APPENDIX A

BASICS OF MISTLETOE ADMINISTRATION

Special thanks to Dr. Nasha Winters, Dr. Peter Hinderberger, and Dr. Steven Johnson for contributions to this section

As we often say in our trainings, "Mistletoe is not a protocol therapy." There is no height and weight chart or tumor type chart that immediately tells the practitioner what dosage to recommend for each patient. Optimal dosage is determined by starting low, titrating up, and observing patient response. That optimal dose will change over time. The guidelines that follow in this appendix are solely starting points, and this is not intended as a comprehensive treatment manual. This material is intended as a general introduction so that practitioners and patients alike may familiarize themselves with the basic principles of VAE therapy administration. This is a brief overview of a well-vetted, research-supported off-label drug use (OLDU) of Viscum album extract (VAE). Like any other botanical therapy, this is not an FDA-approved cancer treatment.

VAE therapy is incredibly nuanced and requires specialized training. Practitioners should administer VAE only upon completion of accredited training and ongoing mentorship by an experienced VAE therapy practitioner. Patients should seek out practitioners who have completed such training. Uriel Pharmacy, Believe Big, and PAAM maintain lists of such practitioners (see Resources). These physicians follow the VAE best practices established at European clinics and approved by the anthroposophic hospitals in Switzerland.

Before subcutaneous (SC) injections or IV administration even begins, VAE therapy starts with appropriate host tree selection (see chapter 4 and appendix E). Once host tree(s) is/are decided upon, SC injection is administered—typically in the abdomen (preferred), thigh, or upper arm, avoiding all radiation fields, recent surgical sites, or infected areas. It is crucial that the injection be administered with a half-inch needle at a 45-degree angle to the skin to ensure the extract reaches the immune-cell rich region just below the skin surface. Patients need to be taught how to use one hand to spread the skin of the injection site, while holding the syringe with their other hand at the appropriate angle and injecting at the correct depth. When patients say they have never experienced a desired VAE reaction, it is almost always because of poor injection technique. Practitioners who complete PAAM-accredited training programs are provided the instruction necessary to teach correct technique to their patients. The first SC injection should always be completed in-office to monitor tolerance and to ensure correct injection angle. Patients may self-administer at home thereafter.

Most SC schedules begin with injections three times per week. Dosage begins low and slowly titrates upward to find the dose at which the patient experiences a desired injection site reaction (see Image 1 "VAE Therapy Dose Escalation Decision Tree"). When a desired reaction occurs, the primary immediate effect is a reddening and swelling of the injection site, no larger than a silver dollar and, for some, a low-grade fever (one to two degrees above normal). Lymph nodes near the injection site may swell slightly. This reaction lasts for 24 to 72 hours. These are not adverse reactions; they are desired responses that indicate immune system activation.

Wait until this reaction has subsided before providing the next SC injection. For some patients, this may necessitate adjusting the dosage schedule (i.e., injections two days/week instead of three days/week). Reaction (redness, swelling) larger than the size of a silver dollar or a fever over 100.4 F may indicate a need to temporarily cease injections and begin again at a lower dose. Conversely, a reaction that is the size of dime or smaller (or no reaction at all) indicates that the patient should graduate to the next dosage level at their next injection. Always

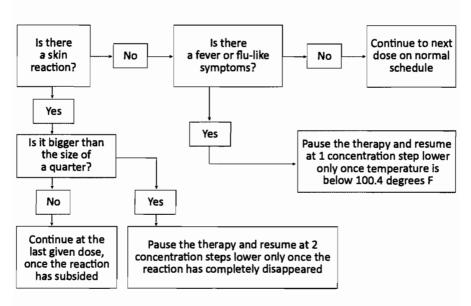


Image 1: VAE Therapy Dose Escalation Decision Tree

be ready to adjust the dose to the patient in order to maintain an optimal injection site reaction.

When the patient achieves their optimal reaction, they should remain at that dosage level. If they reach a point where that dosage no longer incurs a reaction, increase to the next dosage level. As we have mentioned frequently throughout this work, patient response leads the treatment progression.

Each VAE manufacturer provides their own dosage guidelines for how to begin SC mistletoe therapy. Helixor®, the manufacturer that we often recommend for practitioners who are new to VAE therapy, provides some simple dosing guidelines.

Start with Series 1 (1 to 10 mg) three days/week (i.e., on Monday, Wednesday, and Friday).

If Series 1 is tolerated well, increase to Series 2 (10 to 20 mg), again three days/week.

If needed, progress to Series 3 and then Series 4 (20 to 50 mg).

Image 2: VAE Therapy Sample Schedule

TIME	MONDAY	WEDNESDAY	FRIDAY	PACK
Week 1	1 mg	1 mg	1 mg	SE I
Week 2	5 mg	5 mg	5 mg	
Week 3	10 mg	10 mg	10 mg	SE II
Week 4	20 mg	20 mg	30 mg	
Week 5	30 mg	30 mg	20 mg	SE IV
Week 6	20 mg	30 mg	30 mg	
Week 7	50 mg	50 mg	50 mg	
Week 8	70 mg (20+50)	70 mg (20+50)	80 mg (30+50)	SE IV + 50 mg OP
Week 9	80 mg (30+50)	100 mg (50+50)	100 mg (50+50)	
Week 10	100 mg (50+50)	150 mg	200 mg	100 mg GP + 50 mg OP
Week 11 and on	100 mg	150 mg	200 mg	100 mg GP + 50 mg OP

Image 2: "VAE Therapy Sample Schedule" shows how this could play out for a specific patient. Remember, the dose escalation schedule will vary from patient to patient. Depending on the stage of the cancer, aggressiveness, and risk of recurrence, Helixor recommends that patients continue administering their "optimal-reaction dose" three days per week for two to five years. An alternative to that would be to cycle through the above protocol (from Series 1 to 4) repeatedly with breaks in between. After the initial treatment years, depending on the patient's lifestyle and recurrence risk, they may transition to a maintenance pattern of cycling through Series 1 and 2 just twice per year.

What if the visible SC response subsides?

Patients often ask what to do if they get to a point in the maintenance pattern where they no longer experience a reaction at the injection site. A lack of reaction does not necessarily mean the VAE is no longer working. Dr. Hinderberger recommends a technique called the "thigh test" to determine whether the current dosage is still effective. At the next scheduled SC injection, instead of administering in the abdomen, inject it in the outer surface of the thigh, about two inches below the hip bone. There's a little fat there. If there is a reaction in that location, the dosage is still adequate. If there's no reaction, we would then discuss how we might increase to a higher maintenance dose or change host trees.

Ultimately, the local inflammatory reaction is one sign that mistle-toe is working. But there are many other indicators too. Practitioners should check in regularly with patients, asking about their whole picture of health. Is there improvement in mood, vitality, sleep, appetite, strength, and uprightness in posture? Have they experienced increases in temperature? Even a half-degree shift is meaningful if it occurs predictably in relation to the VAE therapy. Improvements in heart rate and pulse quality are significant and so are shifts in warmth distribution. Did they have cold hands at the first patient visit, and do they have warm hands now? All of these are measures of self-regulation. If these shifts occur and persist, it is a good sign that VAE is still conveying beneficial effects.

This section was intended solely as a basic introduction to SC VAE therapy. Practitioners who want to learn more about SC mistletoe, as well as IV administration and intratumoral applications, should connect with the Physicians' Association for Anthroposophic Medicine (PAAM, see Resources) and attend a PAAM-sponsored mistletoe therapy training.