = 31 client owned cats

- Dose: 2-4mg/kg SQ q 24h x 12 weeks

Four died (2-5 days)

26 completed 12 weeks treatment

18 remained healthy to publication

8 relapsed (3 twice) and retreated

1 died, 7 survived.

1 survivor then died of HCM  
(unrelated)

**24 long term survivors (77% survival)**

# No registered formulation of GS-441524



2021



Article

## Curing Cats with Feline Infectious Peritonitis with an Oral Multi-Component Drug Containing GS-441524

Daniela Krentz <sup>1,\*</sup>, Katharina Zenger <sup>1</sup>, Martin Alberer <sup>2</sup>, Sandra Felten <sup>1</sup>, Michèle Bergmann <sup>1</sup>, Roswitha Dorsch <sup>1</sup>, Kaspar Matiasek <sup>3</sup>, Laura Kolberg <sup>2</sup>, Regina Hofmann-Lehmann <sup>4</sup>, Andrea M. Spiri <sup>4</sup>, Jeannie Horak <sup>5</sup>, Saskia Weber <sup>6</sup>, Cora M. Holicki <sup>6</sup>, Martin H. Gruber <sup>7</sup>, Yury Zablotski <sup>1</sup>, Eveline Lesclinier <sup>8</sup>, Berthold Koletzko <sup>5</sup>, Ulrich von Both <sup>2,9,t</sup>



2021



Article

## Unlicensed GS-441524-Like Antiviral Therapy Can Be Effective for at-Home Treatment of Feline Infectious Peritonitis

Sarah Jones <sup>1</sup>, Wendy Novicoff <sup>2</sup>, Julie Nadeau <sup>3</sup> and Samantha Evans <sup>1,\*</sup>

- <sup>1</sup> Department of Veterinary Biosciences, College of Veterinary Medicine, The Ohio State University, Columbus, OH 43210, USA; Sarahejones79@yahoo.com
  - <sup>2</sup> Departments of Orthopaedic Surgery and Public Health Sciences, School of Medicine, University of Virginia, Charlottesville, VA 22903, USA; wmn2v@virginia.edu
  - <sup>3</sup> Hamilton Region Veterinary Emergency Clinic, Hamilton, ON L9P 4W3, Canada; julie.nadeau7@gmail.com
- \* Correspondence: evans.2608@osu.edu; Tel.: +1-614-292-9706

Unlicensed  
sources



2022



Article

## Unlicensed Molnupiravir is an Effective Rescue Treatment Following Failure of Unlicensed GS-441524-like Therapy for Cats with Suspected Feline Infectious Peritonitis

Meagan Roy <sup>1</sup>, Nicole Jacque <sup>2</sup>, Wendy Novicoff <sup>3</sup>, Emma Li <sup>1</sup>, Rosa Negash <sup>1</sup> and Samantha J. M. Evans <sup>1,\*</sup>

Original Article



## Long-term follow-up of cats in complete remission after treatment of feline infectious peritonitis with oral GS-441524

Katharina Zwicklbauer <sup>1</sup>, Daniela Krentz <sup>1</sup>, Michèle Bergmann <sup>1</sup>, Sandra Felten <sup>1</sup>, Roswitha Dorsch <sup>1</sup>, Andrea Fischer <sup>1</sup>, Regina Hofmann-Lehmann <sup>2</sup>, Marina L Meli <sup>2</sup>, Andrea M Spiri <sup>2</sup>, Martin Alberer <sup>3</sup>, Laura Kolberg <sup>3</sup>, Kaspar Matiasek <sup>4</sup>, Yury Zablotski <sup>1</sup>, Ulrich von Both <sup>3,5</sup>, and Katrin Hartmann <sup>1</sup>

# No registered formulation of GS-441524



GS 441524  
& Remdesivir



GC 376



**Veterinary Practitioners Board of New South Wales**

### Black market cat drugs for treatment of feline infectious peritonitis

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has recently become aware of media reporting (Black market cat drugs studied as COVID-19 treatment, 31/01/2020) and the Agricultural and Veterinary Chemicals Code of Practice (AVCC) showing that the unregistered compounds which are reported to be used to treat cases of feline infectious peritonitis are not approved for use by the APVMA. These compounds are not approved for use by the APVMA.

Clients and veterinarians involved in the unlawful importation of these unregistered compounds may be subject to significant financial penalties and importing penalties.

Further information about possible penalties and importing veterinary chemicals is available from this letter to Dr Julie Strous of the AVBC, Dr Julie Strous, Director Compliance and Monitoring of the APVMA.

Unlicensed sources  
"immune supplements"

# Compounded remdesivir & GS-441524

- Under the AgVetCode, compounded products are not defined as veterinary chemicals
- Exempt from registration by the APVMA
- In Australia, a registered veterinarian is allowed to write a valid prescription to registered pharmacists to compound an unlicensed drug for veterinary use in an individual animal they have a direct treatment relationship with

2020

# FIP Treatment outcomes in Australia

Received: 30 October 2022 | Accepted: 27 June 2023

DOI: 10.1111/jvim.16803

STANDARD ARTICLE


Journal of Veterinary Internal Medicine

ACVIM

Open Access

American College of Veterinary Internal Medicine

## Outcomes of treatment of cats with feline infectious peritonitis using parenterally administered remdesivir, with or without transition to orally administered GS-441524

Sally J. Coggins<sup>1</sup>  | Jacqui M. Norris<sup>1</sup> | Richard Malik<sup>2,3</sup> | Merran Govendir<sup>1</sup> | Evelyn J. Hall<sup>1</sup> | Benjamin Kimble<sup>1</sup> | Mary F. Thompson<sup>1</sup>



The University of Sydney - AUSTRALIA

Survival to 6mths

86%



UPDATE: Survival to 18mths

If survive the first 48h

83%

92%



# Pharmacokinetics of remdesivir in cats

1) Remdesivir is rapidly hydrolyses into GS-441524 in cats (in blood)

VETERINARY QUARTERLY  
2024, VOL. 44, NO. 1, 1–9  
<https://doi.org/10.1080/01652176.2024.2305731>



OPEN ACCESS 

## Assessing in vitro stability of remdesivir (GS-5734) and conversion to GS-441524 in feline plasma and whole blood

Sally J. Coggins<sup>a,b</sup> , Benjamin Kimble<sup>a</sup> , Richard Malik<sup>b,c</sup> , Mary F. Thompson<sup>a</sup> ,  
Jacqueline M. Norris<sup>a</sup>  and Merran Govendir<sup>a</sup> 


