

THE USE OF PHARMAX NUTRICEUTICALS IN THE TREATMENT OF CHRONIC LYME DISEASE

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A Few Words on Chronic Lyme Disease

Chronic Lyme disease is a fast-spreading problem in the USA and worldwide. Classical Lyme disease is caused by a bacterial spirochete called *Borrelia burgdorferi*. Conventional belief attributes Lyme Disease conveyance through tick bites. Interestingly to the physician, more recent literature has shown that also certain stinging flies, spiders and even some mosquitoes can infect humans with this spirochete. This means that the disease vector can be more widespread than previously anticipated. Lyme disease typically does not occur alone but together with a number of co-infections. Classical Lyme disease, also known as Borrelia, affects the immune system in predictable ways: it lowers the white blood count and lessens the host's immunity. When the immune system becomes dysfunctional, the patients then become infected with a multitude of secondary bacterial, fungal, mycoplasmal and viral infections. A necessary co-condition for the thriving of infectious organisms in the system is the presence of toxic metals and other environmental toxins.

Chronic Lyme disease affects the immune system by rendering it blind to the existence of Borrelia and other co-infections, including parasites. Lyme can also affect the musculo-skeletal system with recurrent joint problems and fibromyalgia type pain. A third presentation affects the central nervous system with a multitude of related symptoms including emotional changes, psychiatric problems and neurological problems, i.e. numbness, paralysis and strange abnormal sensations. The area most commonly affected is the brain and the face including the teeth, jawbone, ears and sinuses. The symptoms are caused by the presence of neurotoxins that are created by the organisms. Neurotoxins are usually peptides and other substances intended to alter the host's immune system and make the host a comfortable environment for the proliferation of Borrelia and the co-infections.

It is our experience that most Lyme patients, by the time the infection has become chronic, have multiple parasites in their bowel. Co-infections from the herpes virus family, Coxsackie's viruses, influenza viruses, echo viruses and the measles virus seem to be common. Frequently they also have one of several mycoplasma species present and a multitude of other bacterial infections. Fungi always thrive in a Lyme-infected patient. The treatment therefore needs to be broad based and address all these co-infections in order to succeed. Treatment for Lyme disease is often unsuccessful when it targets only the Lyme spirochete but not the existing co-infections.

In Summary

- 1) Borrelia affects the immune system by lessening the host's immunity.
- 2) The host becomes a comfortable environment for co-infections.
- 3) Treatment needs to be broad based, addressing co-infections.

A Few Words on the GI Tract

It is imperative to understand that the reservoir for many of these co-infections is the gastrointestinal (GI) tract. It typically contains eight to twelve pounds of living organisms. Many of these in the chronic Lyme patient are parasites and abnormal bacteria, fungi, viruses and mycoplasmas, which set up housekeeping in the gut and spread from there periodically to the other tissues.

In terms of sheer numbers, the GI tract is home to 100,000 billion microorganisms at any one point in time. Considering that the average person has approximately 10,000 billion mammalian cells in their body, one could say there are 10 times more of 'them' than of 'us'. The monolayer of epithelial cells of the intestinal mucosa constitutes the largest surface in the body that is exposed to the environment. In other words, one cell layer separates you from the outside world in your GI tract! It is estimated that this mucosal surface is equal to the size of two tennis courts. The gut can turn into a storehouse of infectious organisms and must be understood in order to be treated successfully.

A Few Words on Pharmax Nutriceuticals

I have chosen the nutriceuticals from Pharmax LLC for dealing with many of the issues outlined in this article.

Firstly, the company is co-owned by brilliant researchers who have spent years in the trenches as research microbiologists.

Secondly, they manufacture their own nutriceuticals with strict quality controls, as reflected in their ISO 9001 certification. Most companies merely repackage products manufactured elsewhere. As a prime manufacturer, Pharmax produce their own base materials and their unique freeze-drying technology enables the company to use a solvent-free manufacturing process.

Thirdly, I find the products are pure and intelligently designed.

