

## **Frequently Asked Questions About Using GS-441524 (Answers are Dr. Pedersen's word-for-word responses to email questions he has received from patients treating with GS441524)**

\*Please note that these responses were given to individual cat owners by Dr. Pedersen. They are meant as a helpful guide and are not intended as individual veterinary advice. Nor are they intended to act as a replacement for standard veterinary care.

### General questions about administering GS-441524 via injection

What if my cat doesn't respond to GS immediately or his behaviors seems "off" after a few weeks on the drug?

My cat is experiencing "highs and lows" during the treatment protocol. Sometimes she will seem energetic, and other times she will seem lethargic. Is this normal?

What do I do if my cat develops injection-site soreness from using GS? Would lidocaine or anything else help with the soreness?

Is it safe/advisable to continue to give FIO (feline interferon omega) concurrently with GS?

Should my cat continue on prednisone with GS?

My cat is being treated for FIP and I have noticed a change in eye color. Is this caused by the drug?

What is the appropriate dose for cats with ocular/neurological FIP?

What are the chances that I will cure my cat of FIP and he will become re-infected with coronavirus that will again mutate into FIP? Should I treat a cat who is shedding coronavirus?

Should I give vaccinations or spay/neuter my cat while on GS?

What are your thoughts about supplements while on GS?

### Questions about what happens after treatment with GS has ended

My cat has been on GS for several weeks and seems to be doing fine, but his coronavirus antibody titer is still high. Does this mean he is still sick? Should I be concerned?

What if my cat relapses once stopping GS treatment? How will I know? (Question asked for neurologic cat)

Which thermometer should I use to monitor my cat's temperature?

I noticed my cat had a spike in temperature after stopping GS? Has my cat relapsed? We are wondering about adopting another cat after our kitty is done with treatment for FIP. How long should we wait before adopting another kitten? What if the new kitten also underwent treatment for FIP?

Questions about labs during or after treating with GS

My cat is being treated with GS and his lymphocyte count is high. Is this okay?

My cat's labs show elevated levels of SDMA (Symmetric dimethylarginine). Does this indicate kidney damage?

My cat has been on GS for several weeks and there is elevated creatine kinase and phosphorus in the lab reports. Is this a problem?

We are concerned about the seemingly quick increase in BUN and CREA showing in the blood work. Thus, we were wondering if you had any further recommendation, or to just do fluids/diet and hope that kidney disease progression slows, given that he is a young cat and the FIP so far appears to have been successfully treated?

Questions about the oral form of GS

Some labs are producing GS in pill form. Is this form safe/effective?

We are told by the companies producing the oral form to break the dose up and give twice per day. Would you know why this is?

Is there any harm in alternating between the injectable form of GS and the oral form of GS?

General questions about administering GS-441524 via injection

**What if my cat doesn't respond to GS immediately or his behaviors seems "off" after a few weeks on the drug?**

*All that we can do at this point is observe what happens over the next several days and hope for the best. If he is developing a sore at the injection site it is possible that this is the cause of the signs we are seeing. If it is sensitive to touch, it is obviously bothering him. If it is a sore, it will either get worse and possibly become an open wound or quickly get better. If it is a sore, and it becomes an open wound, we will help guide you through the treatment. Although we do not wish for severe injection site reactions, this would be a situation where it would be the better choice.*

**My cat is experiencing "highs and lows" during the treatment protocol. Sometimes she will seem energetic, and other times she will seem lethargic. Is this normal?**

*The most dramatic improvement will be in the first week or two and will become slower after that. Do these cycles correspond with when you give the drugs, i.e., is he less active in the few hours after injections and more active as the time from treatment gets longer? We have noticed that some of our earlier field trial cats seemed get a little depressed for a couple of hours after injections. A higher dose will only make it worse. If she is relapsing it will become apparent and if it is just a reaction to the drug we will have to wait it out and see what happens when the treatment is finished.*

**What do I do if my cat develops injection-site soreness from using GS? Would lidocaine or anything else help with the soreness?**

*We are working on changing the diluent for the drug to decrease the stinging and soreness, but that will probably not come to pass for several months and will only address any problem with the diluent and any effect of the drug itself. Applying lidocaine cream to the area after injection is like locking the barn door after the horses get out. We have also tried using it on injection sites before treatment and the owners that have tried it were not happy with the results and stopped using it.*

**Is it safe/advisable to continue to give FIO (feline interferon omega) concurrently with GS?**

*It will not help and it will not hurt.*

**Should my cat continue on prednisone with GS?**

*No. You can stop the prednisolone after several days. There should be a very rapid response to the GS in a cat with FIP and no other drugs are needed at that point unless there is a definite indication for it.*

