



Review Article: Pharmacology GS-441524, Source, Pharmacodynamics, Pharmacokinetics, And Efficacy in Treatment of Feline Infectious Peritonitis

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Abstract

Feline infectious peritonitis (FIP) is a historically fatal disease caused by a virulent mutation of feline coronavirus, characterized by systemic inflammation, immune dysregulation, and high mortality in untreated cats. The emergence of GS-441524, an adenosine nucleoside analog targeting viral RNA-dependent RNA polymerase (RdRp), has transformed the therapeutic outlook for FIP and represents a significant shift from palliative management to effective antiviral intervention. This review aims to synthesize current evidence on the pharmacology, therapeutic efficacy, safety, accessibility, and regulatory considerations surrounding GS-441524, while identifying remaining knowledge gaps and priorities for future research. GS-441524 demonstrates favorable pharmacokinetic and pharmacodynamic properties, including efficient cellular activation, strong antiviral potency, and adequate tissue distribution, with high clinical success rates across effusive, non-effusive, ocular, and neurological forms of FIP. Its safety profile is generally acceptable, though injection-site reactions, limited penetration into protected compartments, and variability in unregulated formulations present ongoing challenges. Regulatory inaccessibility remains a major barrier in many countries, driving reliance on black-market products and underscoring the need for evidence-based veterinary approval pathways. Overall, GS-441524 represents a highly effective antiviral agent with substantial potential to redefine FIP treatment standards. Continued research is needed to clarify resistance mechanisms, optimize dosing strategies, improve pharmaceutical standardization, and advance regulatory acceptance to ensure safe, reliable, and equitable access for feline patients.

Keywords: *Antiviral Therapy, Feline Coronavirus, Feline Infectious Peritonitis, GS-441524, Pharmacokinetics.*

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Introduction

Feline infectious peritonitis (FIP) is a progressive and highly fatal systemic disorder in cats, arising from a virulent mutation of feline coronavirus (FCoV) that confers tropism for monocytes and macrophages (Pedersen et al., 2019; Thayer et al., 2022). Although most FCoV infections manifest as asymptomatic or mild enteric disease, the transition to the pathogenic FIP virus (FIPV)

precipitates a profound dysregulation of the host immune response, culminating in disseminated pyogranulomatous inflammation. The disease predominantly affects young or immunologically compromised individuals and remains challenging to diagnose antemortem, particularly in non-effusive presentations, owing to the lack of definitive clinical or biomarker-based criteria (Solikhah et al., 2024).

Despite being recognized for over six decades, FIP continues to represent a global clinical and welfare concern within companion animal medicine. The ubiquitous nature of FCoV in multi cat environments, combined with the historically near-universal lethality of FIP, underscores its long-standing status as one of the most consequential infectious diseases in felines. Diagnostic ambiguity, heterogeneity in clinical manifestations, and the absence of curative therapies for much of its documented history have further contributed to delayed intervention and poor prognostic outcomes across diverse veterinary contexts (Thayer et al., 2022).

Recent developments in antiviral therapeutics have reshaped the therapeutic paradigm for FIP, with GS-441524 emerging as the most promising candidate to date. As a nucleoside analog and primary active metabolite of remdesivir, GS-441524 exerts its antiviral activity through inhibition of coronavirus RNA-dependent RNA polymerase, demonstrating substantial clinical benefit in preliminary and field studies. Nevertheless, critical gaps persist regarding its pharmacokinetic and pharmacodynamic parameters, optimal dosing regimens across disease phenotypes, tissue distribution especially within the central nervous system and its comparative therapeutic performance relative to alternative antiviral agents. Accordingly, this review aims to critically appraise current evidence on the pharmacology and therapeutic efficacy of GS-441524 in the management of FIP, while delineating unresolved questions that warrant further systematic investigation.

Review

Feline Coronavirus and Pathogenesis of Feline Infectious Peritonitis

Feline coronavirus (FCoV) is a highly contagious, enveloped, positive-sense single-stranded RNA virus belonging to the genus Alphacoronavirus and family Coronaviridae (Takano et al., 2019). The virus is widely prevalent in domestic cats, particularly in high-density environments such as catteries, shelters, and multi-cat households where fecal–oral transmission is readily facilitated (Thayer et al., 2022; Tasker et al., 2023). Primary infection is most often subclinical or results in mild, self-limiting enteritis associated with the avirulent feline enteric coronavirus (FECV).

