

## Consent for and Understanding Low Dose Naltrexone

Naltrexone has been a FDA-approved drug since 1984, but the varied uses of low dose naltrexone still await application to the FDA for specific disorders. Appropriate off-label use of an already FDA-approved medication such as naltrexone is ethical and legal, but patients need to be made aware of the potential benefits and side effects. Many medicines are used for different purposes than what the FDA has given an "indication" for usage. Naltrexone is an opioid antagonist or an "anti-narcotic" medication. The FDA has approved naltrexone for two conditions at a much higher dose (prevention of abuse of narcotics and alcohol). There is accumulating experience with this medication at a low dose to help a variety of inflammatory and painful disorders.

Short acting low dose naltrexone increases the body's endorphins which then can reduce inflammation and pain. Treatment with Naltrexone has been reported to reduce the symptoms of inflammatory bowel disease in four published case series. We have seen this good effect in our patients with Crohn's disease and ulcerative colitis who have failed traditional therapy. We have used it for many other conditions including fibromyalgia, MS, IBS, RLS, complex regional pain syndrome, pelvic pain syndromes, and sarcoidosis.

Naltrexone can be used as the second phase of treatment of patients with small intestinal bacterial overgrowth (SIBO) to increase the cleansing muscular contractions of small intestine. This can help maintaining remission in patients with SIBO. In irritable bowel syndrome there is are additional potential benefits to using Naltrexone – reduction of pain and inflammation. Preclinical studies have shown that a very low dose of naltrexone can block excitatory opioid receptors without affecting inhibitory opioid receptors, resulting in analgesic potency. For some patients naltrexone can help to produce more effective and regular bowel movements in patients suffering from chronic constipation.

For gastrointestinal disorders, Naltrexone is available in dosage forms of 1.0 mg, 1.5 mg, 2.5 mg and 4.5 mg pills. Normally Naltrexone comes in 50 mg and 100 mg tablets in long-acting formulations. Low dose Naltrexone is available at compounding pharmacies.

In the published double-blind Crohn's disease studies the primary side effect is insomnia (10%). A number of our patients have had various side effects. These include difficulty sleeping, feeling jittery, or being nervous. Other reported side effects include headache, drowsy feeling, altered mood, vivid dreams, dizziness, muscle pain, decreased appetite, abdominal pain, diarrhea, and nausea. In a survey of 96 of our patients, 15 had temporary side effects and 14 had side effects that made the patients stop taking the medication.

**Patients who have become dependant on daily use of narcotic-containing pain medication may require 10 days to 2 weeks of slowly weaning off of such drugs entirely (while first substituting full doses of non-narcotic pain medications) before being able to begin naltrexone safely. Because naltrexone blocks opioid receptors throughout the body for three or four hours, a severe withdrawal reaction can occur if it is given to people who are taking opioids (narcotic medications such as Ultram, tramadol, morphine, Percocet, Duragesic patch or codeine).**

Naltrexone should not be taken during pregnancy until research into that question is completed.

Those patients who are taking thyroid hormone replacement for a diagnosis of Hashimoto's thyroiditis with hypothyroidism ought to begin naltrexone at the lowest range (1.0 mg). Be aware that naltrexone may lead to a prompt decrease in the autoimmune disorder, which then may require a rapid reduction in the dose of thyroid hormone replacement in order to avoid symptoms of hyperthyroidism.

Full-dose naltrexone (50mg) carries a cautionary warning against its use in those with liver disease. This warning was placed because of adverse liver effects that were found in experiments involving 300 mg daily. The 50mg dose does not apparently produce impairment of liver function nor do the much smaller doses used for LDN.

People who have received organ transplants and who therefore are taking immunosuppressive medication on a permanent basis are cautioned against the use of naltrexone because it may act to counter the effect of those medications. We have not seen this as a problem in IBD patients taking immunosuppressants.

**I agree that I will need to be weaned off narcotics completely before naltrexone is given \_\_\_\_\_(Initials Here)**

**I UNDERSTAND THE REASON FOR THE USE OF NALTREXONE AND UNDERSTAND THE RISKS AND SIDE EFFECTS, AS OUTLINED ABOVE. I AGREE TO DO THE APPROPRIATE FOLLOW-UP, INCLUDING BLOOD WORK AND OFFICE VISITS AS DIRECTED BY MY PHYSICIAN. ALL OF MY QUESTIONS REGARDING THIS MEDICATION HAVE BEEN ANSWERED TO MY SATISFACTION AND I AGREE TO PROCEED WITH TREATMENT.**

**Signature of Patient: \_\_\_\_\_ Date: \_\_\_\_\_**

**Patient Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_**