



Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration



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RESEARCH ARTICLE

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ALSUntangled reviews alternative treatments for people with ALS (PALS). Here we review Accilion for ALS, a topic for which we have had 300 requests (1).

Overview

Accilion is a topical mineral cream advertised by Advanced Mineral Compounds, LLC (AMC, 2). It is one of several products with different names and websites (Table I) that trace their origin to a botanist named John Wayne Kennedy (20) and his patent entitled 'Bioavailable minerals for plant health' (19). Three of these products are topical mineral creams while a fourth is a mineral supplement marketed to be sprayed on agricultural crops to promote disease resistance and improve growth. These products appear to have similar ingredients and similar proposed mechanisms, and nearly identical description by which they claim to distinguish themselves from other mineral compounds (Table I). A representative from AMC has told us that these products are different in important ways including "zinc/copper ratios" and "redox", that there is a legal dispute underway between the current owners, and that "efforts to have these compounds independently assessed and thoroughly verified are now routinely obstructed" (21). Interestingly, the same cancer-patient testimonials appear for three of these products and the same ALS-patient testimonial appears for two of them (Table I).

Mechanism(s)

AMC explains the mechanism of Accilion as follows: 'Mutated or non-typical cells do not follow the Krebs cycle with only about 18 steps and absorb all foods (particularly sugars). These cells will also absorb minerals such as zinc and copper; however, the high concentrations (as included in our formulation) are toxic to these mutated, non-performing cells, causing them to die. The surrounding healthy tissues, following the Krebs cycle, take up the amounts of zinc and copper needed to function more efficiently and excrete the excess minerals. Following the Krebs 32 steps, versus the 18 steps that diseased cells follow, saves and replenishes minerals in normal healthy tissue while killing the mutated cells" (3). We found no studies proving that Accilion works this way in any human disease. It is doubtful that this proposed mechanism applies to ALS. While motor neuron death may not be cell autonomous (22), it is not yet clear that there is a particular type of damage-causing cell in any form of ALS that would make sense to attempt to destroy. Even if such a cell was identified, it is not clear how Accilion could be absorbed, cross the blood-brain barrier and target that cell within the central nervous

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Note: this paper represents a consensus of those weighing in. Every investigator in this group does not necessarily share the opinions expressed in this paper.