FCoV comprises two major biotypes—FECV and the pathogenic feline infectious peritonitis virus (FIPV). FECV is restricted to intestinal epithelial cells, whereas FIPV acquires the capacity to replicate within circulating monocytes and macrophages, driving systemic dissemination and immune-mediated disease (Thayer et al., 2022; Gülersoy & Maden, 2021). This shift in tropism is associated with spontaneous mutations, particularly in the spike (S) gene that governs receptor binding and viral entry, enabling escape from intestinal confinement (Jaimes & Whittaker, 2018). Structurally, FCoV is an 80–120 nm virion with a ~29 kb positive-sense RNA genome enclosed in a helical nucleocapsid and a host-derived lipid envelope containing membrane (M), envelope (E), and spike (S) proteins. Two serotypes, Type I and Type II, are recognized, with the latter believed to originate from recombination with canine coronavirus (Takano et al., 2019).

Replication of FIPV in monocytes and macrophages underlies its pathogenesis. Infected cells upregulate pro-inflammatory cytokines such as TNF- α and IL-1 β and express increased levels of adhesion molecules that promote vascular adherence. They also release matrix metalloproteinase-9 (MMP-9), which disrupts endothelial junctions, and vascular endothelial growth factor (VEGF), which increases vascular permeability. These mechanisms together drive the perivascular inflammation and effusion formation characteristic of feline infectious peritonitis (Garrido-

Andersson & Vizi, 2022).

Clinically, FIP occurs in effusive, non-effusive, and mixed forms. The effusive form presents with protein-rich abdominal or thoracic effusions, whereas the non-effusive form manifests as granulomatous lesions in parenchymal organs, including the liver, kidneys, eyes, and central nervous system. Clinical signs such as anorexia, chronic weight loss, persistent fever, and lethargy are nonspecific, and laboratory abnormalities including lymphopenia, neutrophilia, anemia, hyperproteinemia, and hyperglobulinemia lack diagnostic specificity (Moyadee et al., 2025).

Epidemiologically, FIP is most frequently diagnosed in cats younger than 2–3 years or older than 10 years, particularly those exposed to stress or immunosuppressive conditions. Although the proportion of FCoV-infected cats that develop FIP is relatively low ($\approx 10\%$), untreated cases exhibit mortality rates approaching 90% (Gülersoy & Maden, 2021). Historically, management relied on palliative care using immunosuppressive agents such as glucocorticoids or cytotoxic drugs, with rare instances of remission attributed primarily to misdiagnosis or exceptional host responses (Garrido-Andersson & Vizi, 2022). Recent therapeutic advances, particularly the development of nucleoside analogs including GS-441524, remdesivir, and molnupiravir, have substantially improved treatment prospects and challenged the long-held fatal prognosis of the disease (Moyadee et al., 2025).

Characteristic GS-441524

GS-441524 is a nucleoside analog developed by Gilead Sciences Inc. and represents a major advancement in the therapeutic management of feline infectious peritonitis (FIP), a disease historically associated with near-universal mortality in cats infected with the virulent biotype of feline coronavirus (FCoV) (Pedersen et al., 2019). Chemically, GS-441524 is a 1'-cyano-substituted adenine C-nucleoside ribose analog, characterized by a C-glycosidic bond between the ribose moiety and the heterocyclic base rather than the conventional N-glycosidic linkage found in standard nucleosides (Murphy et al., 2018). This structural modification enhances its antiviral potency and has demonstrated activity against multiple RNA viruses, including SARS-CoV, African swine fever virus (ASFV), and feline coronavirus (Huang et al., 2021).

GS-441524 is the parent nucleoside of remdesivir (GS-5734), an antiviral originally developed for Ebola virus and subsequently used in the treatment of COVID-19. Following administration, remdesivir is metabolized into GS-441524, which undergoes intracellular phosphorylation to form the active triphosphate metabolite GS-443902. This metabolite acts as a competitive substrate for viral RNA-dependent RNA polymerase (RdRp), leading to mis-incorporation into nascent viral RNA and premature chain termination during RNA synthesis (Leegwater et al., 2022; Kim & Oh, 2025). Structural and mechanistic studies have further underscored the relevance of synthesizing RNA containing GS-441524 as a precursor for evaluating polymerase–drug interactions in RNA viruses (Moorthy et al., 2021).

