



IT'S TIME TO ASK YOUR DOCTOR ABOUT BLADDER LEAKAGE

Now that you are ready to talk to your healthcare provider about your bladder leakage, we'd like to help you get that conversation going with this discussion guide. Simply print and fill out this guide to make the most out of your conversation with your provider.

About Bladder Leakage (also known as Urinary Incontinence)

Urinary incontinence is the technical name for the involuntary loss of urine. In everyday language, you may hear women refer to this as "bladder leakage". Urinary Incontinence (UI) is common, and UI screening is an important step in taking care of yourself. Up to 51% of adult women experience bladder leakage.¹ There are different types of urinary incontinence, defined by the cause or trigger of urine leakage.

The most common types of Urinary Incontinence

Stress urinary incontinence involves involuntary urine loss that occurs with coughing or sneezing, physical activity or exertion.

Urgency urinary incontinence involves involuntary urine loss that occurs with the strong and typically sudden urge to urinate.

There are also other types of incontinence. For all types of urinary incontinence, it is important to speak with your health care provider about your symptoms, so that you may receive proper diagnosis and treatment for your condition.



Before talking to your healthcare provider:

Answer these questions and share your responses with them.

<p>During the last 3 months, did you leak urine (even a small amount)?</p>	<input type="radio"/> Yes	<input type="radio"/> No	N/A	N/A
<p>During the last 3 months, did you leak urine?</p> <p>(check all that apply)</p>	<input type="radio"/> Yes - when performing some physical activity, such as coughing, sneezing, lifting, or exercise.	<input type="radio"/> Yes - when you had the urge or the feeling that you needed to empty your bladder, but you could not get to the toilet fast enough.	<input type="radio"/> Yes - without physical activity and without a sense of urgency.	N/A
<p>During the last three months, did you leak urine most often:</p> <p>(check only one)</p>	<input type="radio"/> Yes - when you were performing some physical activity such as coughing, sneezing, lifting, or exercise.	<input type="radio"/> Yes - when you had the urge or the feeling that you needed to empty your bladder, but you could not get to the toilet fast enough.	<input type="radio"/> Yes - without physical activity and without a sense of urgency.	<input type="radio"/> Yes - about equally as often with physical activity as with a sense of urgency.

During the discussion:

When thinking about your bladder leakage, here are some questions you can ask your healthcare provider to help make the best decision:

Why am I experiencing bladder leakage?

What type of UI do I have?

What are my treatment options for UI?

What treatment option do you recommend for me?

Is the leva Therapeutic right for me?

If you and your healthcare provider have agreed *leva* Therapeutic is right for you, then your doctor will fill out the medical order form that's included with this guide. Please note, having your doctor fill out the medical order form in no way obligates you to purchase *leva*.

If you feel like you need additional time to learn more about the *leva* Therapeutic, you can ask your provider to fill out the medical order form in case you decide to move forward with *leva*.



After your doctor fills out the medical order form for *leva* and faxes it in to the Renovia Women's Center:

You can expect a call from an Educator at the Renovia Women's Center (RWC) within 1 -2 business days, from a (617) area code phone number.

- There is also no obligation to purchase *leva* after talking to an educator. You make the final purchasing decision.
- RWC Educator will discuss *leva*. Opportunity for Q&A.

IF you decide to purchase *leva*:

- Your RWC Educator will coordinate shipment of the *leva* device and your on-boarding date.
- You'll join onboarding and training sessions with dedicated RWC personal Coach.
- The RWC Offers:
 - Flexible hours to accommodate varying schedules.
 - Product information review.
 - Personalized coaching and support, with a focus on the first two weeks of training with *leva*.

Helpful resources:

Visit www.know/leva.com for more information



Download the *leva*
Therapeutic patient
brochure from the website



Scan the code to see
how *leva* works



Scan the code to
see a demo of the
leva app

1. Markland AD, Richter HE, Fwu CW, Eggers P and Kusek JW. Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. J Urology. 2011;86(2):589-593.

The *leva* Digital Therapeutic System is intended for: (i) strengthening of the pelvic floor muscles; and (ii) rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild to moderate urgency urinary incontinence (including overactive bladder) in women. This product interacts with the user via smartphone technology.

