



LLPMG
Loma Linda Psychiatric Medical Group

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Patient Information and Consent for Neurostar TMS Therapy

This Patient Information and Consent form provides important safety and use information for a treatment service called NeuroStar TMS Therapy®. This consent form outlines the process, effectiveness, limitations, and safety of TMS treatment as prescribed by Dr. _____ / Loma Linda Psychiatric Medical Group.

Introduction to NeuroStar TMS Therapy

Your doctor has prescribed NeuroStar TMS Therapy® to reduce the symptoms of your depression. TMS stands for “Transcranial Magnetic Stimulation”. In NeuroStar TMS Therapy, TMS is delivered by the NeuroStar TMS System as powerful magnetic field pulses. NeuroStar TMS Therapy has been shown to be safe and effective in the treatment of adult patients with depression who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

NeuroStar TMS Therapy is performed in your doctor’s office under his or her care. The treatment is non-invasive, non-systemic, and non-medicated. Treatment with NeuroStar TMS Therapy does not involve anesthesia or sedation, and patients are awake and alert during the treatment session.

This treatment course consists of 36 sessions completed over the course of 36 consecutive business days. Each session lasts as little as 19 minutes per daily session. NeuroStar TMS Therapy is not an appropriate treatment for all patients with depression. You should review this patient guide and discuss the information with your doctor in order to determine if NeuroStar TMS Therapy is an appropriate treatment option for you.

When Can NeuroStar TMS Therapy Be Used?

Indication for Use

NeuroStar TMS Therapy is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.



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When Should NeuroStar TMS Therapy Not Be Used?

NeuroStar TMS Therapy delivers a magnetic field that could cause any metal objects that are near the device to move or to get hot.

- NeuroStar TMS Therapy should not be used in patients who have magnetic-sensitive metals implanted in their head or within 12 inches of the NeuroStar treatment coil.
- NeuroStar TMS Therapy should not be used in patients who have an implanted device that may not properly function in the presence of the NeuroStar TMS System, even if the device is located outside this (12 inch) distance.

Your doctor will ask you to list any metal devices or objects in your head or body in order to determine if those devices could be affected by the NeuroStar TMS System. Use of NeuroStar TMS Therapy in the presence of these objects could result in serious injury or death. Standard amalgam dental fillings are not affected by the magnetic field and are acceptable in patients being considered for treatment with NeuroStar TMS Therapy

Limitations of NeuroStar TMS Therapy

NeuroStar TMS Therapy is indicated for patients who have failed to receive satisfactory improvement from prior antidepressant medication in their current episode of depression. NeuroStar TMS Therapy has not been evaluated in patients who have had no prior treatment with antidepressant medication. It is important that your doctor evaluate your antidepressant medication history to determine if NeuroStar TMS Therapy is right for you.

Most patients who benefit from NeuroStar TMS Therapy begin to experience results by the fourth week of treatment, and will usually receive benefit by six weeks. Some patients may experience results in less time. A goal of antidepressant treatment is to have all the symptoms of depression go away (remission).

- 83% of patients improve in depression symptoms
- 62% of patients experience symptom relief (remission)

Your doctor will discuss with you when to end treatment with this goal in mind. Re-treatment is an option, with different eligibility depending on insurance requirements. In clinical trials, NeuroStar TMS Therapy was administered for six weeks so it is unknown whether longer treatment would be effective for your depression.



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NeuroStar TMS Therapy has not been evaluated in patients with psychoses or psychiatric emergencies where a rapid improvement is needed such as patients at risk of suicide.

As with any antidepressant, there is a risk of worsening of your depression during treatment with NeuroStar TMS Therapy. Contact your doctor immediately if symptoms persist or worsen. The device was shown to be safe and effective in patients who had been able to stop taking their antidepressant medications. If you feel that your depression worsens when you stop your antidepressant medications, contact your doctor immediately. This therapy has not been demonstrated to be safe and effective for patients who have a suicide plan.

NeuroStar TMS Therapy Safety Information

The safety of NeuroStar TMS Therapy was determined in two clinical trials (where one-half of patients received real TMS and one-half received placebo treatment) of 498 patients with moderate to severe Major Depressive Disorder who ranged in age from 18 to 70 years, and who had failed to achieve satisfactory improvement from prior antidepressant treatment.