Despite its therapeutic potential, GS-441524 was not developed further by Gilead Sciences for veterinary approval, even as remdesivir progressed through regulatory pathways for human use. The absence of formal approval has contributed to its widespread off-label administration and emergence within black-market distribution channels among pet owners seeking effective treatment for FIP (Georgopoulou et al., 2024; Sase et al., 2024). This situation highlights an ongoing need for regulatory clarity, controlled clinical evaluation, and official inclusion of GS-441524 within veterinary therapeutic frameworks.

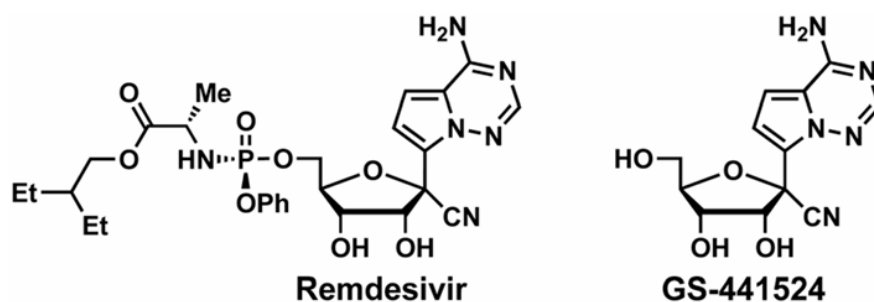


Fig 1. Chemical structure of remdesivir and GS- 441524 (Moorthy et al., 2021)

Mechanism of Action

Once administered, GS-441524 is taken up by host cells and undergoes sequential phosphorylation by intracellular kinases, first to its monophosphate derivative and subsequently to its active triphosphate form. The resulting nucleoside triphosphate analog competes with endogenous adenosine triphosphate (ATP) for incorporation into the nascent viral RNA chain during replication. When incorporated by the viral RNA-dependent RNA polymerase (RdRp), the analog induces premature termination of RNA elongation, effectively halting viral genome synthesis and suppressing viral replication (Garrido-Andersson & Vizi, 2022; Solikhah et al., 2024).

Pharmacokinetics of GS-441524

GS-441524 demonstrates pharmacokinetic characteristics that support its use as a primary antiviral agent for feline infectious peritonitis (FIP). Following administration, the compound is rapidly absorbed and widely distributed across tissues, with renal excretion serving as its principal elimination pathway. In a pharmacokinetic assessment by Coggins et al. (2025), cats receiving a single intravenous dose of 15 mg/kg exhibited a peak plasma concentration (C_{max}) of 2,632 ng/mL at 1 hour (T_{max}), and an elimination half-life (t_{1/2}) of approximately 5.14 hours. These parameters indicate that once-daily dosing can maintain therapeutically relevant systemic exposure in most clinical contexts. Notably, GS-441524 also distributes efficiently into inflamed tissues and body cavity effusions, a property advantageous for managing effusive forms of FIP (Solikhah et al., 2024).

Pharmacokinetic limitations become more pronounced in cases involving neurological or ocular involvement. Murphy et al. (2018) reported that subcutaneous administration of 10 mg/kg resulted in only 7–21% of plasma concentrations being detected in cerebrospinal fluid and aqueous humor, reflecting restricted penetration across the blood–brain and blood–ocular barriers. Consequently, higher dosing regimens (e.g., 8–10 mg/kg SC every 24 hours) are often required to attain adequate antiviral concentrations within these protected compartments.

GS-441524 is also the principal circulating metabolite of remdesivir, and comparisons between the two compounds highlight important pharmacokinetic distinctions. Remdesivir exhibits a very short plasma half-life (~0.48 hours), whereas GS-441524 demonstrates substantially longer persistence ($t_{1/2}$ ~26.6 hours in humans), resulting in more sustained antiviral exposure. Approximately 49% of administered remdesivir is ultimately cleared as GS-441524, and its elimination is significantly influenced by renal function, with reduced clearance documented in individuals with impaired estimated glomerular filtration rates (eGFR). Although feline-specific data remain limited, these findings emphasize the importance of monitoring renal function during prolonged GS-441524 therapy, given its predominantly renal route of elimination (Leegwater et al., 2022).

