



Cholestyramine	Clinical Protocol
Description	
What to Expect from Cholestyramine <ul style="list-style-type: none">• Cholestyramine (CSM) is an FDA approved medication used to lower elevated levels of cholesterol. It has been used safely for over twenty years in millions of patients who have taken the medication for extended periods of time. You have been given a prescription for CSM to be used for only a short period of time to treat your chronic, neurotoxin-mediated illness.• The FDA (6/28/99) ruled that there was no reason to expect an increased risk to health from CSM in a group of patients who have illnesses such as pfiesteria, ciguatera and blue green algae syndromes compared to those who don't. Your prescription is given to you under this FDA exemption.• Cholestyramine is not absorbed. Provided that CSM is not taken with food, it binds cholesterol, bile salts and biological toxins in the small intestine. Because it binds toxins tightly, the toxins can not be reabsorbed; the CSM-toxin complex is excreted harmlessly in the stool. Provided there is no re-exposure to toxin or reacquisition of toxin, the CSM treatment will remove all the toxin over time, curing the chronic, toxin-mediated illness. Most patients are cured or have significant improvement in 2-4 weeks, but depending on the amount of toxin in your body, the time to cure may be longer. We are aware of cases in which the neurotoxins have caused additional damage to nerve/hormone pathways, often in the hypothalamus, that require additional treatment protocols. These treatments target additional aspects of toxin binding and proinflammatory cytokines.• Use at the FDA approved dose of 9 grams of Questran ®, 4 grams of Questran Light ®, 9 grams of generic Cholestyramine, or 9 grams of Cholestyramine with additives approved for use in MCS or sensitive patients (Email the webmaster for a source MCS additive safe CSM), taken four times a day. The dose for children (under 100 lbs. or 12 years of age) is 60 mgCSM/kg body weight.• There are potential side effects, primarily acid reflux and/or constipation, that are potentially annoying but are not dangerous and should never prevent you from finishing your treatment program. Our treatment protocol attempts to anticipate these possible troublesome side effects; you will be given two additional prescriptions to keep on hand "just in case." CSM can be used with other medications. See further in this document for use of CSM with other medications.• You may wish to take a multiple vitamin with minerals if you will be taking CSM for an extended period of time. Reflux of stomach acid, also called heartburn or indigestion, is commonly experienced early on in treatment. The symptom abates spontaneously in most patients within a few days. A medication to stop over-production of stomach acid, taken before beginning the CSM doses, can prevent heartburn. Mixing the CSM in apple juice, cranberry juice, berry punch or dissolving CSM, first in hot water and then adding ice, helps reduce heartburn [most patients do not like using CSM in orange juice]. Bloating and belching can also be caused initially by CSM.	

- Fortunately, those side effects are rarely a major problem. Constipation is commonly seen. Many patients simply increase their consumption of fruit or fiber products, such as psyllium (Metamucil ®), to avoid this problem. A non-absorbable, sweet tasting liquid, Sorbitol, in a 70% solution, taken one tablespoon four times a day with food, will hold water in the stool, making bowel movements soft and preventing constipation. Even though Sorbitol tastes sweet, it will not worsen your diabetes or make you gain weight.
- Because many patients with chronic, neurotoxin-mediated illnesses have diarrhea or more frequent, softer stools, this side effect of CSM can become a welcome, early benefit. CSM has been extensively tested in multiple clinical trials involving patients with chronic, neurotoxin-mediated illnesses. The benefit has been substantiated by a double-blinded placebo controlled crossover study. That study was terminated prematurely due to ethical considerations: withholding treatment could not be justified, given the clearly demonstrated prompt clinical benefit.
- Your physician will be following your case carefully. If you have questions regarding any phase of your treatment, please notify your doctor promptly. There is no detail too small to ignore in cases like yours. You will be given special tests of visual contrast sensitivity on a regular basis. Your treatment will continue until your symptoms have resolved and your visual contrast is normal. Your physician will review your case in detail as your treatment progresses.

Information on Cholestyramine

Description

- Cholestyramine for oral suspension, USP, the chloride salt of a basic anion exchange resin, a cholesterol lowering agent, is intended for oral administration. Cholestyramine resin is quite hydrophilic, but insoluble in water. The Cholestyramine resin in Cholestyramine is not absorbed from the digestive tract. Nine grams of Cholestyramine Powder contain 4 grams of anhydrous Cholestyramine resin.

