



Information Packet

Thank you for your interest in the restiffic restless leg foot wrap. In this packet you will find helpful information for both you and your clinician, including:

1. A custom prescription form for restiffic. restiffic is a prescription only medical device in the USA and you must receive a prescription from an authorized clinician in order to receive your restiffic.
2. Safety information on restiffic.
3. An overview of restiffic's clinical trial.
4. An RLS symptom journal to help you track your symptoms and discuss them with your clinician.

If you or your clinician has any questions regarding restiffic, please contact us at:



restiffic Prescription

This prescription may be completed by any healthcare practitioner (GP, psychiatrist, physician’s assistant, nurse practitioner, pharmacist, etc.) who is licensed in the state in which he or she practices. Please take this completed prescription to your local pharmacy.

Patient Name _____

Date _____ Patient Phone or Email _____

Diagnosis: Primary Restless Legs Syndrome

Treatment: restiffic restless leg foot wrap

Quantity: One (1) pair

Size: I II III

Physician Signature _____
(Do Not Substitute)

Printed Name _____

NPI #: _____

Use shoe size and width to determine the correct size. If between two sizes, choose the larger size.

Men	Shoe Width		
	Narrow	Regular	Wide
USA			
6			
6.5			
7			
7.5			
8		II	
8.5			
9			
9.5			
10			III
10.5			
11			
11.5			
12			
12.5			
13			

Women	Shoe Width		
	Narrow	Regular	Wide
USA			
5			
5.5			
6			
6.5			
7	I		
7.5			
8			
8.5			
9			
9.5			
10			
10.5			
11		II	
11.5			
12			



Safety Information



restiffic is a foot wrap for the treatment of primary Restless Legs Syndrome (RLS). It is a non-invasive device that has been cleared by the FDA for prescription use as a Class 1 Medical Device. The device promotes a gentle, relaxing pressure on targeted muscles in the foot – the abductor hallucis and the flexor hallucis brevis – which reduces the uncontrollable impulses to move the legs. Patients may wear the foot wraps at any time when they are not putting pressure on their feet (ex. Sleeping, reclining, sitting) and it may be used in conjunction with any medication.

Indications:

- Primary Restless Legs Syndrome/Willis-Ekbom Disease

Contraindications:

- Do not use when engaging in activity that puts pressure on the feet (ex. Walking, running, operating a vehicle). Do not use in water.
- Do not use if you have neuropathy, poor circulation, peripheral vascular disease, varicose veins, deep vein thrombosis, a history of blood clots, or foot and/or leg swelling.
- Do not wear if you have breaks, bruises, sprains, wounds, sores, fragile skin, cuts, rashes, or abrasions involving your feet and/or legs.
- Consult with your doctor if you have diabetes, kidney failure, heart problems, are pregnant, or have any other medical condition that may contraindicate the use of restiffic.

Cautions:

- In the event of pain, numbness, burning, cramping, tingling, or other sensations in the feet, loosen the straps of the device immediately. If the symptom does not go away after loosening the device, remove it completely. If the symptom does not go away after removing the device, consult with your healthcare professional.

NEXT STEP: Patients in the United States are required to obtain a prescription from a licensed healthcare professional in order to purchase restiffic. Patients may take completed prescriptions to their local pharmacy:

restiffic Clinical Evidence

Using restiffic to manage moderate to severe primary Restless Legs Syndrome

Original Publication: Targeted Pressure on Abductor Hallucis and Flexor Hallucis Brevis Muscles to Manage Moderate to Severe Primary Restless Legs Syndrome

Journal: The Journal of the American Osteopathic Association

Publication Date: July 2016

Authors: Phyllis J. Kuhn, MS, PhD; Daniel J. Olson, DPM; John P. Sullivan, MD

OBJECTIVE

The objective of this study was to assess the efficacy and safety of the restiffic restless leg foot wrap which applies targeted pressure on the abductor hallucis and the flexor hallucis brevis muscles to reduce the symptoms of moderate to severe RLS, and to compare the current findings with findings from studies of ropinirole use in patients with primary RLS.