<sup>a</sup>Sydney School of Veterinary Science, The University of Sydney, Camperdown, Australia; <sup>b</sup>Centre for Veterinary Education, The University of Sydney, Camperdown, Australia; <sup>c</sup>Animal and Veterinary Science, Charles Sturt University, Wagga Wagga, Australia

2) The pharmacokinetics of GS-441524 that is formed following administration of remdesivir in clinical healthy cats has also been described



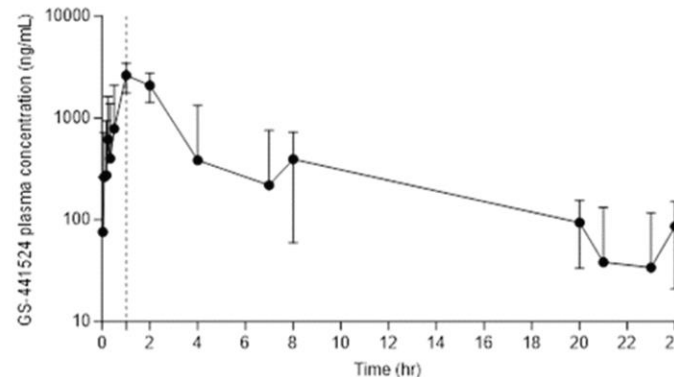
Article

## An Optimized Bioassay for Screening Combined Anticoronaviral Compounds for Efficacy against Feline Infectious Peritonitis Virus with Pharmacokinetic Analyses of GS-441524, Remdesivir, and Molnupiravir in Cats

Sarah Cook<sup>1,\*</sup>, Luke Wittenburg<sup>2</sup>, Victoria C. Yan<sup>3</sup> , Jacob H. Theil<sup>4</sup> , Diego Castillo<sup>1</sup>, Krystle L. Reagan<sup>5</sup> ,  
Georgia Williams<sup>1</sup>, Cong-Dat Pham<sup>3</sup>, Chun Li<sup>3</sup>, Florian L. Muller<sup>6</sup> and Brian G. Murphy<sup>1</sup> 

3) The pharmacokinetics of remdesivir in FIP affected cats has also been documented, with preliminary TDM recommendations

Coggins SJ unpublished data

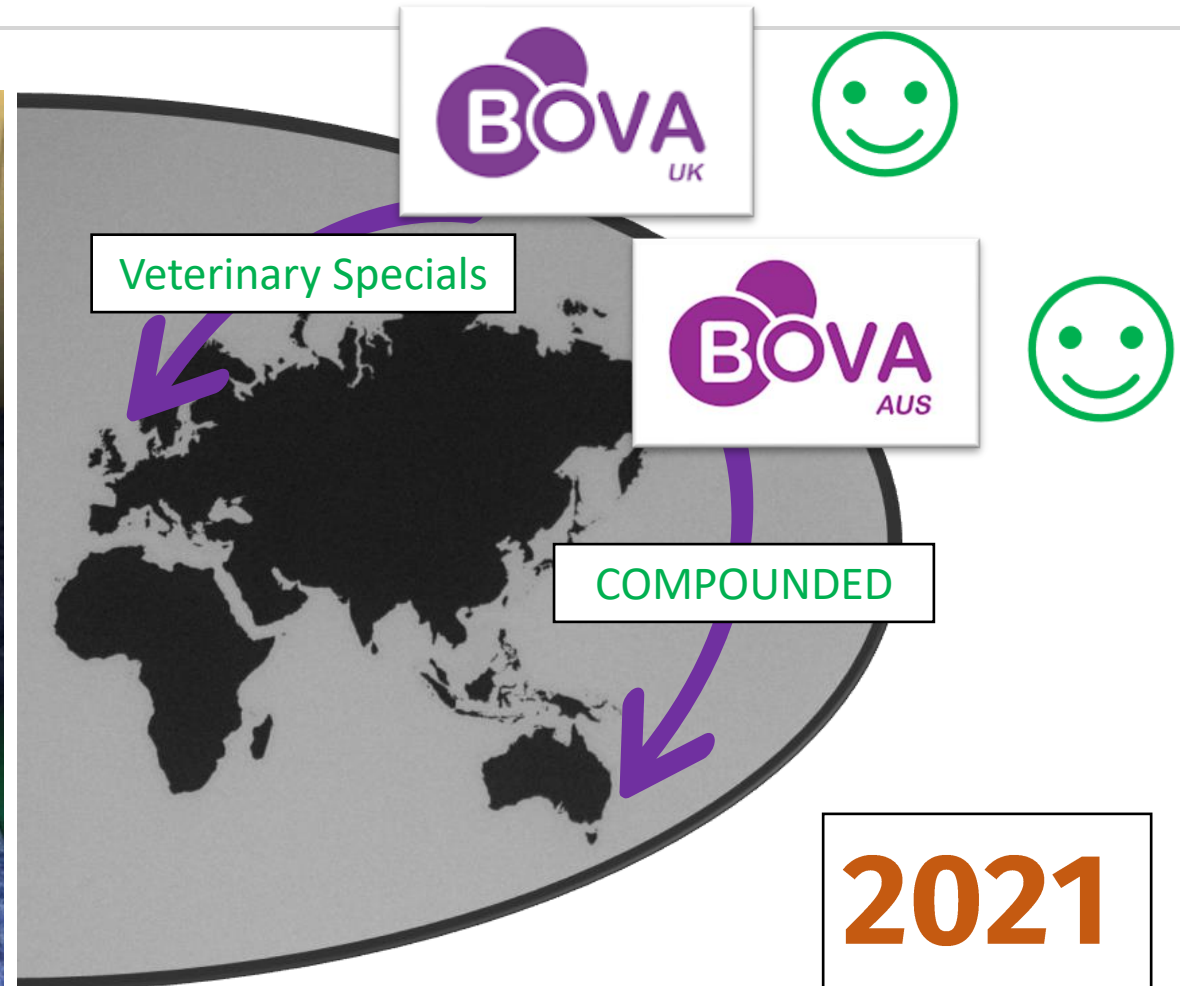




## Funding

- **Cat Protection Society of NSW**
- **EveryCat Health Foundation W21-006**
  - *Determining the in vitro clearance (feline microsomes) and in vivo pharmacokinetic profile of remdesivir in cats with naturally occurring feline infectious peritonitis (FIP).*
- **EveryCat Health Foundation W21-018**
  - *Determining the clinical efficacy and safety of remdesivir for the treatment of naturally occurring feline infectious peritonitis.*
- **Bequests:** Christine Atkins Bequest