Important Safety Information for the *leva* Digital Therapeutic: Do not use while pregnant, or if you think you may be pregnant, unless authorized by your doctor. Do not leave the *leva* in your body for longer than necessary to complete the training session. Do not use in any other place in your body or have sexual intercourse while the *leva* is inserted. If you experience odor, fever, diarrhea, any signs of infection, or of an allergic reaction, contact your doctor immediately. For a complete summary of the risks and instructions for *leva* Digital Therapeutic, see its Instructions for Use available at Renovia's website. Treatment with *leva* Therapeutic is prescribed by your doctor. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your doctor should discuss all potential benefits and risks with you.

Healthcare Prescriber Information

*Prescriber First Name: _____ *Last Name: _____

*Address: _____ *City: _____ *State: _____ *Zip: _____

*Phone: () _____ Fax: () _____ *Practice Name: _____

Medical Order

I am prescribing Renovia's leva[®] Digital Therapeutic.

*Diagnosis & ICD-10 Codes (check all that apply):
 N32.81 Overactive Bladder N39.3 Stress Incontinence
 N39.41 Urgency Incontinence N39.46 Mixed Incontinence N81.84 Pelvic Muscle Wasting Other: _____

*Quantity: 1 with refills approved for replacements within one year If other, specify: _____

*Directions for use: Use twice daily (morning & evening), approx 2½ minutes each time, following app Training Mode. Remove after use.

If different directions for use apply, please indicate: _____

I certify I am the Prescriber identified in this form and authorized by law to order the products requested herein. I also certify the prescribed treatment is medically necessary, reasonable and appropriate according to accepted standards within the medical community for the treatment of the patient's diagnosed condition.

*Prescriber Signature (required): _____ *Date: ____/____/____

Patient Information

*First Name: _____ *Last Name: _____ *Date of Birth: ____/____/____

*Mobile: () _____ *Phone: () _____ *Email: _____

*Address: _____ Apartment, suite, etc. (optional): _____

*City: _____ *State: _____ *Zip: _____ *Phone type: iOS Android

HCP | OFFICE INSTRUCTIONS

PLEASE SEND THE FULLY COMPLETED AND SIGNED MEDICAL ORDER EITHER BY
FAX: (877) 800-4371
 OR
EMAIL: RWC@RENOVIAINC.COM

COMMENTS: _____

If you have any questions, please contact Renovia at (866) 735-8423.

6 Month Money Back Guarantee

Renovia guarantees your satisfaction with the leva® Digital Therapeutic if you use it as recommended for 30 days – or we'll provide your money back.

If you follow the leva® Digital Therapeutic's protocol for use (summarized below) for thirty (30) consecutive days within six (6) months of shipment and you are not satisfied, you can contact the Renovia Women's Center for a full refund.

You must request your refund within six (6) months of shipment by Renovia. To qualify for this Money Back Guarantee, you must complete your twice daily exercises in the **leva** app's Training Mode for thirty (30) consecutive days within six (6) months of shipment. All five (5) Training sessions must be completed.

A representative of the Renovia Women's Center will review your usage of the **leva** device to understand the reasons you are dissatisfied and to confirm you have completed your twice daily Training sessions for thirty (30) consecutive days.

Please contact Renovia to confirm the terms of this 6 Month Money Back Guarantee prior to your purchase. Renovia reserves the right, at its discretion, to cancel this offer or modify its terms at any time prior to your purchase.

This Money Back Guarantee is only available to self-paying customers purchasing **leva** directly from Renovia. If you purchase **leva** from your healthcare provider, other terms and conditions will apply and the refund (if any) would come from your healthcare provider. The amount of the refund (if any) from your healthcare provider may vary. Contact your healthcare provider for further information.

STEP 1: Download the **leva** app

- Download the free **leva** app from the App Store® for iPhone® or from Google Play for Android™ phones.
- Launch the **leva** app. Select **Sign Up** at the bottom of the screen.
- Enter your First Name, Last Name, Email, and Password. Indicate if you'd like to receive emails and if you'd like to stay signed in. Click **Sign Up**.
- Review the Renovia Privacy Policy and the Terms and Conditions.
- Enter the 4-digit code from the email you receive. Click **Get Started** to complete creating your account.

STEP 2: Connect and pair **leva**

- **leva** connects to your Apple or Android smartphone via Bluetooth®. Once the app is installed, you can pair your smartphone to **leva**.
- Press the button on the case, slide **leva** out carefully to not bend or twist the vaginal insert. **leva** will automatically turn on when removed from its case.
- Detach the battery. With the marker on the battery facing you, hold the base of the **leva** vaginal insert and rotate the battery to the left. Remove the battery sticker and re-attach the battery by pressing it toward the insert and rotating it to the right.
- The **leva** app will search for your **leva** device ID using a Bluetooth signal. The **leva** App will confirm once it is connected and ready to use.