Contraindications

- Cholestyramine is contraindicated in patients with complete biliary obstruction where bile is not secreted into the intestine and in those individuals who have shown hypersensitivity to any of its components.

Warning: Phenylketonurics: *Cholestyramine contains Phenylalanine*

Precautions

- The use of Cholestyramine in this study is not under chronic use. There is a possibility that prolonged use of Cholestyramine, since it is a chloride form of anion exchange resin, may produce hyperchloremic acidosis. This would especially be true in younger and smaller patients where the relative dosage may be higher. Caution should also be exercised in patients with renal insufficiency or volume depletion, and in patients receiving concomitant spironolactone.
- Cholestyramine may produce or worsen pre-existing constipation. Increased fluid intake and fiber intake should be encouraged to alleviate constipation and a stool softener may occasionally be indicated. Constipation associated with Cholestyramine may aggravate hemorrhoids.

Drug Interactions

- Cholestyramine for Oral Suspension, USP may delay or reduce the absorption of concomitant oral medication such as phenylbutazone, Warfarin, thiazide diuretics (acidic), or propranolol (basic), as well as tetracycline, penicillin G, Phenobarbital, thyroid and thyroxin preparations, estrogens and progestin's, and digitalis. Interference with the

absorption of oral phosphate supplements has been observed with another positively charged bile acid sequestrants. Cholestyramine may interfere with the pharmacokinetics of drugs that undergo enterohepatic circulation. The discontinuance of Cholestyramine could pose a hazard to health if a potentially toxic drug such as digitalis has been titrated to a maintenance level while the patient was taking Cholestyramine.

- Because Cholestyramine binds bile acids, Cholestyramine may interfere with normal fat digestion and absorption and thus may prevent absorption of fat-soluble vitamins such as **A, D, E and K.**

Pregnancy

- Pregnancy Category C There are no adequate and well controlled studies in pregnant women. The use of Cholestyramine in pregnancy or lactation or by women of childbearing age requires that the potential benefits of drug therapy be weighed against the possible hazards to the mother and child. Cholestyramine is not absorbed systemically, however it is known to interfere with absorption of fat-soluble vitamins; accordingly, regular prenatal supplementation may not be adequate.

Cholestyramine Protocol

- One (1) scoop of Cholestyramine (9grams) taken four (4) times daily. Should be taken on an empty stomach, 30 minutes before meals or other medication. See dosage details above in "What to Expect from Cholestyramine" section.
- CSM will NOT interfere with any other medication program if used properly. Take digitalis preparations 2 hours after CSM and 2 hours before next CSM dose to be sure of adequate absorption. If you are going to be on CSM for an extended period of time, recheck medication levels frequently. You may wish to take a multiple vitamin with minerals if you will be taking CSM for an extended period of time. Zantac, 150 mg. taken two times per day if necessary to treat heartburn or bloating from CSM. Your physician may decide to use more potent stomach acid medications. Sorbitol, 70%, 1 tablespoon taken three times as needed to prevent constipation from CSM.

Protocol for Prevention of Intensification Reaction (HERXHEIMER) by Actos in Chronic Lyme Patients Beginning Cholestyramine

- Do VCS Test at 18" with adequate illumination on day 1 BEFORE taking Actos.
- Begin Actos 45 mg. one time a day with/or without food, with or without other medications on day 1. You will take Actos once a day for 10 days.
- Do a finger stick (random) blood sugar on day 3 to prove that your blood sugar isn't dropping too low. Low blood sugar occurs extremely rarely while on Actos and the special diet (see Actos Information Sheet below), but if you feel lightheaded, eat something containing sugar or two packets of sugar right away. If symptoms clear up quickly, notify your prescribing physician and do not take the next Actos until directed. If you can get a blood sugar done immediately, do so. If symptoms don't clear up quickly, see your family physician, as the problem is likely to be something other than a low sugar reaction. Remember that even though you have Chronic Lyme, you still can have something else causing your symptoms.
- After taking Actos for 5 days, repeat the VCS Test, and begin taking Cholestyramine (CSM) 1 scoop four times a day, on an empty stomach, 30 minutes before you eat anything or take any medication. Read through the information sheet "What you should know about Cholestyramine." Be prepared to treat reflux, bloating and constipation if necessary.
- Continue the Actos for 5 more days. On day 7 of the study (day 2 of CSM) repeat the vision test. A Herxheimer-like reaction (which we call an intensification reaction to