# Compounded remdesivir & GS-441524



# Treatment of FIP in the UK 2021

- Initially only human remdesivir available
  - Cost prohibitive, painful to inject
- Australian experience very useful
  - Open information sharing
  - 6 months later remdesivir and GS available in the UK
- Via export from UK to other countries (Japan, Sweden, SA)
- Great successes witnessed
- Formed the FIP advice email group (feline and internal medicine specialists)
- Answered 2500 emails so far worldwide



# How we use antivirals in the UK



- System of prescribing called 'cascade'
- If no available licensed veterinary drug we can use human drugs
- We can also use drugs from Specials Manufacturers if they are given permission from the UK Veterinary Medicines Directorate

# Evolution of our study

- Drugs proving effective in countries allowed to use it
- Yet many countries could not import
- Blocked by regulations
- We knew it worked and wanted to prove it
  - Would like it to be available legally worldwide



THE UNIVERSITY OF  
SYDNEY



International Society of Feline Medicine



# The cats

- Recruited from around the world (UK, Aus, Japan, SA, Europe)
- Only if treated with the legal medications
- Outcome and follow up information

Helped us make  
recommendations  
and proved it  
works!





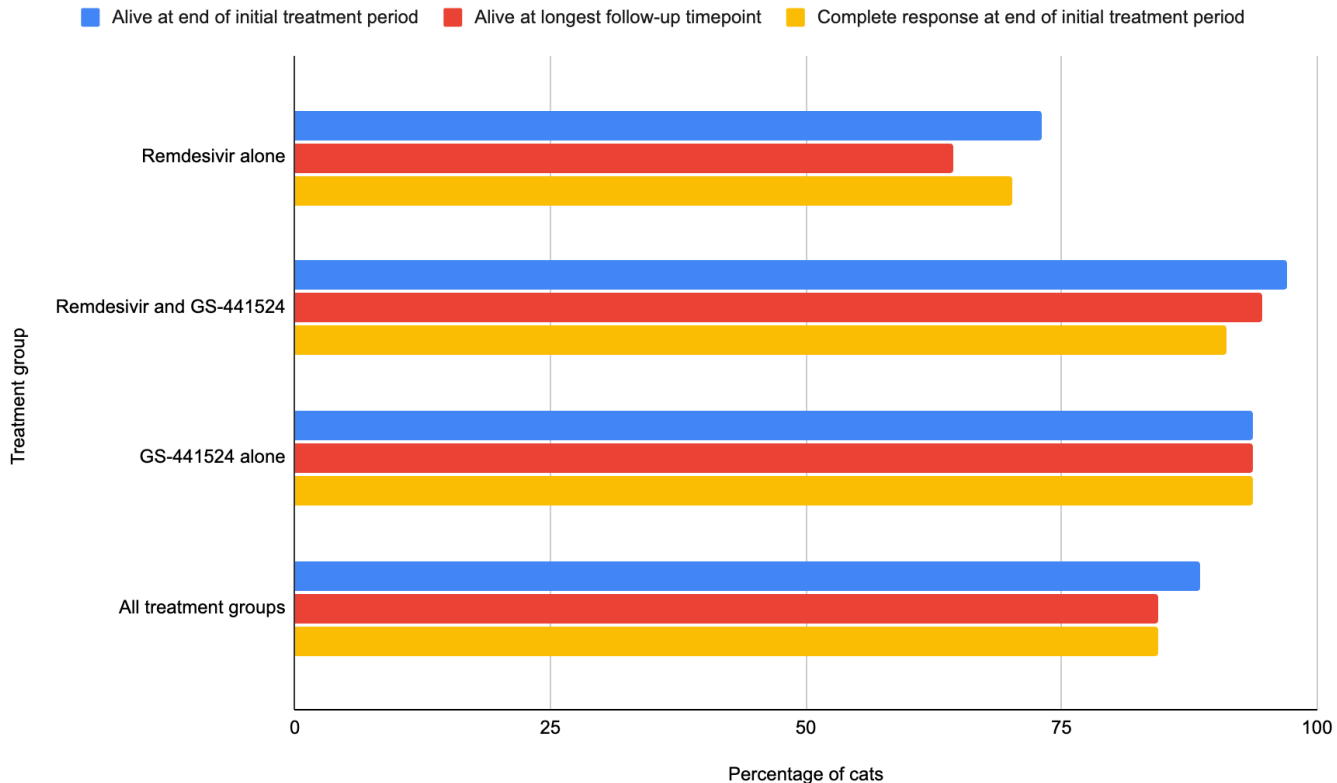
# Retrospective study and outcome of 307 cats with feline infectious peritonitis treated with legally sourced veterinary compounded preparations of remdesivir and GS-441524 (2020–2022)

All cats treated with legal drugs from BOVA

- Examined the treatment, duration, response and outcome
- Also looked at presentation and diagnosis