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'Mutated or non-typical cells do not follow the Krebs cycle with only about 18 steps and absorb all foods (particularly sugars). These cells will also absorb minerals such as Zinc and Copper; however, the high concentrations (as included in our formulation) are toxic to these mutated, non-performing cells, causing them to dier. The surrounding healthy tissues forming cells, causing them to dier. The surrounding healthy tissues, following the Krebs cycle take up the amounts needed to function and the Krebs cycle, take up the amounts of Zinc and Copper needed to function and the Krebs cycle, take up the amounts needed to function and the Krebs cycle, take up the amounts needed to function and the Krebs cycle, take up the amounts healthy tissues following the Krebs spels, versus the 18 steps that diseased cells follow, saves and replenishes minerals in normal healthy	Advanced Mineral Compo Advancedmineralcompoun "Water, Cetearyl Alcohol, J Phosphate, Ceteth-10-P Dimethyl Isosorbide, Ci Triglycerides, Butyrospe Butter), Cetyl Alcohol, Hyaluronate, Zinc Sulfa Ammonium Sulfate, Cir Silver Citrate, Farnesol, Dimethicone, Copper S Hydroxide' (3).	unds ds.com Diacetyl hosphate, aprylic/Capric rmum (Shea Sodium tte, Tric Acid, Phenyl ulfate, Sodium	Biominix Biominix.com Purified Water (Aqua), Mineral Oil, Propylene Glycol, Isopropyl Palmitate, Vegatable Glycerin, Stearyl Alcohol, Cetyl Alcohol, Dimethicone, Steareth- 21, Steareth-2, Grapeseed Extract (Vitai Vinifera), Co-Q10 Enzyme (Ubiquinone), Tocopheryl Acetate (Vitamin B5), Superoxidase Dismutase, Maganesium Aluminum Silicate, Tetrasodium EDTA, Citric Acid, Saccharomyces Lysate Extract, Phopholipids, Lecithin, Sodium Milkamidopropyl PG-Dimonium Chloride Phosphate, Methyparaben, Propylparaben, Diazolidinyl Urea. Active Ingredient Two: Copper Sulfate, Zinc Sulfate, Ammonium Sulfate, Sulfuric Acid, Sodium Hydroxide' (6).	CC Treatment www.cancer-cell-treatment.com "The CC Formula uses zinc and copper in a 7:2 ratio (11)" "Water, Cetearyl Alcohol, Dicetyl Phosphate, Shea Butter, Dimerhyl Isosorbide, Caprylic/ Capric Triglyceride, Ceteth-10 Phosphate, Cetyl Alcohol, Sodium Hyaluronate, Zinc Sulfate, Ammonium Sulfate, Farnesol, Phenyl Dimethicone, Copper Sulfate, Citric Acid, Sodium Hydroxide, Silver Citrate (11)."	Zero Gravity Solutions www.zerogsci.com 'The BAM-FX formula contains zinc and copper in a 7:2 ratio, in a patented formulation of Bio-Available Minerals for easy uptake by the plantBAM- FX contains a balanced ratio of ionic Zinc and Copper, a small percentage of which are surrounded by Ammonia Ligands together with Sulfate' (18).
	'Mutated or non-typical ce follow the Krebs cycle w 18 steps and absorb all ticularly sugars). These absorb minerals such as Copper; however, the h tions (as included in ou are toxic to these mutat forming cells, causing the surrounding healthy tiss the Krebs cycle, take up of Zinc and Copper neetion more efficiently and excess minerals. Follow; 32 steps, versus the 18 sties diseased cells follow, say replenishes minerals in tissue while killing the n cells'(3).	ills do not rith only about foods (par-cells will also Zinc and igh concentrar formulation) ed, non-perem to die. The amounts of the amounts ded to functil excrete the ng the Krebs steps that res and tormal healthy nutated	'Abnormal cells do not follow the Krebs cycle and absorb all foods (particularly sugars). The abnormal cells take up excessive amounts of minerals such as Zinc and Copper (which is in our formulation) in amounts that are toxic to the abnormal cells causing them to die. The surrounding healthy tissues following the Krebs cycle take up the amounts needed to function and excrete the excess minerals' (7).	'Diseased and/or mutated cells (such as cancer cells) do not follow the Krebs cycle. Rather they follow an alternative metabolic cycle with only about 18 steps and absorb all foods (particularly sugars). The diseased cells will also take up excessive amounts of minerals such as Zinc and Copper (in our formulation) in amounts that are toxic to them, causing the diseased cells to die. The surrounding healthy tissues (following the Krebs cycle's 32 steps) take up only the amounts of Zinc and Copper needed to function and excrete the excess minerals. Following the Krebs 32 steps versus the 18 steps that cancer and other diseases follow saves normal healthy tissue while killing the diseased cells' (12).	'The Krebs cycle describes the metabolic pathways of the higher plants and animals where the parallel use of available fuels, oxygen, water, and other essentials follow the same basic metabolism of the sugars, fats and proteins The metabolic system is a well documented and familiar process. The protection provided by at least thirty-two steps in the process provides a system that protects oxygen-driven plants and animals Any excess ionic elements will be discarded unless supplied at extremely high rates. Lower order organisms are not as complex regarding the metabolic pathway as the higher order organisms. The cycle followed by lower order diseases such as bacteria, fungi and

Not applicable

Bonnie Butler (cancer, 16)

C Wells (cancer, 15)

Not available

\$299 for 3.38 ounces (17)

\$339 for 1.7 ounces (10)

\$300 for 2.1 ounces (5)

C Wells (cancer, 4) Bonnie B (cancer,4)

Common patient testimo-

nials (condition)

between this product and other mineral

compounds

Reported difference

Published human clinical trials in any condition

None

Table II. TOE grades for Accilion in ALS.

	Grade	Explanation
Mechanism	F	Mechanism proposed by AMC does not seem plausible in PALS
Pre-clinical	U	No studies of Accilion in pre-clinical ALS models
Cases	C	One case with validated ALS diagnosis and improvements
Trials	U	No clinical trials of Accilion in PALS
Risks	C	At least 10% of exposed patients experienced harms (no hospitalizations or deaths)

system. Most PALS do not have a definable mutation in their cells that would make them targetable by this compound (23). We are aware of no data in PALS demonstrating that any particular cell type has this shortened Krebs cycle.