Specific Treatment for Co-infections in the GI Tract

1) Freeze Dried Garlic (700mg freeze dried garlic concentrate [Allium sativum] per capsule)

The active antimicrobial in garlic is allicin (Ankri & Mirelman, 1999). It has MIC (minimum inhibitory concentration) values very similar to antibiotics and antifungals for their prospective targeted organism. For example, the MIC for *Staphylococcus aureus* is 26, *Escherichia coli* is 44 and *Candida albicans* is 36 (these are all astoundingly low numbers, indicating that allicin is a potent antibiotic or antifungal for these organisms!). Allicin also kills protozoa's such as *Cryptosporidium, E. histolytica* (Mirelman *et al.*, 1987) and *Giardia* (Harris *et al.*, 2000). Allicin is effective against viruses such as the Rotavirus (Blake, 1983), Influenza virus (Fenwick & Hanley, 1985) and viruses from the herpes family (i.e. HHV-6 and others), to name just a few (Tsai *et al.*, 1985). Yet it is not cytotoxic and does not harm the beneficial bacteria in the gut, i.e. the lactic acid bacteria such as *Lactobacillus acidophilus* and *Bifidobacterium bifidum* (Rees *et al.*, 1993).

In treatment, I advise 2 capsules after each meal - a total of between 4 and 6 capsules each day.

2) AlliCinn (500mg freeze dried garlic concentrate [*Allium sativum*], 200mg freeze dried cinnamon bark oil concentrate [*Cinnamomum cassia*] per capsule)

If tolerated, it is preferred to use the Pharmax product called AlliCinn. The cinnamaldehydes have a wonderful antibacterial action (Chang *et al.*, 2001). However, sometimes a patient gets cramps as a side effect and cannot tolerate the cinnamon oils. In that case we either discontinue this product, or add two drops of peppermint oil every time the patient takes a capsule of the

AlliCinn. The peppermint oil completely prevents the cramping and therefore makes the AlliCinn well tolerated.

I generally give 2 capsules, three times a day after a meal.

3) Antimicrobial Complex (200mg barberry bark standardized extract [*Berberis vulgaris*], 50mg goldenseal standardized extract [*Hydrastis canadensis*], 100mg freeze dried garlic concentrate [*Allium sativum*], 50mg freeze dried wormwood oil concentrate [*Artemesia absinthium*] per capsule)

We also include the Antimicrobial Complex to treat other often-undefined bacterial coinfections. *Artemesia absinthium* has been shown to be an ideal agent to treat Babesia, which is one of the organisms frequently present as a co-infection with Lyme disease (it is an intracellular parasite similar to malaria). *Berberis vulgaris* is a potent antibacterial agent (Ruggeri *et al.*, 1991).

I generally advise one capsule, three times a day with meals.

4) **Intestinal Purifier** (3g psyllium husk, 1.75g FOS, 1g L-glutamine, 2g resistant starches, 2g freeze dried prune puree and 0.25g quercetin per 10g scoop)

We recommend a fiber laxative along with the treatment so that the dead microorganisms can be carried out of the system easier. To this end, we use Pharmax's product Intestinal Purifier, which acts like a stool expander. It turns the stool into a brush, cleaning the bowel wall of the residues of dead or ailing microorganisms and parasites.

I give one scoop (10 grams) mixed with water or juice and taken with a meal.

5) **HLC High Potency** (4 billion *Lactobacillus acidophilus* and *Bifidobacterium bifidum* per capsule)

To replace the normal bowel flora, we always recommend Pharmax's human lactic commensals, i.e. HLC High Potency for bowel restoration.

I recommend 1 - 2 capsules after each meal.

6) **Intestinal Complex** (150mg slippery elm bark extract 4:1 [*Ulmus fulva*], 100mg marshmallow root extract 4:1 [*Althaea officinalis*], 85mg camomile flower standardized extract [*Matricaria recutita*], 100mg marigold flower extract 4:1 [*Calendula officinalis*], 50mg licorice root standardized extract [*Glycyrrhiza glabra*], 50mg gamma-oryzanol per capsule).

In addition, we also include the Intestinal Complex. The slippery elm bark prevents the reattachment of freshly hatched worms to the bowel wall. The other ingredients have a synergistic effect and a relative laxative effect that is desired during this phase of the treatment period.

I give one capsule, three times a day with meals.