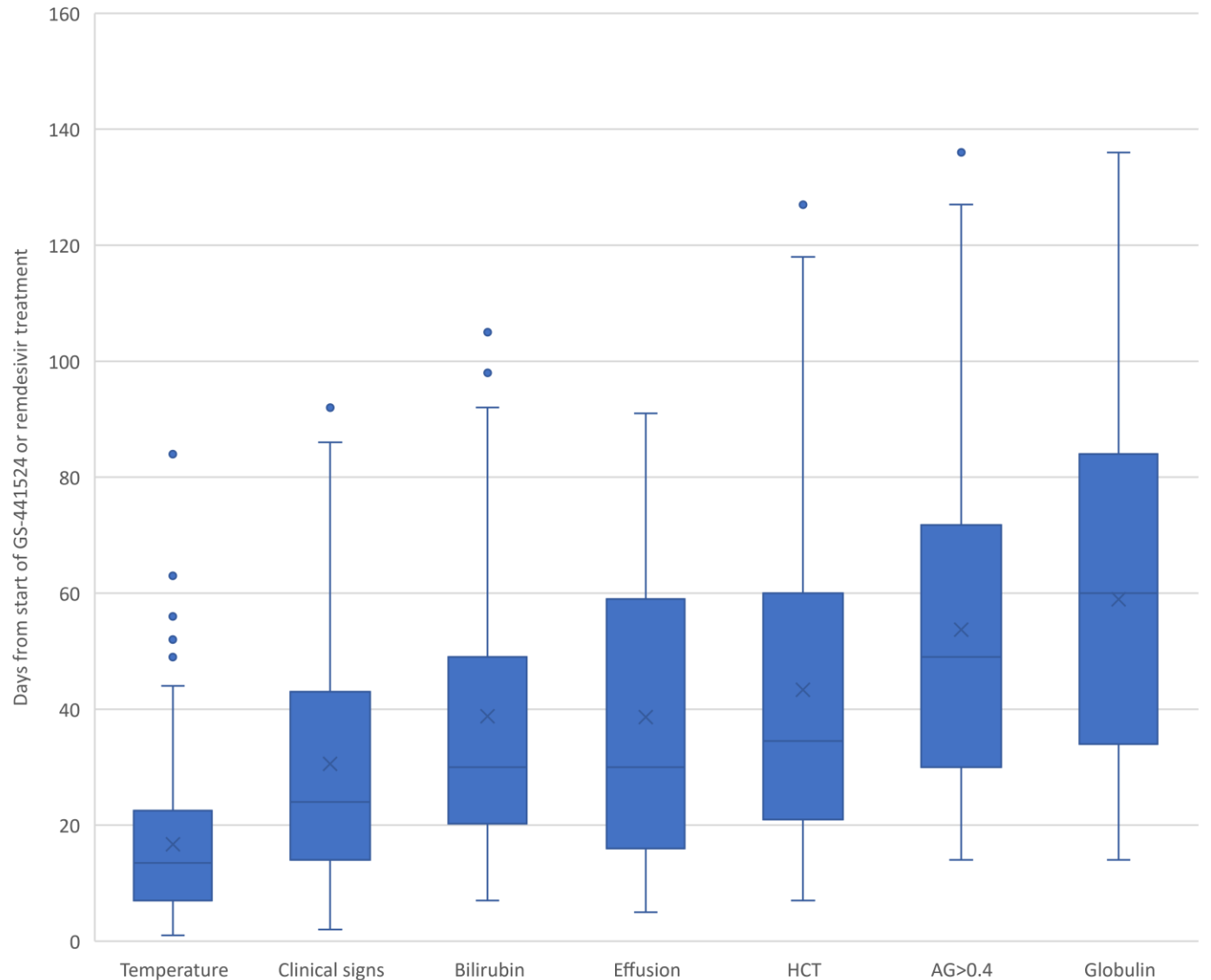
# Response and relapse



- Overall complete response 84.4%
- 9.1% no response
  - Often very sick cats
  - Severe neuro signs
  - Sepsis
- 4.9% relapsed during treatment
- 6.6% after treatment
  - 2 cats at day 390 and 450
- Complete response in first 30 days = better prognosis

# Speed of response

- Pyrexia and clinical signs: days
- Effusions: 1-3 weeks
  - If present longer might need dose increase
- Bilirubinaemia: rapidly (<14 days)
- Globulins can spike ~25%
  - High protein effusions reabsorbed
- Anaemia: few weeks to resolve
- AGP should normalise before globulins
- Hyperglobulinaemia: slowest to resolve (median ~ 60 days)



# Adverse effects

- Elevated ALT in 1/3 cats (GS>rem)
- Elevated ALP less common (8%)
- Eosinophilia/lymphocytosis

Liver enzyme elevations do not seem clinically important or require treatment – SAME prescribed?  
 - Consider caregiver burden and more medications

## HAEMATOLOGY

ALERT	TEST	RESULT	UNITS	REF.INTERVAL	
	RBC	10.01	10 <sup>12</sup> /L	7.12 - 11.46	
	Haematocrit	0.471	l/L	0.282 - 0.527	
	Haemoglobin	14.9	g/dL	10.3 - 16.2	
	MCV	47.1	fL	39.0 - 56.0	
	MCH	14.9	pg	12.6 - 16.5	
	MCHC	31.6	g/dL	28.5 - 37.8	
	Reticulocytes	17.0	10 <sup>9</sup> /L	<=50.0	
	Reticulocyte Haemoglobin	17.9	pg	15.3 - 22.9	
	WBC	11.2	10 <sup>9</sup> /L	3.9 - 19.0	
	% Neutrophils	31.7	%		
	% Lymphocytes	62.6	%		
	% Monocytes	1.1	%		
	% Eosinophils	4.5	%		
	% Basophils	0.1	%		
	Neutrophils	3.55	10 <sup>9</sup> /L	2.62 - 15.17	
High	<b>Lymphocytes</b>	<b>7.01</b>	<b>10<sup>9</sup>/L</b>	<b>0.85 - 5.85</b>	
	Monocytes	0.12	10 <sup>9</sup> /L	0.04 - 0.53	
	Eosinophils	0.50	10 <sup>9</sup> /L	0.09 - 2.18	
	Basophils	0.01	10 <sup>9</sup> /L	0.00 - 0.10	
Low	<b>Platelets</b>	<b>52</b>	<b>10<sup>9</sup>/L</b>	<b>155 - 641</b>	
	*Blood Film Evaluation	No morphological abnormalities detected in red blood cells			

Lymphocytes	42 %	5.8 x10 <sup>9</sup> /L	1.5 - 7.0
Monocytes	H 7 %	1.0 x10 <sup>9</sup> /L	0.0 - 0.8
Eosinophils	H 16 %	2.2 x10 <sup>9</sup> /L	0.0 - 1.5
Basophils	0 %	0.0 x10 <sup>9</sup> /L	

# Additional UK study (Royal Vet College)



STANDARD ARTICLE | Open Access |

**Thirty-two cats with effusive or non-effusive feline infectious peritonitis treated with a combination of remdesivir and GS-441524**

Jodie Green , Harriet Syme, Sarah Tayler

First published: 04 July 2023 | <https://doi.org/10.1111/jvim.16804> | Citations: 3

- 87.5% clinical response to treatment
- 26/32 alive at end of 12-week treatment
- 6/32 died (most often within 3 days of therapy)
- Minimal adverse effects

# Positive outcomes



Think about compliance: helping caregivers



# Don't just give antivirals

## Pain management

Pleuritis and peritonitis are painful!

- NSAIDs
- Opioids

## Fluid therapy

Monitor BP  
Pressors if needed

Nursing care and stress management (home and clinic)



## Nutrition and body condition

Mirtazapine  
Feeding tubes  
Digestible diet  
Monitoring weight and BCS

## Antiemetics

Maropitant  
Ondansetron

## Specific ocular and neuro medications

Antiseizure meds  
Topical steroids  
Corticosteroids?