Limited Warranty

Renovia warrants the **leva**® Digital Therapeutic ("leva" or the "device") against defects in materials and workmanship for twelve (12) months from the date of original purchase; provided, however, that the probe and case battery packs are instead warranted for against defects in materials and workmanship for six (6) months from the date of original purchase. Alleged defects must be reported to Renovia by the original purchaser prior to the end of the warranty. Warranty claims must be supported with reasonable evidence of the claimed defect. Renovia may require the device be returned and if required, will provide customer with a Return Material Authorization number, which must be displayed on the outside packaging sent to Renovia.

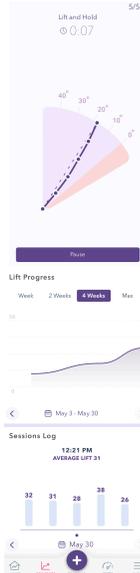
Renovia reserves the right to determine whether to repair or replace a device determined to be defective. In the event of replacement, the warranty period of the replacement device will be run from the date of the original purchase. Repair or replacement of your device will not extend the time period of this limited warranty.

This limited warranty does not cover cosmetic or battery deterioration or damage caused by general wear and tear, physical or natural destruction, accident, misuse, neglect or other external causes. Any attempt to disassemble the device will invalidate this limited warranty and any use of the device that is contrary to its Instructions for Use (available on Renovia's website) may invalidate this limited warranty.

REPAIR OR REPLACEMENT OF THE DEVICE OR ITS AFFECTED COMPONENT ARE THE EXCLUSIVE REMEDIES PROVIDED IN CONJUNCTION WITH THE PURCHASE AND USE OF THE DEVICE. TO THE EXTENT PERMITTED BY LAW, THIS WARRANTY AND THE REMEDIES SET FORTH ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES AND CONDITIONS, WHETHER ORAL, WRITTEN, STATUTORY, EXPRESS OR IMPLIED. RENOVIA DISCLAIMS ALL STATUTORY AND IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND WARRANTIES AGAINST HIDDEN OR LATENT DEFECTS. IN SO FAR AS SUCH WARRANTIES CANNOT BE DISCLAIMED, RENOVIA LIMITS THE DURATION AND REMEDIES OF SUCH WARRANTIES TO THE DURATION OF THIS EXPRESS WARRANTY AND, AT RENOVIA'S OPTION, REPAIR OR REPLACEMENT AS DESCRIBED ABOVE. SOME STATES DO NOT ALLOW CERTAIN WARRANTY LIMITATIONS, SO THE LIMITATION DESCRIBED ABOVE MAY NOT APPLY TO YOU.

Please contact Renovia to confirm the terms of this Limited Warranty prior to purchase. Renovia reserves the right, at its discretion, to modify its terms at any time prior to your purchase.

STEP 3: Train using the **leva** Digital Therapeutic & **leva** app



Practice your first "lift"

The **leva** App provides a tutorial on how **leva** works and what to expect when Training. The **leva** App instructs you on how to perform a correct pelvic floor muscle contraction by displaying the motion produced by your pelvic floor muscles on your smartphone. Once you are done practicing, you are ready to train.

Training Sessions

Each Training Session can be completed in 2 ½ minutes. To begin Training, click on the large "+" button at the bottom of the screen. The app will guide you through a series of 5 lifts with resting periods between. After each lift, you will be shown your **Lift** and **Hold Time** results. After all lifts are completed, you will be shown the average of all 5 **Lift** and **Hold Time** results from your session.

The recommended use is 2 ½ minutes, twice daily.

The **Progress Screen** in the **leva** app keeps a record of the Training Sessions you have completed.

Your Training Session history is automatically stored on the Renovia database and is always available to you.

For further information, please see the Instructions for Use for the **leva** Digital Therapeutic available at Renovia's website.

STILL WAITING...

to do something
about bladder
leakage?