METHODS

- Design: 8-week single-arm, open-label, clinical trial with a repeated measures design conducted between April 2009 and August 2012 in 2 offices in Erie, PA.
- Demographics: 30 participants (22 women; 8 men); mean age 51.5 years
- Inclusion criteria:
 - o Adults age 18-75 with moderate to severe primary RLS
 - o Evening & nighttime symptoms with sleep impairment (patient-reported)
 - o RLS symptoms 2-3/week for 6+ months
- Outcome measures:
 - o International Restless Legs Syndrome Study Group (IRLSSG) Rating Scale – patient generated
 - o Clinical Global Impression (CGI) Scale – clinician-generated
- Meta-analysis: compared restiffic with historic reports of ropinirole and a placebo

RESULTS

IRLSS Scores:

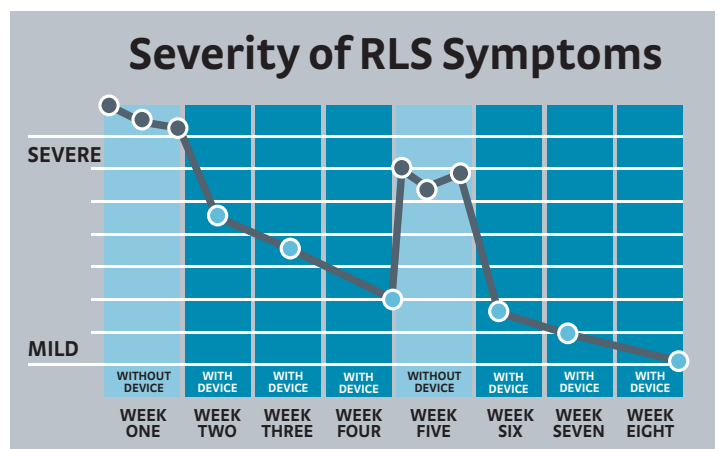
- Decreased from 25.05 ± 5.33 (“Severe”) to 7.83 ± 6.33 (“Mild”) from first day to last day.
- Indicates a 2 level drop in the severity of symptoms.
- 69% decrease in average IRLSS scores (Figure 1).

Sleep loss due to RLS symptoms:

- Decreased from 119.5 minutes to 22.1 minutes per night.
- Over 90 minutes of sleep gained per night on average.

Clinical Global Impression Scale:

- All patients improved; none became worse.
- 90% of patients were “much improved” or “very much improved.”
- 60% of patients showed complete or nearly complete remission of all symptoms.
- 93% of patients showed no side effects.



RLS Symptom Journal

Complete in the morning when waking up:	Date:	Date:	Date:	Date:	Date:	Date:	Date:
Time I went to bed:							
Time it took me to fall asleep:							
How many times I woke up in the night, if any:							
Total hours slept:							

Complete in the evening before bed:

I experienced RLS symptoms at these times:	<input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening <input type="checkbox"/> Night	<input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening <input type="checkbox"/> Night	<input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening <input type="checkbox"/> Night	<input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening <input type="checkbox"/> Night	<input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening <input type="checkbox"/> Night	<input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening <input type="checkbox"/> Night	<input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening <input type="checkbox"/> Night
From 1 to 5 (5 being the worst), my symptoms were this severe:							
I consumed any of these substances during the day (with times):							
<input type="checkbox"/> Caffeine <input type="checkbox"/> Alcohol <input type="checkbox"/> Tobacco products <input type="checkbox"/> Medications (please list) <input type="checkbox"/> Other (please list)							
Additional comments (ex. Events, stresses, personal notes):							

What should you do if you think that you have Restless Legs Syndrome? Make an appointment with your healthcare provider to discuss your RLS symptoms. It may be helpful to bring your RLS Symptom Journal to help your doctor determine what factors may or may not be contributing to your symptoms.

Talk to your doctor about restifc. Learn how restifc works, watch patients discuss their experiences, and read more about RLS at www.restifc.com. Download the [restifc prescription](#) and take it to your doctor to discuss