Owner support

- Compliance
- Open communication

# Compounded remdesivir & GS-441524

Received: 30 October 2022 | Accepted: 27 June 2023  
DOI: 10.1111/jvim.16803

STANDARD ARTICLE

Journal of Veterinary Internal Medicine **ACVIM**  
American College of Veterinary Internal Medicine

## Outcomes of treatment of cats with feline infectious peritonitis using parenterally administered remdesivir without transition to orally administered GS-441524

Sally J. Coggins<sup>1</sup> | Jacqui M. Norris<sup>1</sup> | Richard Malik<sup>1</sup>  
Evelyn J. Hall<sup>1</sup> | Benjamin Kimble<sup>1</sup> | Mary F. Thompson<sup>1</sup>

The University of Sydney - AUSTRALIA

86%

Journal of Feline Medicine and Surgery

isfm

Impact Factor: 1.7 / 5-Year Impact Factor: 1.9

Open access | Research article | First published online September 21, 2023

Retrospective study and outcome of 307 cats with feline infectious peritonitis treated with parenterally administered remdesivir and GS-441524

Samantha S Taylor, Sally Coggins, and Séverine Tasker

<https://doi.org/10.1177/1098612X231194460>

Multi-institutional collaboration – UK & AUSTRALIA

84.4%

Received: 24 November 2022 | Accepted: 27 June 2023  
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STANDARD ARTICLE

Journal of Veterinary Internal Medicine **ACVIM**  
American College of Veterinary Internal Medicine

## Thirty-two cats with effusive or non-effusive feline infectious peritonitis treated with a combination of remdesivir and GS-441524

Jodie Green | Harriet Syme | Sarah Tayler

The Royal Veterinary College - UK

81.3%

Prospective studies also underway in many academic institutions in Europe

The University of Munich, GERMANY

The University of Zurich, SWITZERLAND


The University of Bern, SWITZERLAND



# Compounded GS-441524 &/or RDV

Article

# Unlicensed GS-441524-Like Antiviral Therapy Can Be Effective for at-Home Treatment of Feline Infectious Peritonitis

Sarah Jones <sup>1</sup>, Wendy Novicoff <sup>2</sup>, Julie Nadeau <sup>3</sup> and Samantha Evans <sup>1,\*</sup> 

**Abstract:** The goal of this study was to formally evaluate the administration of unlicensed, crowd-sourced antiviral GS-441524-like therapy for cats suspected to have feline infectious peritonitis (FIP), a previously fatal disease. Members of a large social media support and GS-441524-like drug distribution group were surveyed via the Internet. The survey was targeted toward owners who had treated their cats for at least 12 weeks with unlicensed GS-441524-like drugs. Of the 393 analyzed surveys which met inclusion criteria, 73.7% of owners utilizing this therapy were from the United States. Only 8.7% of owners reported receiving help from their veterinarian in administering the treatment to their cat. The mean cost of treatment was USD 4920. A majority of owners (88.2%) reported noticeable improvement in clinical signs within one week of initiating therapy. **At the time of the survey, 96.7% (380 cats) were alive**, with 54.0% of them considered cured and another 43.3% being monitored in the 12-week observation period. A total of 12.7% of the cats suffered a relapse of clinical signs of FIP, and 3.3% of the cats died despite GS-441524-like therapy. Reported complications were mostly related to owner administration of subcutaneous injections of the acidic GS-441525-like therapy, such as vocalization, pain, struggling, and injection-site wounds. Limitations of this study include a retrospective design, bias in case selection, reliance on owner-reported data, and inability to confirm the contents of unlicensed pharmaceuticals; however, important lessons can be learned from the experiences of these owners. While unconventional, and certainly not free from medical and legal risks, unlicensed, at-home GS-441524-like therapy, according to owner reports, can apparently offer benefits in the treatment of cats suspected of FIP.

**Table 3.** How cat owners first learned about the existence of GS-441524 therapy for FIP. Owners were able to list more than one source, so the total number of responses is higher than the total number of respondents.

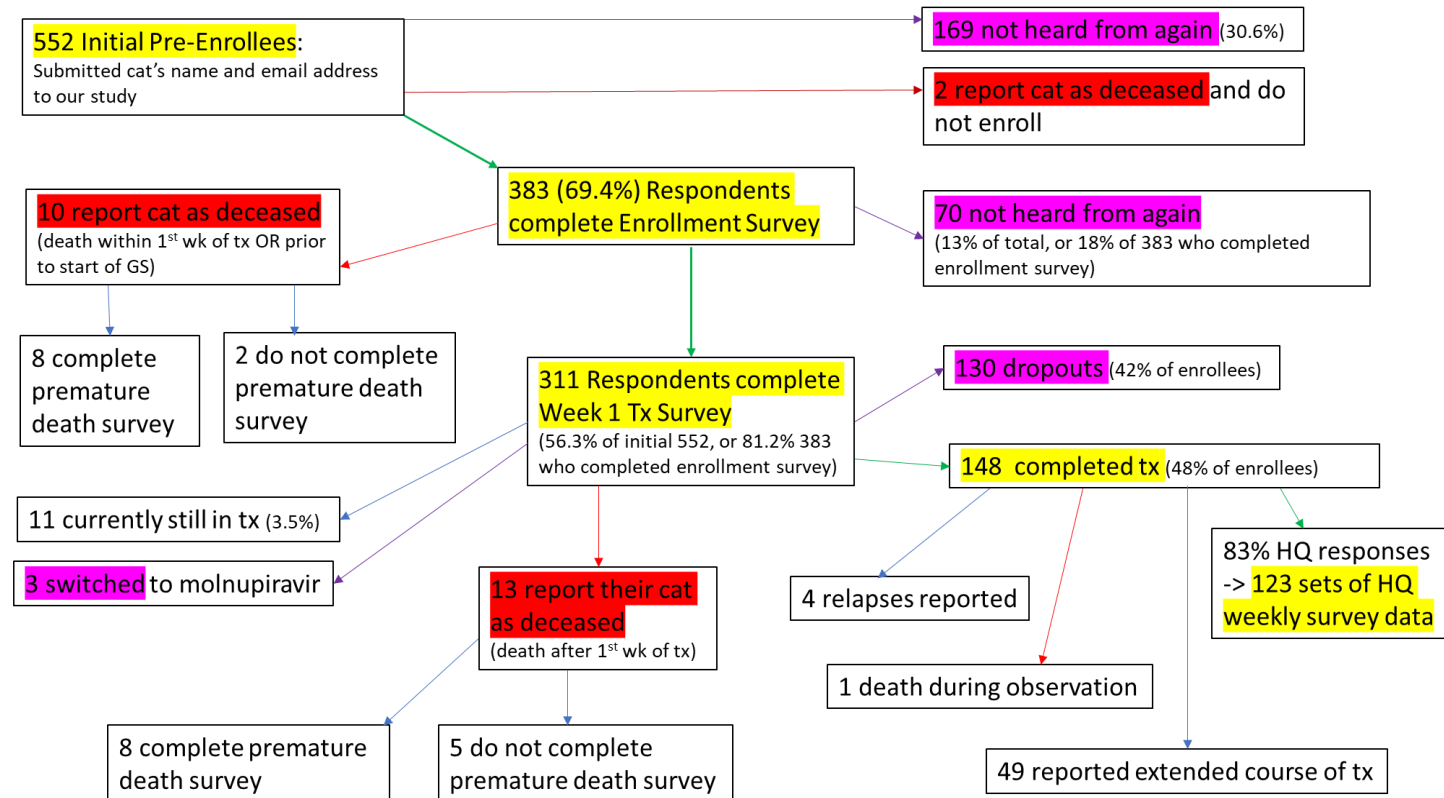
Method	Count of Responses	Percent
Website, not Facebook	119	30.36
Facebook	91	23.21
Veterinarian (directly)	57	14.54
Friend	56	14.29
Veterinarian (indirectly)	47	11.99
Rescue	12	3.06
Breeder	8	2.04
Conference	2	0.51