**My cat is being treated for FIP and I have noticed a change in eye color. Is this caused by the drug?**

*The change in eye color means that the infection has invaded the iris of the eye. If the drug were working as it usually does, you should see a rapid and progressive improvement and not further spread of the infection. You should also look very closely for any neurological signs such as posterior incoordination and refusal to jump to higher places. The only option is to increase the dosage, and the prognosis for a cure is going to be decreased. Also, a small proportion of cats appear to be resistant to the treatment.*

**What is the appropriate dose for cats with ocular/neurological FIP?**

*We recommend 84 days (12 weeks of treatment) and neurological cats do require a dosage greater than the usual 4-5mg/kg once a day. You can treat at the present dosage as long as you feel there is progressive improvement in neurological function and weight. However, if you feel is at a plateau, it would be wise to increase the dosage to 8mg/kg, though on one cat we ultimately had to raise the dosage to 10mg/kg because the cat was not growing as fast as we had expected and had some residual neurological signs.*

**What are the chances that I will cure my cat of FIP and he will become re-infected with coronavirus that will again mutate into FIP? Should I treat a cat who is shedding coronavirus?**

*Although theoretically possible, we have not yet seen cats cured of FIP develop the disease at a later date. Therefore, I would concentrate on curing your cat with FIP. Do not treat the cat that is shedding the enteric coronavirus. This cat is at very low risk for developing FIP, and treating carriers with the enteric coronavirus will only encourage the emergence of drug-resistant strains.*

**Should I give vaccinations or spay/neuter my cat while on GS?**

*There is no need to worry about routine vaccinations or spaying/neutering at this time. We need to worry first about getting the cat cured. We have plenty of time to worry about spaying/neutering after that. I am also personally not a big fan of FVRCP boosters after the kitten-hood series, the necessity of even vaccinating cats for rabies (unless required by state or local law), or the need to give FeLV vaccines in cats that are at low risk for infection. However, if we can cure the cat of FIP he should be treated according to the standard of care agreed to by the profession, locality (rabies), and your practice policy. In short, treat him like any other normal cat, but let him get cured first.*

**What are your thoughts about supplements while on GS?**

*I really am not a believer in all these supplements and some of them may interfere with treatment. They are not necessary.*

## Questions about what happens after treatment with GS has ended

**My cat has been on GS for several weeks and seems to be doing fine, but his coronavirus antibody titer is still high. Does this mean he is still sick? Should I be concerned?**

*We do not follow coronavirus antibody titers so I cannot answer your question. However, we would expect it to fall over many months if he were to go into a sustained remission. The fact that it is still high at this early stage does not worry us, but it is perhaps something we should follow if he does not relapse. If he relapses it is somewhat academic. All being said, we are optimistic. His disease signs went into a complete remission and equally important, he gained a lot in weight and stature over the last few weeks. These have been favorable signs with our other cases that suffered non-neurologic disease. The high coronavirus titer also reflects the intense response of his immune system to FIP virus. We would this titer to remain high for a while and then slowly return to a much lower titer.*

**What if my cat relapses once stopping GS treatment? How will I know? (Question asked for neurologic cat)**

*We are hopeful that your cat will remain healthy after he stops his treatment, but we must also be prepared if he should relapse. Relapses can occur within 1-84 days, based on our experience with other cats we have treated. The clinical signs of relapse will be obvious in neurologic cases and will basically be a recurrence of the same problems. He will become febrile, stop eating, become less active, and the neurologic signs he had before will return. It is now a matter of documenting what occurs. You can also take his temperature every day for a couple of weeks and then every other day until we reach the 84 day mark. It will be important to monitor his activity level and weight through this period of time.*

**Which thermometer should I use to monitor my cat's temperature?**

*I prefer the digital rectal thermometers that are fast reading. Also, are you taking the temperature when he is resting and not after a period of exercise? You can see that the temperatures of the two cats are erratic with some being higher at one time than another. The fact that they are both very active and alert and their temperatures are similar does not lead me to be concerned at this point. Let us stay calm and see what happens. However, we realize how difficult this waiting period can be.*

**I noticed my cat had a spike in temperature after stopping GS? Has my cat relapsed?**

*Cats and other small animals are not nearly as consistent in their systemic temps as humans and the fluctuations you see are not uncommon. The problem is that the more worried you are, the more temps you will take, and the more of these fluctuations you will see. Therefore, we worry*

