

Restless Legs Syndrome and the *RELAXIS*[®] System

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Currently, there are only a few non-drug treatments that may be helpful for treating Restless Legs Syndrome (RLS) symptoms. The major focus of non-pharmacological therapy is to avoid drugs (antihistamines, antidepressants, anti-nausea drugs) and substances (alcohol, tobacco and caffeine) that tend to worsen RLS. Regular mild to moderate exercise and maintenance of bedtime habits and sleep patterns may be beneficial. Treatments such as biofeedback, acupuncture, chiropractic manipulation, neuromuscular stimulation (TENS device) and external counter pulsation devices may also be helpful but have not been proven as beneficial.

Relaxis presents a new option that does not involve medication to treat RLS symptoms. It is the only non-medication treatment cleared by the FDA for treating RLS-related problems and does not need a prescription from a doctor. *Relaxis* has been medically evaluated in scientific studies, which have demonstrated the device to be both effective and safe for improving sleep in patients with primary RLS. Although we do not fully understand the mechanism of how *Relaxis* relieves RLS symptoms (or how any other treatments help RLS), it is thought that the vibration from the device provides a counterstimulation that competes with and diminishes the RLS sensations. This is very similar to the relief you get from massaging your legs to reduce RLS symptoms. Of course, when you stop massaging or moving your legs, the effect of the counterstimulation ends and RLS symptoms will likely resume if you sit down, rest, or try to go back to sleep. Therefore, massaging or moving your legs as well as getting up and walking around are not very practical for falling asleep since these voluntary activities clearly perpetuate the insomnia. *Relaxis* provides continuous counterstimulation while you lie comfortably in your bed, allowing you to fall asleep. The device will shut off automatically after 35 minutes and can be restarted, if needed, or can remain off if you fall asleep and stay asleep.

How do you use *Relaxis*?

Relaxis should be placed under your legs (below the area where you experience your strongest RLS sensations) when you begin to feel the oncoming symptoms of RLS, perhaps just as you go to bed or if you wake up in the middle of the night with RLS symptoms. Once the device is positioned appropriately, it may be turned on by pressing the power button. The intensity of the vibration impulses may be adjusted to suit your individual preferences and fine-tune your vibration treatment.

Relaxis will provide 30 minutes of uninterrupted vibration after being activated and then slowly wind down over an additional 5 minutes to complete the 35-minute therapy cycle. If needed, it may be restarted one more time to provide another 35 minutes of continuous treatment.

How do you decide whether *Relaxis* is the right choice of treatment for you?

Relaxis has been scientifically studied and demonstrated to be effective in helping RLS patients get to sleep and fall back asleep. It is intended to improve the quality of sleep in patients with primary RLS. Therefore, patients whose sleep is affected by RLS are excellent candidates for

the vibration device. There are several categories of RLS patients who should consider *Relaxis*. The first group consists of patients who are not yet on any medication and wish to avoid taking drugs. *Relaxis* is ideal for treating RLS symptoms in the evening or at bedtime that prevent the onset of sleep. The next group includes patients who are currently taking medication but are still experiencing bothersome RLS symptoms. Instead of increasing or adding medication, using *Relaxis* may relieve those bothersome RLS symptoms sufficiently to maintain current drug therapy. The third group includes patients who are controlled on their current therapy but wish to reduce or eliminate their medication treatment (often due to unwanted side effects or financial expense). Adding *Relaxis* might help these patients reduce or eliminate their drug therapy.

Will *Relaxis* work for everyone?

There are almost no medical treatments that will be appropriate or work for everyone. Some people may not like vibration sensations and some may find that *Relaxis* does not provide enough benefit (especially if they have very severe RLS) to warrant its use. However, the majority (we estimate about 85% or more) of RLS sufferers should tolerate the device very well and benefit from using it. *Relaxis* has been scientifically studied only in the primary RLS population, and so it is not indicated for use by secondary RLS patients.

Are there any potential adverse effects from using *Relaxis*?

A small minority of patients may experience a worsening of RLS upon using the device, but this may also occur with medications that are FDA-approved for treating RLS. In the case of *Relaxis*, this worsening of RLS symptoms typically resolves within 3 weeks or less of discontinuing use of the device. Uncommonly, leg cramping, tingling, soreness, pain, and motion sickness may occur but will quickly resolve after discontinuing use of the device. There are no known long-term concerns with using *Relaxis*.

Who should not use the *Relaxis*?

It is very important that patients who have been diagnosed with deep vein thrombosis (in one or both legs within the last six months) not use *Relaxis*, since the device could break up the clot(s). Additionally, patients who have skin disorders such as eczema, psoriasis, cellulitis or non-healing wounds on their legs should avoid using *Relaxis*. It is possible that the device may worsen these leg skin problems. Finally, patients who know they are allergic to cotton or plastics should avoid using *Relaxis* because the device is made with these materials.