Pharmacodynamics of GS-441524

GS-441524 is a nucleoside analog that exerts potent antiviral activity through selective inhibition of the viral RNA-dependent RNA polymerase (RdRp), the essential enzyme mediating replication and transcription of the feline coronavirus (FCoV) genome. RdRp possesses a conserved “cupped right-hand” structural architecture composed of finger, palm, and thumb subdomains, with catalytic motifs (A–G) located within the palm region that coordinate divalent metal ions to facilitate phosphodiester bond formation during RNA chain elongation (Venkataraman, Prasad & Selvarajan, 2018). Following intracellular phosphorylation to its active triphosphate form, GS-441524 competes with adenosine triphosphate (ATP) for incorporation into nascent viral RNA. Mis-incorporation leads to premature termination of RNA synthesis, effectively arresting viral genome replication (Garrido-Andersson & Vizi, 2022; Solikhah et al., 2024).

The significance of RdRp as a therapeutic target is underscored by its intrinsic lack of proofreading capability, which contributes to the high mutation rates characteristic of RNA viruses, including FCoV. Additionally, RdRp is capable of mediating recombination via template switching—an evolutionary mechanism implicated in the transition of feline enteric coronavirus (FECV) to its virulent counterpart, feline infectious peritonitis virus (FIPV). Targeting this enzyme thereby addresses both viral replication and evolutionary adaptability (Venkataraman et al., 2018).

Beyond direct antiviral effects, GS-441524 may exhibit secondary immunomodulatory properties relevant to FIP pathogenesis. Infected macrophages play a central role in driving immune-mediated vasculitis and systemic inflammation. Treatment with GS-441524 has been associated with reduced macrophage activation and downregulation of pro-inflammatory cytokines including TNF- α and IL-1 β , mitigating the pathological inflammatory cascade that characterizes both effusive and non-effusive forms of FIP (Pedersen et al., 2020; Thayer et al., 2022). Through this combined mechanism—targeted inhibition of RdRp and attenuation of dysregulated host immune responses—GS-441524 delivers a multidimensional therapeutic effect in a disease historically regarded as uniformly fatal.

Clinical Application

GS-441524 is administered primarily via subcutaneous (SC) injection or oral formulations. The SC route remains the preferred method due to its consistent therapeutic performance; however, it is frequently associated with localized adverse effects, including pain, swelling, and injection-site inflammation attributable to the acidic pH of the injectable preparation. Chronic local inflammation has raised theoretical concerns regarding feline injection-site sarcoma (FISS), with rare cases of tumorigenesis reported in association with repeated injections (Krentz et al., 2021; Porcellato et al., 2017). To improve practicality and owner compliance, oral formulations—such as the commercially available Mutian® Xraphconn—have been developed and have shown promising clinical performance (Georgopoulou et al., 2024).

Dosing regimens are tailored to the clinical phenotype of feline infectious peritonitis. Standard dosing for non-ocular, non-neurological presentations ranges from 4–6 mg/kg SC every 24 hours. Cats with ocular involvement typically require 8 mg/kg SC q24h, whereas neurological cases necessitate higher doses of approximately 10 mg/kg SC q24h to overcome limited penetration across the blood–brain and blood–ocular barriers. Oral formulations generally require higher weight-adjusted doses (10–20 mg/kg q24h), with variability dependent on product-specific bioavailability (Pedersen, 2022). Treatment is typically continued for 12 weeks, though some cats may achieve clinical remission within 6–10 weeks. Failure to respond to SC doses exceeding 15 mg/kg/day is considered a potential indicator of antiviral resistance, warranting reassessment of therapeutic strategy (Pedersen, 2022).

Efficacy and Safety of GS-441524

GS-441524 has emerged as one of the most effective antiviral agents for the treatment of feline

infectious peritonitis (FIP), demonstrating consistently high therapeutic success across both effusive and non-effusive disease forms. In a pivotal field study, Pedersen et al. (2020) reported that 80–90% of treated cats exhibited rapid clinical improvement, with restoration of appetite, increased activity, and resolution of pyrexia typically observed within 24–36 hours of initiating therapy. Comparable outcomes were documented by Dickinson et al. (2020), who noted high survival rates and durable remission when treatment was administered early and maintained for the recommended duration. Collectively, these findings underscore the robust clinical efficacy of GS-441524 in reversing the hallmark pathological manifestations of FIP.

The compound also demonstrates a broad safety margin. Georgopoulou et al. (2024) reported that GS-441524 is non-toxic at concentrations up to 100 μ M and effectively inhibits viral replication at concentrations as low as 1 μ M, indicating a wide therapeutic index. These data support its suitability as a long-term antiviral agent, particularly in the context of FIP treatment protocols that often span 12 weeks or longer.