*less about these sort of fluctuations and much more worried when temps are consistently 103 and above. Most importantly, we always look at the entire picture and appetite, activity levels, and clinical signs are even more important. In short, fluctuations like this are OK as long as they do not become constant and are associated with a loss of appetite and activity. If your cat is otherwise ok, and given that there is no evidence yet of a sustained fever, I would recommend that we keep her at home where she can be freed from unnecessary stress and closely watched. A visit to the veterinarian may calm nerves, but it may also make the nerves worse.*

**We are wondering about adopting another cat after our kitty is done with treatment for FIP. How long should we wait before adopting another kitten? What if the new kitten also underwent treatment for FIP?**

*Go ahead and adopt the second cat. It will not affect the ultimate outcomes of treatment for both cats.*

## Questions about labs during or after treating with GS

**My cat is being treated with GS and his lymphocyte count is high. Is this okay?**

*The lymphocyte count is just a bit higher than normal, but this is actually good. A low lymphocyte count would indicate that the infection is active and severe, while high indicates that he is mounting an immune response.*

**My cat's labs show elevated levels of SDMA (Symmetric dimethylarginine). Does this indicate kidney damage?**

*The SDMA is only slightly above normal and we do not get excited about it unless it gets much higher and is associated with changes in BUN and Creatinine. We have not seen any significant renal damage in any of our treated cats to date. Continue monthly testing to see which direction the kidney values are going.*

**My cat has been on GS for several weeks and there is elevated creatine kinase and phosphorus in the lab reports. Is this a problem?**

*No worry about kidney function as the BUN and Creatinine are within the normal range. We disregard the high phosphorous. Even if these were high, a urinalysis would not tell us anything at this point. We can revisit these values in a month.*

**We are concerned about the seemingly quick increase in BUN and CREA showing in the blood work. Thus, we were wondering if you had any further recommendation, or to just**

**do fluids/diet and hope that kidney disease progression slows, given that he is a young cat and the FIP so far appears to have been successfully treated?**

*Yes, there is evidence of kidney damage and given the recent change and the fact that your cat is on this treatment, my guess is that your cat may have sustained some moderate kidney damage. We have only observed kidney damage, which was milder than this, in one of over 30 cats we treated for 12-36 weeks in total and even at higher dosages than what you used. However, this type of drug is known to cause kidney toxicity in some humans treated for HIV/AIDS or hepatitis C. This damage is reversible if you stop treatment soon enough, and I assume that you have already stopped treatment. If not, and you are at or near the end of the 12 weeks, stop it now. It will not reduce the chance of a cure. Make sure that your cat has ready access to water, and if his appetite is affected, feed him wet food that he loves with water added. Cats love wet food with gravy and this is where you can mix in a little extra water. There are commercial and home made diets for cats with kidney disease, but they are not very palatable and they do not treat kidney disease but rather help reduce the stress on the remaining healthy kidney tissue. I would also make sure that your veterinarian does a urinalysis to see how low the specific gravity has gone - the lower it is the more kidney damage. Also, the more water they consume and urine they produce, the more damage. You will also want to look at the urine for any sign of bacterial infection either in the urine sediment or by culture - if found, he should be immediately put on antibiotics.*

## Questions about the oral form of GS

**Some labs are producing GS in pill form. Is this form safe/effective?**

*Yes, at least one enterprising person in China has made an oral form of GS-441524 that she claims will work as well as the injectable formulation. This is not surprising, as the modifications required to make injectable drugs into an oral form are well known. All the drugs for HIV/AIDS and hepatitis C have been converted to oral forms. However, you may find, as do many others, that it is harder to pill cats than to give them injections. They will usually adjust to the shots over a short period, but if they object to pilling, it will only get worse and not better. Therefore, if you go this route, do not invest heavily in it until you are sure that it is going to work for your cat.*

**We are told by the companies producing the oral form to break the dose up and give twice per day. Would you know why this is?**

*I know nothing about the oral form of GS. Therefore, it is impossible for me to provide any reliable help. However, there must be a reason why this Chinese maker is telling people to give it twice a day and not once a day. Perhaps it is because giving it all at once is upsetting to their system. It does not make sense that the drug is cleared from the bloodstream faster when given*

*by mouth, which is another possible reason why they want to split the dose. It is significant to me that these people are heavily pushing the oral drug but have not provided any preliminary data on how it behaves in normal cats and in preliminary field studies on cats with FIP.*

**Is there any harm in alternating between the injectable form of GS and the oral form of GS?**

*You should not mix the two medications on a daily basis. However, there is no problem in changing from one form of medication to the other, as you are suggesting. The diluted drug that they supply usually contains 15-16.5 mg per ml and the dosage for your cat is 4 mg/kg, SC, once a day or around 14 mg (1.1 ml) once a day. Therefore, the dosage they gave you is correct, but will need to be increased as he gains weight.*