- Less than 5% of all patients dropped out of the clinical trials because of side effects from the treatment.
- There was no weight gain, sexual problems, stomach problems, sleepiness, and dry mouth which are side effects that commonly occur with antidepressants taken by mouth.
- There were no deaths or seizures in patients who took part in the clinical trials.
- There was no change in memory function during the clinical trials.
- There was no change in hearing function during the clinical trials (earplugs were used)

This section provides information about side effects observed with the use of the NeuroStar TMS Therapy System in clinical trials. Warnings and precautions to be considered prior to receiving NeuroStar TMS Therapy are also provided and should be discussed with your doctor to determine what, if any, precautions should be taken during your treatment with NeuroStar TMS Therapy.

Worsening Depression or Suicidality

Depression is a serious medical illness. Not all patients treated with an antidepressant will get better with treatment. Because of this, some patients may experience worsening of their



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depression before they begin to see improvement of their symptoms. NeuroStar TMS Therapy may require up to 4-6 weeks of treatment before symptom improvement occurs and has not been studied in patients who need rapid improvement in their depression symptoms.

You should inform your doctor if your symptoms do not improve, or if they get worse. If you have thoughts of death or suicide you should immediately discuss this with your doctor. Your doctor will determine whether NeuroStar TMS Therapy should be discontinued and, if so, what other treatment options are available. You should be carefully monitored for worsening symptoms, signs or symptoms of suicidal behavior and/or unusual behavior. Families and caregivers should also be aware of the need to observe the patient and notify the treatment provider if symptoms worsen.

Other Risks

Seizures (sometimes called convulsions or fits) have been reported with the use of TMS devices. No seizures were observed with use of the NeuroStar TMS System in clinical trials that included over 15,000 treatment sessions. Since the introduction of the NeuroStar TMS System into clinical practice, seizures have been rarely reported. The estimated risk of seizure under ordinary clinical use is approximately 1 in 30,000 treatments (0.003% of treatments) or 1 in 1000 patients (0.1% of patients). You should discuss with your doctor if you have had a seizure, or if you have a medical condition that you have been told may put you at increased risk of having a seizure. Your doctor will decide if it is appropriate for you to receive NeuroStar TMS Therapy.

The NeuroStar TMS System produces a loud click with each magnetic pulse, patients treated with the NeuroStar TMS System must always wear earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction during treatment. In clinical trials, NeuroStar TMS Therapy had no effect on hearing when earplugs were used.

The long term effectiveness of NeuroStar TMS Therapy for treating depression has not been evaluated in clinical studies where one-half of patients received real TMS and one-half received placebo. In other clinical studies, NeuroStar TMS Therapy was safely tolerated in patients for periods up to 24 continuous weeks, and no negative effects of treatment were seen during a 6 month follow-up period. However, effectiveness has not been established for treatment beyond a six week course.



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Longer term effects of exposure to the NeuroStar TMS System magnetic field are not known. However, exposure to other devices (such as MRI scanners) with the same type and strength of magnetic fields produced by the NeuroStar TMS System coil are not associated with significant short-term or long-term safety concerns.

Adverse Events

Temporary pain or discomfort at the area of the head where the treatment coil is placed is a common side effect. Inform your doctor if you experience discomfort during treatment. Your doctor can decrease the NeuroStar TMS dose or temporarily move the NeuroStar TMS coil slightly to ease or eliminate the discomfort. In clinical trials, treatment site discomfort went away rapidly with time, usually getting better within the first week of treatment.

Headaches were reported by about half of the patients who took part in the clinical trial regardless of whether they were treated with real TMS or with the sham (placebo) treatment. In general, the headaches got better over time, and could be relieved by using common over-the-counter pain medications such as acetaminophen.

I have read the information contained in this Patient Information and Consent form about NeuroStar TMS Therapy and its potential risks. I have discussed it with Dr. _____ who has answered all of my questions. I am signing this consent of my own free will and I am not under the influence of any drugs or alcohol. I understand there are other treatment options for my depression available to me and this has also been discussed with me. I understand that I may discontinue treatment at any time.

I therefore permit Dr. _____ and Loma Linda Psychiatric Medical Group staff to administer this treatment to me.

PATIENT NAME: _____

PATIENT SIGNATURE: _____

DATE: _____