distinguish it from the worsening condition people experience when taking antibiotics), if it occurs, is likely to start at dose 6 to dose 10 of CSM. If baseline symptom intensity or number increase, repeat the VCS, as the VCS score will usually fall. Our recent studies have shown that we can prevent or reduce the severity of the intensification reaction. Stay on the CSM if possible. The "bumpy ride of the Herx" leads to a soft landing on the other side.³

- Have medications available (H2 blockers or proton pump inhibitors) to treat reflux. Treat constipation with fiber or Sorbitol 70%, one TBSP three times a day.
- Repeat VCS at day 7 of CSM and day 14 of CSM (day 12 and day 19 of the study respectively).
- Continue CSM until endpoints of normal VCS (www.biotoxin.info) and resolution of symptoms achieved (BIR score <50).
- Some patients have elected to continue Actos longer than 10 days. Provided that safety is assured, there is no contraindication for this protocol to continuing the medication, but the protocol only suggests a short course of Actos.

Actos Information Sheet

- Actos, (pioglitazone is the generic name) is FDA approved to help in treatment of diabetes in patients who make insulin. Actos accomplishes the task of improving diabetic control not by lowering blood sugar (hypoglycemia, blood glucose less than 50, is rare in patients taking the medication), but by helping the body transport glucose more efficiently into liver and muscle cells where it can be used to supply energy.
- The increased efficiency of transport of glucose is due to activation of a gene that makes two different proteins that assist the cell with movement of glucose. The glucose transport protein the activation is a direct result of the effect of Actos that turns on a "master switch," a nuclear receptor called PPAR gamma, that regulates activity of many genes.
- Actos turns on PPAR gamma which then turns on activity of all the genes under its control, not just the glucose transport protein gene. One of the Actos-PPAR gamma controlled genes is the anti-TNF gene that blocks production of TNF (under control of the cytokine nuclear receptor) and blocks TNF effect on cells. Read Chapter 15 of Desperation Medicine for more information on how TNF can hurt us.
- Actos can cause diarrhea and light-headedness, especially if you eat foods that make your blood sugar go up quickly. Avoiding the so-called "high glycemic index" foods will help prevent these bothersome side effects. I suggest you avoid foods enriched with sugar (including unsweetened fruit juices, low fat foods full of corn syrup) and anything that contains maltodextrins. Read the label on salad dressings and "sugar free" sports drinks if you aren't sure.
- The high glycemic index food all have one thing in common - a complex carbohydrate plant starch called amylose. Amylose is a storage starch; the seed or root that will grow into a new plant from the seed or root uses amylose for fuel to grow. Unfortunately for us, we have an enzyme called amylase in our saliva that rapidly converts the long chain of glucose molecules in amylose into a collection of individual glucose molecules. As a result, the rate of rise of blood sugar that occurs after you eat a whole wheat bagel is no different than the rate of rise of blood sugar that follows eating a tablespoon of table sugar. While you are taking Actos, avoid amylose!
- Amylose is easy to find. If the food is made from wheat, rice, oats, barley or rye, you must avoid it. Corn products are safe for different reasons. All vegetables that grow beneath the ground (yes, including peanuts, carrots and radishes) are off not to be consumed, although onions and garlic are safe. The only fruit to avoid is bananas.

- Eat 6 to 8 small meals daily while you are taking Actos. Eat lots of protein, fresh fruit and any of the vegetables that grow above the ground. The minor inconveniences of eating only low-glycemic index foods will be balanced by the safe prevention of the intensification reaction that can occur when you begin taking Cholestyramine.
- Many patients have found that the Actos and low amylose diet results in welcome weight loss. Those patients are encouraged to read more about the complete No Amylose Diet, including Dr. Shoemaker's presentation to the 83rd Endocrine Society, June, 2001, in his book, Loose the Weight You Hate

Reference

- Ritchie Shoemaker