7) Permeability Complex I (1,500mg FOS, 1,000mg L-glutamine, 500mg aspartic acid, 500mg L-arginine, 20mg magnesium, 330mg vitamin C, 100mg N-acetyl glucosamine [NAG], 100mg quercetin, 15mg zinc, 20mg essential oil of ginger [*Zingiber officinale*], 5,000iu vitamin A, 100iu vitamin E)

Provides luminal nutrients for a healthy GI mucosa (Souba, 1990).

I advise 1 - 2 scoops (5 – 10 grams), three times a day with meals

Specific Treatment for Borrelia, Ehrlichiosis, Babesia and Mycoplasma Infections

1) Freeze Dried Garlic (700mg freeze dried garlic concentrate [Allium sativum] per capsule)

For the specific treatment of Borrelia, we use Freeze Dried Garlic in the dose already recommended. The garlic will first eliminate the microorganisms and parasites in the bowel before the allicin and its breakdown products can be active in the connective tissue and later also in the brain. Allicin, the primary active ingredient, has been shown to cross the blood-brain barrier and it is a surprisingly effective antimicrobial agent against the Lyme spirochete even in the brain and the CNS.

However, high doses are recommended, usually upwards from 5,600mg total daily intake given in divided doses every 6 hours. This translates to 4 capsules QID. The way I often titrate the individual dose is by body odor. When a patient gets a slight garlic body odor, the desired dosage is reached.

2) **Pyloricin** (700mg total capsule fill of freeze dried oregano oil concentrate [*Thymus capitus*], freeze dried clove oil concentrate [*Syzygium aromaticum*], freeze dried ginger oil concentrate [*Zingiber officinale*] and freeze dried wormwood oil concentrate [*Artemesia absinthium*])

Babesia, Ehrlichiosis and Borrelia are often sensitive to the product Pyloricin. The most effective ingredient here is again oil of artemesia for its tremendous effect on Babesia. The second most important ingredient is the oregano oil, which we found to be most effective against Borrelia, Babesia, Ehrlichiosis and Mycoplasmas. Clove oil and ginger have a synergistic effect.

I usually give one capsule TID taken on an empty stomach along with the rest of the program. (Again, if the patient experiences cramping as a result of the treatment, a drop or two of peppermint oil in a little bit of water taken at the same time will alleviate the symptoms. Peppermint also potentiates the effect of all the other essential oils.)

Specific Treatment for Yeast Infections

1) Freeze Dried Garlic (700mg freeze dried garlic concentrate [Allium sativum] per capsule)

In my experience, freeze dried garlic is most often sufficient in eliminating yeasts, which is consistent with the recent literature (Ghannoum, 1988; Yoshida *et al.*, 1987; Adetumbi *et al.*, 1986; Sandhu *et al.*, 1980).

I give 2 capsules TID with meals. Other beneficial products can be added to the protocol such as Colon Guard and Caprylate Complex.

 Colon Guard (350mg freeze dried garlic concentrate[*Allium sativum*], 60mg freeze-dried cinnamon bark oil concentrate[*Cinnamomum cassia*], 150mg magnesium caprylate, 215mg calcium caprylate per capsule)

Caprylic acid has been shown for many years to be a very active anti-fungal along with freezedried garlic (Yoshida *et al.*, 1987) and cinnamon oil (Singh *et al.*, 1995).

I give 2 capsules with each meal.

3) **Caprylate Complex** (500mg magnesium caprylate and calcium caprylate per capsule)

I also use Caprylate Complex.

I give one capsule three times per day with meals along with Colon Guard if fungal infection predominates.

Summary of the Protocol for Co-infections

- 1. Freeze Dried Garlic or AlliCinn:
- 2. Antimicrobial Complex:
- 3. **Pyloricin**:
- 4. HLC High Potency:
- 5. Intestinal Complex:
- 6. Intestinal Purifier:
- 7. Colon Guard:
- 8. Caprylate Complex:
- 9. Permeability 1

2 capsules three times daily with meals. One capsule three times daily with meals. One capsule twice daily with meals. One capsule twice daily with meals. One capsule three times daily with meals. One 10g scoop taken once daily with a meal. 2 capsules three times daily with meals. One capsule three times daily with meals. One to 2 scoops twice daily with meals

Detoxification

Heavy metals and environmental toxins change the inner environment of the patient. This milieu is a necessary *sine qua non* for the presence of harmful microorganisms and the inability of the immune system to deal with them. Therefore, every patient with chronic Lyme Disease has to be detoxified. We have developed new simple steps in the elimination of toxic metals from the body. We are using a product that contains a large amount of branched chained amino acids and is most effective in detoxifying heavy metals from the central nervous system. Also, glutathione is critically important and must be added.