Despite its therapeutic promise, certain limitations related to administration and tolerability remain. Subcutaneous injection is the most common route of delivery and provides reliable systemic exposure; however, it is frequently associated with local adverse reactions including pain, swelling, and inflammatory responses attributed to the acidic pH of the formulation (Krentz et al., 2021). In rare cases, repeated or chronic injection-site inflammation has raised concerns regarding the potential development of feline injection-site sarcoma (FISS), a malignancy linked to persistent local inflammatory processes (Porcellato et al., 2017). Furthermore, the need for daily injections can strain compliance, particularly in home-care settings, and may compromise treatment consistency or patient welfare.

To mitigate these constraints, oral formulations of GS-441524 have been introduced, offering improved ease of administration and reduced risk of injection-related complications. Mutian® Xraphconn, one of the earliest commercially available oral products, has demonstrated encouraging clinical outcomes, although issues such as variable bioavailability and inconsistent labeling—particularly in unregulated markets—highlight the need for standardized pharmacokinetic validation (Georgopoulou et al., 2024). Regulatory limitations continue to represent a major barrier to broad therapeutic access. GS-441524 remains unapproved in many countries, prompting reliance on unlicensed or black-market sources with uncertain quality control and dosing accuracy. Recent decisions by regulatory authorities in the United Kingdom and Australia to authorize controlled veterinary use mark a significant shift toward formal recognition and may pave the way for more consistent and safe access to GS-441524 worldwide (Sase et al., 2024).

Regulatory and Accessibility

Although GS-441524 has not received official approval from Indonesia’s veterinary regulatory authorities, its clinical use has become increasingly widespread across the country. Field observations and informal reports from practicing veterinarians indicate that several unregistered formulations—such as Basmi FIP and Anti FIP—are readily accessible through unofficial distribution channels, including online marketplaces, private suppliers, and cat owner networks. These products are absent from the regulatory databases of the Indonesian Food and Drug Authority (BPOM) and the Directorate General of Livestock and Animal Health Services (Ditjen PKH), and therefore lack formal authorization for veterinary application.

Despite this absence of regulatory recognition, anecdotal clinical experiences suggest that these unofficial formulations have contributed to notable recovery outcomes in cats with both effusive and non-effusive forms of FIP. Practitioners frequently describe rapid clinical responses, including resolution of pyrexia, restoration of appetite, and improvement in ocular or neurological signs

within a short period following treatment. Although these observations fall outside the scope of controlled clinical trials, their consistency has reinforced the perceived therapeutic value of GS-441524 among Indonesian veterinarians and cat owners.

However, reliance on unregulated products introduces significant risks. The lack of standardized manufacturing processes, quality control, and transparent ingredient labeling raises concerns regarding drug purity, potency, stability, and potential toxicity. Variability in formulation quality may compromise therapeutic outcomes or lead to adverse reactions, especially in a treatment protocol that requires prolonged, precise dosing. The widespread dependence on black-market sources also reflects a regulatory deficit, wherein clinical demand has advanced more rapidly than policy development, leaving veterinarians and owners operating within ethically and legally uncertain boundaries.

These challenges underscore the urgent need for evidence-based regulatory action. National authorities should consider prioritizing scientific evaluation of GS-441524 for veterinary approval, drawing on robust international data as well as accumulating local field evidence. Establishing formal legal pathways for the distribution of quality-assured GS-441524 formulations would enhance treatment safety, safeguard animal welfare, and ensure that veterinarians can provide care in accordance with established legal and professional standards. Such regulatory clarity is essential to reconcile clinical necessity with public health oversight and to prevent continued reliance on unverified and potentially unsafe products.

Conclusion

GS-441524, through its targeted inhibition of RNA-dependent RNA polymerase and favorable pharmacokinetic–pharmacodynamic characteristics, has become the leading antiviral candidate for feline infectious peritonitis (FIP), demonstrating consistently high remission and survival rates across diverse clinical presentations while maintaining a broad therapeutic index and generally acceptable safety profile. However, challenges remain, including limited penetration into protected compartments such as the CNS and ocular tissues, injection-site reactions associated with subcutaneous formulations, and the clinical risks posed by unregulated products in regions where the drug lacks formal approval. To advance its therapeutic utility, future research should prioritize elucidating resistance mechanisms, optimizing dosing strategies for neurological and ocular forms, improving pharmaceutical standardization particularly for oral formulations and accelerating regulatory evaluation to ensure safe, equitable, and evidence-based access to GS-441524 for feline patients worldwide.

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