Altered copper homeostasis has been proposed as part of ALS pathogenesis (24), although it remains unclear whether, how or in which direction it should be manipulated. Some animal studies suggested that lowering copper levels with chelators might be useful (24), but a small human trial of a copper chelator showed no benefit (25). A very recent animal study suggested that supplementing a specific form of copper (CuATSM) was beneficial (26), though 'killing mutated cells' has not been suggested as a mechanism for these beneficial effects. While a small human trial of CuATSM will start soon, we are aware of no mechanism whereby the copper in Accilion skin cream could find its way into motor neurons in the central nervous system, least of all in just the right amount to influence disease progression. Based on all this, ALSUntangled assigns a TOE 'Mechanism' grade of F (Table II).

Pre-clinical data

We found no studies of Accilion in any pre-clinical ALS models. ALSUntangled assigns a TOE 'Mechanism' grade of U based on this information (Table II).

Clinical data

Cases

The AMC website has a video of a person named Jenny H who is reported to have ALS and to have had improved motor function on Accilion (4). With her permission (27), medical records were forwarded to us to validate this report (28). We confirmed that she did have a slowly progressive upper and lower motor neuron disease involving bulbar, cervical and lumbar segments. It is not clear what ALS mimic testing she had, but multiple neurologists including a recognized ALS expert (29) agreed with this diagnosis. Approximately seven years into her disease, she started using Accilion. Within one month, she and her family noted increased voluntary movements in her arms and legs. Comparing her neurologist's notes from just

before treatment to what is seen later on the video, there does appear to be modest objective improvement in her distal upper and lower extremity strength (going from less than antigravity to barely antigravity). Her chiropractor also documented improvements in "surface paraspinal electromyographic scanning"; however, it is not clear that this is a useful outcome measure in ALS (30). No other ALS outcome measures were consistently obtained throughout her course. A lengthy testimonial ascribed to Jenny H also appears on the CC formula website with the title "Testimonial - ALS - Lou Gehrig's Disease My Improvement is Indisputably Due to My Use of the CC Formula" (14). Jenny H denies using CC formula or other similar mineral creams, and states that the use of her video to promote any product other than Accilion is "being done without my knowledge or permission" (27).

AMC sent us the contact information of two clinicians who used Accilion in other patients with ALS (21). Only one of these responded to our requests for information, reporting that he had used Accilion in two PALS (31). One of these had slower progression of ALS symptoms by patient report. This was not quantified with any objective outcome measures. The other PALS had no change (31). No PatientsLikeMe members reported taking Accilion. Google search identified no additional PALS reporting use of Accilion. Based on all this, ALSUntangled assigns a TOE 'Cases' grade of C (Table II).

Trials

We found no published trials of Accilion in PALS. Based on this, ALSUntangled assigns a TOE 'Trials' grade of U (Table II).

Risks, dosing and costs

We found no large case series in which Accilion safety monitoring was done in any systematic way. The AMC website states 'use of this formula may produce one or more of the following 'expected' reactions: redness or discolored skin, skin crusting resulting in temporary scabbing, flaking and/or peeling of the skin, small black and/or red 'pinpoint' spots on the treated or other areas (some with white halos around them), stinging, itching and/or scabbing of the skin, skin nodules of various sizes and colors, extreme or mild fatigue (depending upon seriousness of condition, age and strength of the

immune system), bowel and/or urine incontinence, white cloudy material in urine and/or stools, itchy foot bottoms, unusual body and/or stool/urine odors, a metallic taste in the mouth, flu like symptoms and sensitivity to direct sunlight. Other reactions may include manageable to severe pain' (3). The expected frequency of these is not listed. The clinician we corresponded with had used Accilion in four patients (two with ALS and two with cancer), and noted skin irritation in one that resolved with varying the application site (31). We found no evidence of hospitalizations or deaths associated with Accilion. Based on all this, ALSUntangled assigns a TOE 'Risks' grade of C

Accilion is currently being sold on one website at a cost of \$300 per bottle (5). The seller-recommended dosing is as follows: 'As a minimum treatment, apply once. For maximum treatment, apply three times each day initially and two times each week thereafter. A non-allergenic bandage may be used to concentrate the treatment. If the area is washed, reapply it for maximum benefit. Do not use a metal applicator or allow metal to contact the skin cream" (5).

Conclusions

In our opinion, Accilion does not have a mechanism that is plausible for the treatment of ALS. There is one patient with a confirmed diagnosis of slowly progressive ALS who had modest objective improvements in motor function while using Accilion. However, improvements such as these have been described before, even in patients taking a placebo (32). We believe improvements in PALS are important to study, but they may have multiple explanations and thus are not proof of treatment efficacy (32). At this time we do not recommend the use of Accilion for ALS.

Declaration of interest: ALSUntangled is sponsored by the ALS Association and the Motor Neurone Disease Association.

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