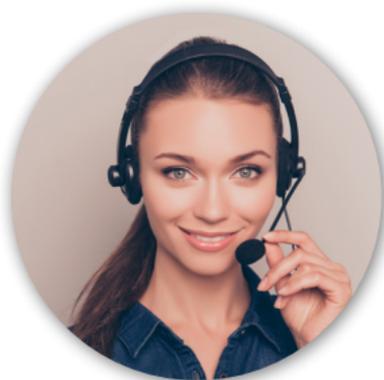
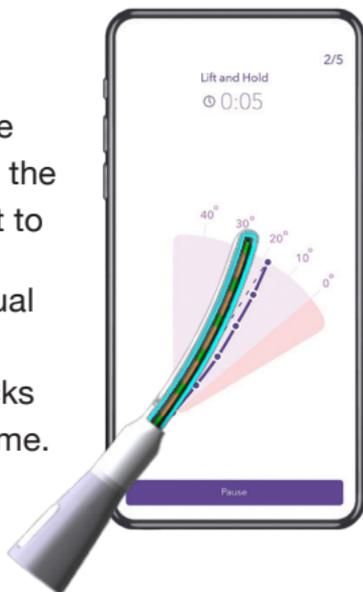
GET HELP WITH *leva*

leva is FDA-cleared for strengthening a woman's pelvic floor muscles for the treatment of urinary incontinence (UI) in women.



1 MOTION SENSOR: While performing exercises, the sensors detect and measure movement when the pelvic floor muscles contract.

2 *leva* APP: The sensor sends the measurement to the App so that you can get real-time visual feedback on your exercises. And it tracks your progress over time.



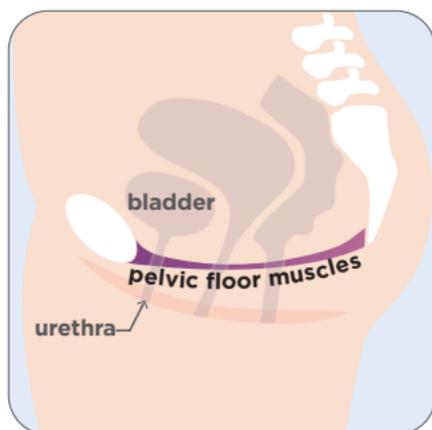
3 SUPPORT: A Personal Coach from the Renovia Women's Center will help you get started.

"leva is so easy to use. Both leva and the coach are exactly perfect for me."

—76-year-old woman with overactive bladder and Urinary Incontinence

BLADDER LEAKAGE IS COMMON

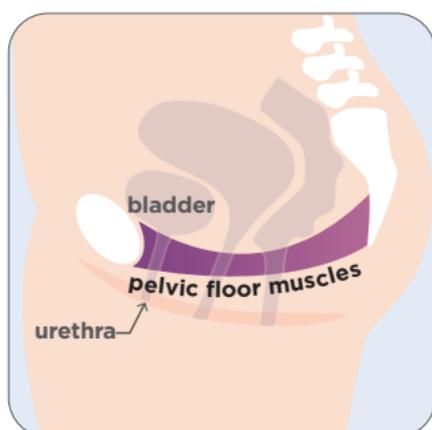
UP TO
51%
of women experience
Bladder Leakage (also
known as Urinary
Incontinence or UI)^{1*}



Weakened Pelvic Floor

Leakage may be caused by pelvic floor muscles that weaken over time.²

Some causes of weakened pelvic floor muscles include childbirth, pregnancy, aging and obesity.³



Strong Pelvic Floor

Training pelvic floor muscles can help decrease symptoms of bladder leakage.

Like any muscle, pelvic floor muscles can be exercised and strengthened.⁴

**n=8,779 non-pregnant women 20 years old or older, community-dwelling in the United States. Participants of the 2001 – 2008 cycles of the National Health and Nutrition Examination Survey. §§n=325 women, averaging 57.8 years of age. All patients were presenting for evaluation of pelvic floor complaint and had one or more pelvic floor disorders.*

1. Markland AD, Richter HE, Fwu CW, Eggers P and Kusek JW. Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. *J Urology*. 2011;86(2):589-93.

2: Eickmeyer SM. Anatomy and Physiology of the Pelvic Floor. *Phys Med Rehabil Clin N Am*. 2017;28(3):455-460. doi:10.1016/j.pmr.2017.03.003

PELVIC FLOOR MUSCLE TRAINING (PFMT) IS BROADLY RECOMMENDED BY DOCTORS^{5,6,7} BUT...