Detoxification Treatment - One Year Duration.

1) **BMI Balance** (100µg chromium, 23.75g whey protein concentrate, 1.5g conjugated linolenic acid, 225mg L-carnitine, 1.2g FOS per 30g scoop)

It is made from whey protein, which contains these important amino acids in ideal amounts. I get patients to take 30g per meal.

2) **Glutathione Precursors** (300mg N-acetyl cysteine, 200mg glutamic acid, 200mg alpha-lipoic acid per capsule)

Glutathione is needed by the cell to detoxify itself from heavy metals and other toxins (Srivastava *et al.*, 2002). It is also an effective antiviral agent (Clarke *et al.*, 2002). Glutathione Precursors contains alpha lipoic acid and N-acetyl cysteine, which are effective heavy metal detox agents on their own (Kelly, 1998; Hagen *et al.*, 2002).

Glutathione Precursors is always advised. I give one to 3 capsules per day to raise glutathione levels.

Mineral Replacement Treatment

Metals are bound to various structures in the connective tissue, the cell walls and the surfaces of intracellular organelles. They are in the cell on binding sites that are usually reserved for other beneficial minerals. Only when the body is depleted of minerals do heavy metals permanently attach to those sites. In order to displace the heavy metals from those binding sites, the system has to be saturated with beneficial minerals.

Trace Mineral Complex (20mg iron, 10mg manganese, 200µg chromium, 200µg selenium, 200µg iodine, 1mg copper, 25mg zinc, 200µg molybdenum, 100µg vanadium, 2mg boron, 450mg vitamin C, 25µg nickel, 35µg of silica per capsule - all listed in elemental amounts).

I recommend one capsule with each meal for 6 to 12 months.

2) Selenium CWS (100µg elemental selenium per drop)

Selenium is our prime agent to treat the chronic viral co-infections (Beck, 2001; Beck *et al.*, 2001). Selenium works like a birth control pill for viruses. It stops viral replication. However, the dosage needed is higher than the normal recommended dosages of selenium. The patient should have a total input of selenium of about $1,200\mu g$ per day to reach an effective antiviral level. This should be sustained no longer than 6 months before the maintenance dose of 200 to $400\mu g$ is reached. We use the Selenium CWS, which is dropped over the patients' food. When minerals or vitamins are taken with food we have observed that the patient hardly ever becomes allergic to them. When they are taken away from food the patient often becomes sensitized to it.

I advise 12 drops per day over food for 6 months.

3) **Trace Mineral CWS** (50µg chromium, 50µg selenium, 50µg molybdenum, 50µg boron, 50mg manganese, 50µg of iodine per 4 drops - all listed in elemental amounts.)

To increase the mineral uptake, we also use the Trace Mineral CWS, which does not contain zinc and is therefore ideal to increase the mineral levels without increasing the zinc. Zinc is a potentiating agent for mercury toxicity and has to be dosed carefully.

I typically advise adding 5 to 10 drops of the Trace Mineral CWS, ideally taken in salad dressing or soup, to the 3 capsules of the Trace Mineral Complex.

4) Mag:Cal Citrate (75mg calcium, 75mg magnesium, 100µg boron, 15mg of vitamin B6 per capsule - the minerals are listed in elemental amounts.)

Most patients with heavy metal toxicity need extra calcium and magnesium.

I typically give 2 to 4 capsules of the Mag:Cal Citrate, to be taken with the evening meal.

Summary of the Detoxification and Mineral Replacement Protocols

1.	BMI Balance:	One scoop (30grams) per meal replacement, with water or milk
		for one year.
2.	Glutathione Precursors:	One capsule per day, taken with food for one year.
3.	Trace Mineral Complex:	One capsule with each meal for 6 to 12 months.
4.	Selenium CWS:	12 drops per day dropped over food, for 6 months.
5.	Trace Mineral CWS :	5 to 10 drops with each capsule dose of the Trace Mineral
		Complex.
6.	Mag:Cal Citrate:	2 to 4 capsules with the evening meal.