# 2022 Prospective Study (unpublished)

Out of 179 cats with complete outcome data at 6 months:

- **149 (83%) considered cured**
- **25 (14%) deceased**
- **5 (3%) relapsed**



## Unlicensed antiviral products used for the at-home treatment of feline infectious peritonitis contain GS-441524 at significantly different amounts than advertised

Alycia M. Kent MPH , Su Guan PhD, Nicole Jacque, Wendy Novicoff PhD, and Samantha J. M. Evans DVM, PhD, DACVP

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### OBJECTIVE

To analyze the content of unlicensed GS-441524-like products being used as a largely successful at-home treatment for cats suspected to have FIP. The remdesivir content and pH were also measured.

### SAMPLE

127 injectable and oral samples from 30 of the most popular brands of black market producers.

### METHODS

Unlicensed GS-441524-like products were procured through donations and tested for GS-441524 and remdesivir content by liquid chromatography with tandem mass spectrometry. A pH meter measured the pH of injectable samples.

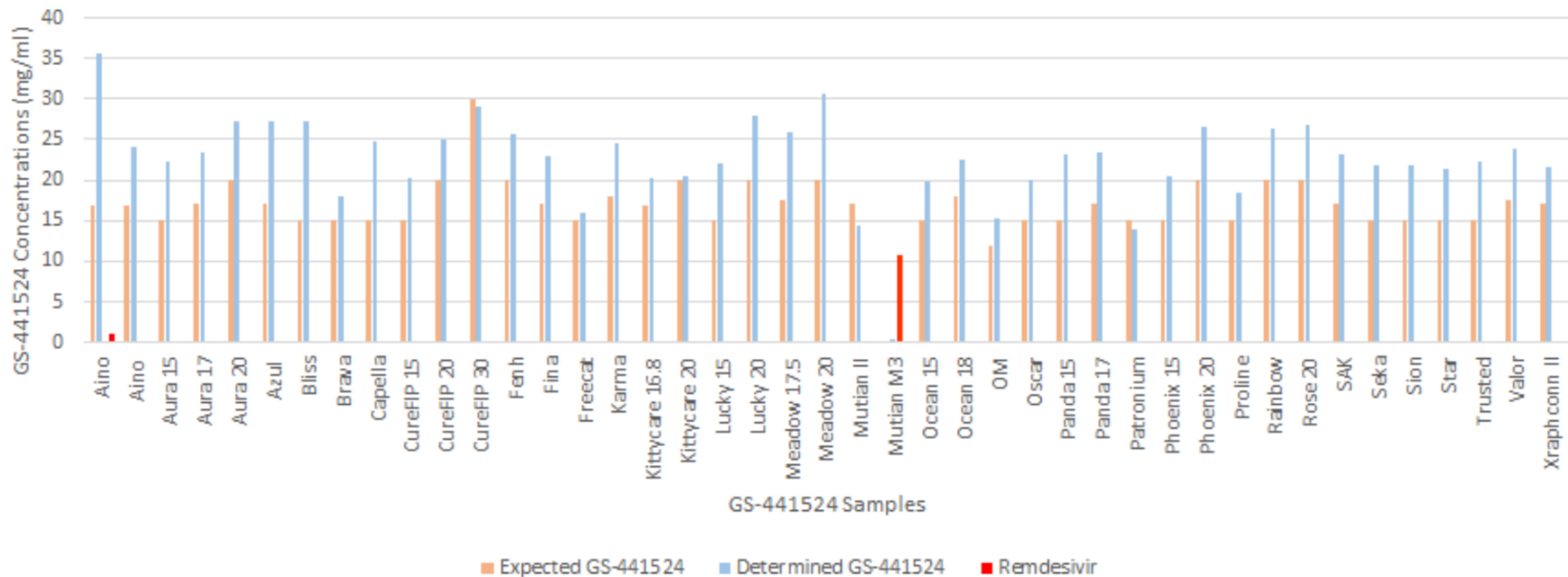
### RESULTS

Of the 87 injectable formulations, 95% contained more (on average 39% more) GS-441524 than expected based on the producer's marketed concentrations. The average pH (1.30 pH) was well below the physiologic pH conditions recommended for SC injections. The oral formulations were more variable, with 43% containing more GS-441524 (on average 75% more) than expected and 58% containing less (on average 39% less) than the expected content. There was minimal variability in GS-441524 content between replicate samples in the injectables formulations (measured by coefficient of variation). One injectable and 2 oral samples additionally contained remdesivir.