Doing these exercises correctly & consistently can be difficult

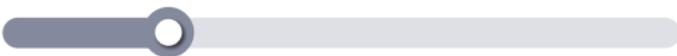
75%



of women with a pelvic floor disorder did not perform PFMT (study of 325 women)^{8,9}

OF THOSE THAT DID,

25%



performed their exercises adequately^{8,9}

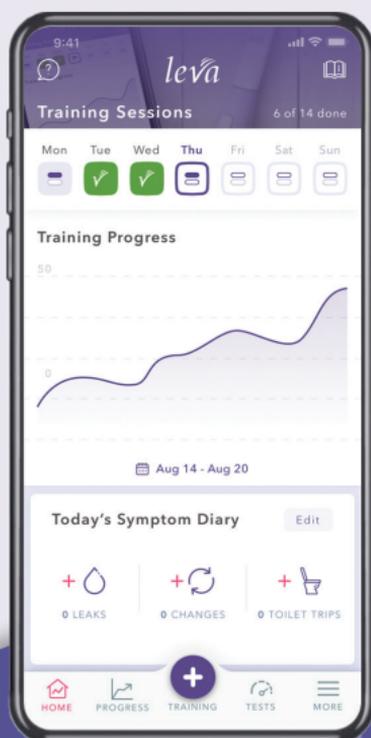
leva®

Helps to train & strengthen your pelvic floor muscles

leva® is an innovative way to train and strengthen weak pelvic floor muscles.

Convenience: Can be done in the privacy of your own home.

Easy: leva takes just **5 MINUTES A DAY.**



* Pelvic Floor Muscle Training (PFMT) is recommended by the American College of Obstetrics and Gynecology, the American Academy of Family Physicians, and the American College of Physicians as first-line, conservative therapy for stress, urgency and mixed UI.

“I find that I no longer pee a lot during burpees and jumps in kickboxing class, so I consider this an absolute win.”

—44-year-old woman with Stress Incontinence

NO NEED TO WAIT GETTING STARTED IS EASY:

- 1 **Talk to your doctor** about getting a prescription for *leva*.
- 2 When your prescription has been sent to the Renovia Women’s Center, **an Educator will contact you within 1-2 business days** to discuss *leva* with you. There is **no obligation to purchase *leva*** to talk to an Educator.
- 3 When you’re ready to start, your **Personal Coach from the Renovia Women’s Center will guide you through the process** of using *leva* as well as help you set goals to get the most out of your training for symptom improvement.

The Renovia Women’s Center will communicate the results of your therapy back to your doctor so they know how you are progressing with symptom relief.



3: Fritel X, Ringa V, Quiboef E, Fauconnier A. Female urinary incontinence, from pregnancy to menopause: a review of epidemiological and pathophysiological findings. *Acta Obstet Gynecol Scand.* 2012;91(8):901-910. doi:10.1111/lj.1600-0412.2012.01419. 4: Dumoulin C, Cacciari LP, Hay-Smith EJC. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database Syst Rev.* 2018;10(10):CD005654. Published 2018 Oct 4. doi:10.1002/14651858.CD005654.pub4 5. Urinary Incontinence in Women. Practice Bulletin No. 155. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015; 126:e66-81. 6. Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD. Clinical Guideline Nonsurgical Management of Urinary Incontinence in Women : A Clinical Practice Guideline From the American College of Physicians. 2014;(September 2013). doi:10.7326/M13-2410. 7. Hersh L, Salzman B. Clinical Management of Urinary Incontinence In Women [published correction appears in *Am Fam Physician.* 2013 Oct 1;88(7):427]. *Am Fam Physician.* 2013;87(9):634-640. 8. Moen MD, Noone MB, Vassallo BJ, Elser DM. Pelvic floor muscle function in women presenting with pelvic floor disorders. *Int Urogynecol J.* 2009;20(7):843-846. doi:10.1007/s00192-009-0853-6.

DON'T WAIT...

to start laughing without anxiety or embarrassment! Get started today.

leva[®]

Non-surgical, Non-drug, Non-invasive

Strengthen & train pelvic floor muscles to help reduce the symptoms of bladder leakage

855-538-2594 | [knowleva.com](https://www.knowleva.com)

The leva Digital Therapeutic is intended for: (i) strengthening of the pelvic floor muscles; and (ii) rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed, and mild to moderate urgency urinary incontinence (including overactive bladder) in women. This product interacts with the user via smartphone technology. Important Safety Information for the leva Digital Therapeutic: Do not use while pregnant, or if you think you may be pregnant, unless authorized by your doctor. Do not leave the leva in your body for longer than necessary to complete the training session. Do not use in any other place in your body or have sexual intercourse while the leva is inserted. If you experience odor, fever, diarrhea, any signs of infection, or of an allergic reaction, contact your doctor immediately. For a complete summary of the risks and instructions for leva Digital Therapeutic, see its Instructions for Use available at Renovia's website. Treatment with leva Therapeutic is prescribed by your doctor. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your doctor should discuss all potential benefits and risks with you.