Treating Neurological Symptoms

When the patient's presentation is primarily neurological, we have to pay attention to the fatty acids. Fatty acids make up 80% of the weight of the brain, and are necessary to maintain healthy barriers within the brain. The cell walls are made up to a large degree of lipids that can only be intact if a patient has a good input of lipids on a daily basis. Fish oil and fish oil derivatives are the most important component to be observed in the treatment of Lyme Disease.

My current most popular way of dosing this is to use DriCelle EFA 950.

1) DriCelle EFA 950 (300mg DHA, 400mg EPA, 100mg GLA, 150mg ALA per teaspoon)

This equals the total input of EPA of about 800mg per day. This is also an effective dose in the treatment of cancer and extremely effective in stopping the replication of viruses. Therefore it is an important part of the antiviral program.

I recommend one half-teaspoon DriCelle EFA 950 QID

It is best to test the different oil products with ART or EAV, or through Ared-cell Membrane Fatty Acid Test. The current "Body Bio Fatty Acid Test" is also good. The test, however, overlooks the fact that we like patients to have extremely high levels of EPA and DHA in the abnormal range, which is protective against viral replication and neurological damage from Lyme disease.

Whenever the patient takes oils that are meant to be absorbed into the blood and to then travel from there into the brain, the oil absorption should be enhanced by giving an enzyme with a high amount of lipase.

We therefore recommend that the patient take the product called:

2) **Pure Pancreatin** (700mg vegetable pancreatin per capsule)

Each capsule contains 11,200 lipase USP units.

I therefore recommend that patients should take 1 to 2 capsules every time one of the essential oils from Pharmax is used.

Summary for Treating Neurological Symptoms

- 1. **DriCelle EFA 950** One half teaspoon, four times a day in water or juice with a meal.
- 2. **Pure Pancreatin** One to 2 capsules every time DriCelle EFA 950 is taken.

For severe neurological symptoms such as paralysis, check for the presence of a co-infection called *Bartonella henselae* (also called cat scratch disease). This illness responds to high doses of antibiotics, which should be the preferred treatment of choice. We have been treating Lyme Disease with the above protocols plus the addition of bee venom therapy two to three times a week for a prolonged period of time, and have often seen good and lasting results with this approach. For the treatment of Babesiosis, we have sometimes to include the antibiotic Mepron for 3 to 6 weeks.

Treating Immune System Symptoms

If the immune system symptoms predominate, I like to include:

1) **Ginseng Combination** (350mg Siberian ginseng root, 350mg Korean panax ginseng root per capsule)

This has a multitude of beneficial effects on the immune system.

I give 2 capsules BID with meals.

2) **Immusol** (2ml *Echinacea angustafolia*, 2ml *Echinacea purpurea*, 2ml Elderberry liquid extract, 0.3ml CLA, 300mg Vitamin C, 10mg Zinc)

A combination of immune stimulating factors, which is also excellent (Coeugniet & Elek, 1987; Craig, 1999).

I give 3 teaspoons daily with food.

Summary for Treating Immune Symptoms

- 1. **Ginseng Combination** Two capsules BID with meals
- 2. Immusol Three teaspoons daily with food.

Neurotoxin Binding

Neurotoxins are constantly excreted by the body through the liver into the bile ducts and from there into the small intestines. Neurotoxins have a high affinity for nervous system tissue. The small intestines are lined with nerve endings. On the way through the small intestine, most neurotoxins are re-absorbed by the nerve endings and travel from there to the spinal cord and back up into the brain.

They are on an endless rotation through these different systems without leaving the body. It has been shown that several substances can intercept the neurotoxins on their way down and bind them in the stool so they are excreted.

1) **Beta Sitosterol** (100mg b-sitosterol per capsule)

Most commonly we use Beta Sitosterol for this purpose.

My current dosage recommendation is that the patient takes 1 to 2 capsules, four times a day between meals. It is good to take 2 of these doses at night since most of the detox functions happen at night. This product should be given for 3 weeks on, 3 weeks off, for 6 to 12 weeks.