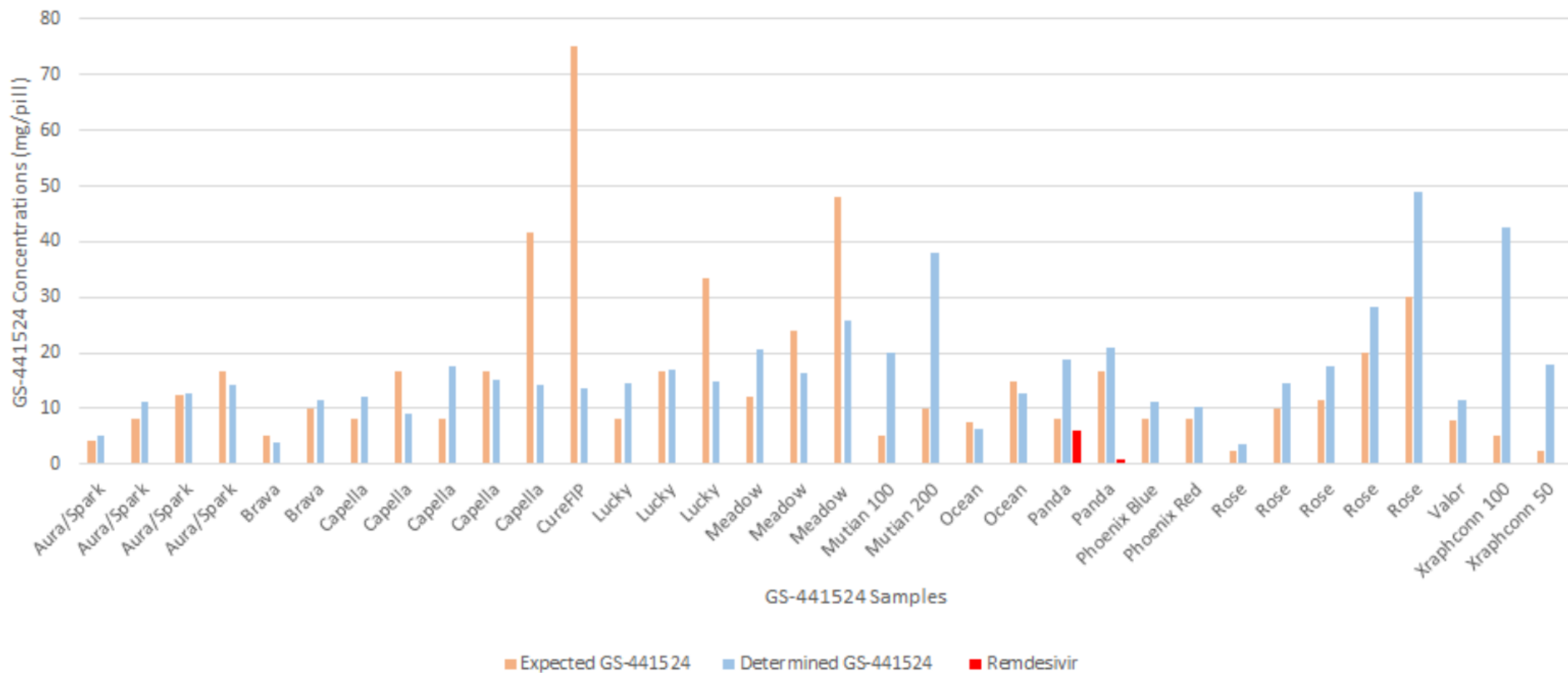
### CLINICAL RELEVANCE

All unlicensed products used for the at-home treatment of FIP that we tested contain GS-441524. The injectables generally contain significantly more drug than advertised at a below-physiologic pH. Unlicensed oral products vary more widely in drug content and suffer from unconventional dosing and labeling. These data should highlight the need for regulation of these products and the development of legal pathways to procure GS-441524.

## Expected and Determined GS-441524 Concentrations (Injectables)



## Expected and Determined GS-441524 Concentrations (Oral Formulation)



# Labeling on unlicensed oral products

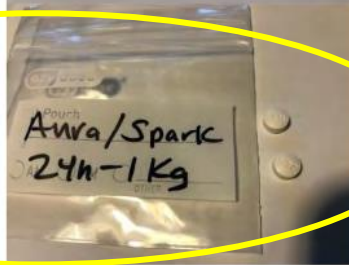
Sample Brand

Photo

Aura/Spark 12h-1kg



Aura/Spark 24h-1kg



Aura/Spark 12h-3kg



Aura/Spark 24h-2kg



**Supplementary Table S2**—A complete list of the presumed and actual amount of GS-441524 in the oral formulations. Samples were procured from different donors across the world. A presumed concentration was calculated based on treatment instructions, the recommended 5 mg/kg/day dosage, and the approximately 50% bioavailability of GS-441524.

Product	Presumed GS-441524 Content (mg/pill)	Actual GS-441524 (mg/pill)
Aura/Spark 12h-1kg	5	5.1
Aura/Spark 12h-3kg	15	12.9
Aura/Spark 24h-1kg	10	11.2
Aura/Spark 24h-2kg	20	14.2
Brava 5mg	10	3.9
Brava 10mg	20	11.4
Capella 1kg	10	12.1
Capella 1kg	10	17.6
Capella 2kg	20	9.0
Capella 2kg	20	15.1
Capella 5kg	50	14.2
CureFIP 2.5-4kg	75	13.7
Lucky 1kg	10	12.2
Lucky 1kg	10	17.2
Lucky 2kg	20	15.0
Lucky 2kg	20	19.3
Lucky 4kg	40	15.0
Meadow 12	12	20.5
Meadow 24	24	16.6
Meadow 24	24	16.3
Meadow 48	48	31.3
Meadow 48	48	20.2
Mutian 10mg	20	38.1
Mutian 5mg	10	17.6
Mutian 5mg	10	22.2



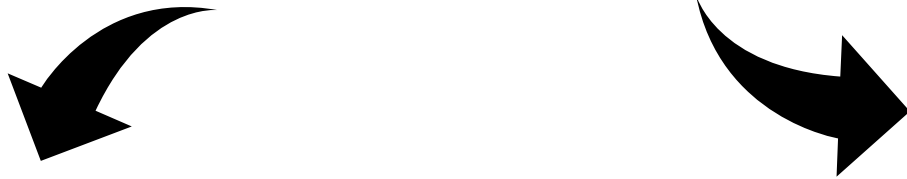
# Labeling on unlicensed oral products

- Often assume ~50% bioavailability and labeled with the amount of the drug which is expected to be absorbed
- Often labeled on a per-kg of cat basis, with an unknown target dosage

**Oral dosages CAN NOT be directly translated from black market products to this new product!**



# Unlicensed sources of GS-441524 have produced GS-441524 uroliths



Uroliths composed of antiviral compound GS-441524 in 2 cats undergoing treatment for feline infectious peritonitis

[Marissa Allinder](#),<sup>1</sup> [Beth Tynan](#),<sup>2</sup> [Cara Martin](#),<sup>3</sup> [Amelia Furbish](#),<sup>4</sup> [Glenn Austin](#),<sup>5</sup> [Joe Bartges](#),<sup>3</sup> and [Bianca N. Lourenço](#)<sup>3</sup>