2) Liver Support and Detoxification (200mg choline bitartrate, 100mg milk thistle seed standardized extract [Silybum marianum], 25mg inositol, 25mg L-methionine, 80mg turmeric standardized extract [Curcuma longae], 50mg licorice root standardized extract [Glycyrrhiza glabra], 50mg calcium glucarate, 25mg indole-3-carbinol, 50µg biotin, 25mg limonene, 25mg Lglycine per capsule)

To increase the liver detoxifying abilities we include the product Liver Support and Detoxification at the suggested dosage. This product provides a comprehensive combination of nutrients and phytochemicals with known activity in stimulating liver function, with special emphasis on detoxification reactions. While both Phase 1 and Phase 2 reactions are stimulated, there is a greater qualitative stimulation of Phase 2, providing a net gain in elimination of toxic materials, which then sets up a gradient of drainage from other tissues. Take 2 capsules BID with meals.

Summary for clearing Neurotoxins

1. Beta Sitosterol

One to 2 capsules four times a day between meals 2. Liver Support and Detoxification Two capsules per day with a meal.

Laboratory Diagnosis

Lyme Disease is a chronic disease that is responsible for a multitude of illnesses including chronic low back pain, migraine headache, fibromyalgia, chronic fatigue and even some cancers. It is most often misdiagnosed as another illness. For the diagnosis, we are currently recommending the lymphocyte transformation test that is not available in the USA. Here, the most successful diagnostic procedure is the direct proof of the microbial presence through phase contrast dark field microscopy after using species-specific fluorescent stain (Bowen Research laboratory). Other tests used: Western Blot Elisa Test, PCR Test and Lymphocyte Transformation Test.

Optimal Diet and The Four Pillars of Nutrient Supplementation from Pharmax.

Multivitamins and minerals, fatty acids, antioxidants and probiotics form the Four Pillars of the Pharmax approach, and these, along with an optimal diet form the necessary underlying base upon which sound treatment is built. However, as long as a significant amount of parasites and microorganisms are present in the gut, these also are fed with the multivitamins approach.

Therefore we usually suggest an initial three-week approach of using the anti-infectious agents and bowel restoration products only to reduce the amount of pathogenic flora in the gut <u>before</u> starting on the multivitamins, antioxidants and other rich nutrient sources. After the initial three weeks of antimicrobial use, the following Four Pillars can be brought into play:

Summary of the Four Pillars of Supplementation (see Pharmax flier)

1. Vitamins and Minerals:

Multivitamin & Mineral (adult formula)Two capsules per day with foodorTwo scoops per day with food.

(The Multi Omega Plex combines vitamins and minerals with essential fatty acids. Therefore the vitamin and mineral pillar and the fatty acid pillar are combined in one product).

Vitamin C Powder	One gram per day with food.
Natural E 300	One capsule per day with food

2. Fatty Acids

DHA/EPA 1000	Five grams per day with food
or	
EFA 950 or	Five grams per day with food
Omega 3:6:9	Ad lib with food

3. Antioxidants

	Endogenous Antioxidants	One capsule per day with food
	or Glutathione Precursors	One capsule per day with food
	plus Carotenoid Complex plus	Two capsules per week with food
	Phyto Antioxidants	Two capsules per week with food
4.	Probiotics & Prebiotics:	
	HLC High Potency	Two capsules per day with food

The Use of Antibiotics in Treating Lyme Disease

The recommended medical treatment for Lyme disease and the associated co-infections is the use of antibiotics. The typical treatment of mycoplasma infections takes several six-week cycles of high doses of antibiotics. We currently believe that the approach using natural antibiotics and antimicrobials has superior long-term effects. However sometimes the patient cannot respond to a particular approach and another approach has to be chosen. We occasionally have to include the use of intravenous antibiotics.

We recommend the following web sites for further information:

- 1. <u>www.Lymenet.com</u>
- 2. www.chronicneurotoxins.com
- 3. <u>www.neurotherapy.com</u>
- 4. <u>www.pharmaxllc.com</u>

(antibiotic schedules) (neurotoxin binding agents) (bee-venom therapy) (nutriceuticals)

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