College of Veterinary Medicine

College of Veterinary Medicine  
Minnesota Urolith Center

## Mysterious New Stone Type In Cats

August 2023

Figure 2  
FT-IR Spectroscopy of  
patient urolith and GS-441524 Reference

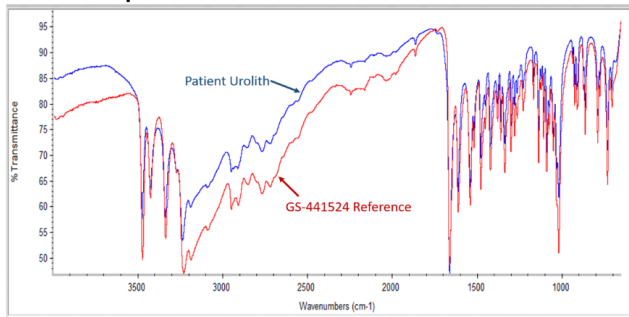


Figure 1 - Feline Uroliths

There are zero reports of uroliths with BOVA remdesivir or GS-441524

# OK, but is this really legal...?

The image is a screenshot of a webpage from the U.S. Food & Drug Administration (FDA). The page features a dark blue header with the FDA logo and the text 'U.S. FOOD & DRUG ADMINISTRATION'. To the right of the header are search and menu buttons. Below the header is a breadcrumb trail: 'Home / Animal & Veterinary / News & Events / CVM Updates / FDA Announces Position on Use of Compounded GS-441524 to Treat FIP'. The main heading of the article is 'FDA Announces Position on Use of Compounded GS-441524 to Treat FIP'. Below the heading are social media sharing options for Facebook, X, LinkedIn, Email, and Print. The article is dated 'May 10, 2024' and is categorized under 'CVM Updates'. The main text states: 'Because no FDA approved drug is available to treat Feline Infectious Peritonitis in cats, the U.S. Food and Drug Administration does not intend to enforce new animal drug approval requirements for products compounded from GS-441524, when prescribed by a veterinarian for a specific cat patient for the treatment of Feline Infectious Peritonitis under the conditions listed in [Guidance for Industry \(GFI\) #256 Compounding Animal Drugs from Bulk Drug Substances](#).' On the right side, there is a note: 'Content current as of: 05/10/2024'.

FDA U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Home / Animal & Veterinary / News & Events / CVM Updates / FDA Announces Position on Use of Compounded GS-441524 to Treat FIP

## FDA Announces Position on Use of Compounded GS-441524 to Treat FIP

Share Post LinkedIn Email Print

May 10, 2024

CVM Updates

Because no FDA approved drug is available to treat Feline Infectious Peritonitis in cats, the U.S. Food and Drug Administration does not intend to enforce new animal drug approval requirements for products compounded from GS-441524, when prescribed by a veterinarian for a specific cat patient for the treatment of Feline Infectious Peritonitis under the conditions listed in [Guidance for Industry \(GFI\) #256 Compounding Animal Drugs from Bulk Drug Substances](#).

Content current as of: 05/10/2024

# What about office stock?

## List of Bulk Drug Substances for Office Stock Drugs for Use in Non-Producing Animals

## Bulk Drug Substances Currently



[List of Bulk Drug Substances for Compounding Drugs for Use in F or Free-Ranging Wildlife Species](#)

[List of Bulk Drug Substances for Compounding Office Stock Drugs Producing Animals](#)

[Bulk Drug Substances Reviewed and Not Listed](#)

These bulk drug substances are currently being evaluated by FDA. **are being completed, the agency generally intends to refrain from taking enforcement action** when these bulk drug substances are used to compound a finished drug in a state-licensed pharmacy or federal facility or by a state-licensed veterinarian as described in the initial nomination.

The screenshot shows a document page on Regulations.gov. At the top, the site logo 'Regulations.gov' and tagline 'Your Voice in Federal Decision Making' are visible, along with a 'SUPPORT' button. Below the header, there is a navigation breadcrumb '< View Docket' and a 'Share' button. The main heading is 'Nomination from Samantha Evans', with a sub-heading 'Posted by the Food and Drug Administration on May 12, 2024'. A 'Document Details' tab is active. Below this, the document ID 'FDA-2018-N-4626-0953' and tracking number 'lw1-8q13-8mps' are listed. A 'Comment' section contains a text box with a pre-filled nomination for GS-441524, an antiviral for feline infectious peritonitis (FIP). An 'Attachments' section shows one file: 'Animal-Drug-Bulk-Drug-Substance-Nomination-2 GS-441524 Evans Jacque', with a 'Download' button and a 'More Information' dropdown.

# Bottom Line

- Compounding of GS-441524 is not legal, but expressly "allowable" by the FDA under GFI #256's enforcement discretion
- GS-441524 is under review as a substance approved for office stock, and can be ordered and kept as office stock in the meantime
- GS-441524 remains under patent until 2029, but there have been no efforts to stop compounding pharmacies from producing it in other countries

**It is legal for a DVM in the USA to prescribe GS-441524 to a cat with suspected FIP through a licensed compounding pharmacy**



# Register for parts 2 & 3

Scan the QR codes provided or go to [epicurpharma.com/webinars](https://epicurpharma.com/webinars)



## FIP Diagnosis: Now we can treat it, how sure do we need to be?

*Dr. Samantha Taylor, BVetMed(Hons), CertSAM, DipECVIM-CA, MANZCVS, FRCVS*

**June 20, 2024 | 5-6 pm ET**

**RACE-Approved CE Credit Hours: 1**



## Legal FIP Treatment in the USA: Learn how to start treating FIP cases in your practice.

*Dr. Sally Coggins, BVSc (Hons I) MANZCVS (Feline Medicine), PhD Candidate (Science)*

**June 27, 2024 | 8-9 pm ET**

**RACE-Approved CE Credit Hours: 1**



*Sponsored by*



# FIP Resources for Veterinarians

Feline Infectious Peritonitis (FIP) is a disease that continues to perplex and challenge veterinary professionals worldwide. With no legal access to treatment for veterinarians in the U.S., FIP was often seen as a death sentence for cats. However, recent advancements in antiviral therapy have shown that effective treatment for Feline Infectious Peritonitis (FIP) is now a reality.

[Learn About Stokes Pharmacy's Treatment](#)



*Treatment protocols & advice resource written by:*

*Dr. Stephanie Sorrell, Prof. Séverine Tasker, Dr. Sam Taylor, Dr. Emi Barker, and Prof. Danielle Gunn-Moore*

Treatment for FIP in Cats will be available **June 1st** in the US!

# FIP Advice link

Advice support for vets is provided by Dr. Samantha Taylor

<https://bit.ly/FIP-Advice>



Simply follow the link and fill out your specific case details in the form and Samantha will be available to assist you.



# QUESTIONS?

Sally Coggins: [sally.coggins@sydney.edu.au](mailto:sally.coggins@sydney.edu.au)

Sam Taylor: [Thecatspecialistuk@gmail.com](mailto:Thecatspecialistuk@gmail.com)

Sam Evans: [samantha.evans@colostate.edu](mailto:samantha.evans@colostate.edu)



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BOVA



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