



pelviva[®]

Pelvic floor muscle re-trainer
with reactive pulse technology

This pack contains Pelviva[®] and a corresponding number of sachets of OptiLube[™] 2.7g lubricating jelly.

Please read this instruction leaflet carefully before you start using Pelviva[®] because it contains important information that you need to know.

Please note the Contraindications and Warnings before use.

pelviva.com

In this leaflet

1. Indications for use
2. What is Pelviva®?
3. Why do you need Pelviva®?
4. How often should you use Pelviva®?
5. Contraindications – DO NOT USE if...
6. Precautions
7. Warnings
8. How to use Pelviva®
9. Safe Disposal
10. How do you know Pelviva® is working
11. Possible side effects
12. Toxic Shock Syndrome (TSS)
13. Looking after your Pelvic Floor health
14. OptiLube™ and use
15. How to store Pelviva®
16. Pelviva® Manufacturers Declaration
17. Pelviva® Technical Specification
18. Symbol Meanings

Keep this leaflet. You may need to read it again.

If you need more information or advice, please contact your Doctor or healthcare professional, you may also contact our helpline 0800 681 6008 or visit the Pelviva website at www.pelviva.com

INTENDED PURPOSE

Pelviva® is a single use device intended to be used intra-vaginally, providing neuromuscular stimulation and re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urgency, and mixed urinary incontinence in women.

WHY DO YOU NEED PELVIVA®?

If you have weak Pelvic Floor muscles, you're not alone. 1 in 3 women experience leaks from time to time.¹

Your Pelvic Floor muscles have a difficult job helping to hold up your bladder and your uterus. They can weaken with childbirth, menopause, getting older or just because you are made that way.

Pelvic Floor muscle exercises are recommended as the best treatment for bladder leakage in women BUT up to 50% of women are unable to identify their Pelvic Floor muscles correctly or have such weak muscles that they are unable to exercise effectively on their own.

This is where Pelviva® can help. It's designed to stimulate and strengthen your muscles, so you won't have to rely on pads and can just get on with your life.

In a clinical study², 84% of women who used Pelviva® for 12 weeks improved their bladder control and reported a significant reduction in the impact that bladder leaks had on their lifestyle which was four times greater than in women who tried to do Pelvic Floor exercises on their own.

¹ Hunskaar et al. (2004) BJUJ ² Oldham et al. (2013) NUU

WHAT IS PELVIVA®?

Made of soft foam, each Pelviva® contains a microprocessor that delivers the unique Pelviva® reactive pulse technology. Designed to be easy to use and hygienic, each Pelviva® is used once and is disposable.

The soft foam adapts to your individual size and shape and the reactive pulse ensures that the treatment is kept at an effective treatment level for you even if you move around during your treatment.

The unique Pelviva® reactive pulse mimics the way your body works naturally, causing your Pelvic Floor muscles to contract as they should helping you to recognise the feeling of correct Pelvic floor muscle contractions.

Pelviva® is started by removing the pull tab, it is then positioned in the vagina in a similar way to a tampon. Each Pelviva® delivers a programme of stimulation to your Pelvic Floor muscles with specially designed pulses that simultaneously target both the power and endurance muscles in the Pelvic Floor to help restore control if you leak when you exercise, cough or laugh or to hold on when you urgently need to go to the toilet.

Each Pelviva® works for 30 minutes, with a series of 10-second pulses and rest periods. When finished Pelviva® is easily removed by pulling gently on the cord.

Pelviva® is designed to fit the majority of women. The soft foam compresses for ease of insertion and makes Pelviva® so comfortable to wear that you can get on with other things during your Pelvic Floor muscle workout.

Please note warnings in regards to certain activities.

HOW OFTEN SHOULD YOU USE PELVIVA®?

Because it's discreet and simple to use Pelviva® can fit easily into your usual routine.

1. Pelvic Floor muscle re-training

To re-train your Pelvic Floor muscles it is recommended that you use Pelviva® for 12 weeks. Pelviva® should be used every other day except when menstruating. If you forget to use a Pelviva® or cannot use due to menstruation, use one every day to ensure you use 15 in each month. Use 1 sachet of OptiLube™ lubricating jelly with each Pelviva®.

2. Pelvic Floor muscle maintenance

Following completion of your Pelvic Floor muscle re-training you will need to maintain your muscle fitness. Continue with your own Pelvic Floor muscle exercises once every day or alternatively to help maintain your Pelvic Floor muscle fitness you may choose to use 4-6 Pelviva® each month.

Please note, you may notice an improvement in your symptoms within the first few days of using Pelviva® as you become more aware of your Pelvic Floor muscles, but you should continue with the programme until you are sure that the improvement is lasting.

⚠️ CONTRAINDICATIONS – DO NOT USE IF...

Before you use Pelviva®, check this list carefully and DO NOT use if you:

- Are pregnant, planning a pregnancy or have had a baby in the last 3 months
- Have a cardiac pacemaker
- Have suffered from TSS (Toxic Shock Syndrome)
- Have had pelvic surgery within last 3 months
- Are undergoing any active therapy or review appointments for pelvic malignancy
- Have anything else in your vagina, such as a tampon or a diaphragm or while you are engaging in sexual intercourse
- Are male. Pelviva® is not suitable for men to use
- Have had a recent haemorrhage, haematoma or tissue damage in or close to the vagina**
- Have a severe vaginal prolapse (a lump or bulge in the vagina) that you can see or feel at the vaginal opening**
- Have complete loss of sensation in the vagina**
- Have urinary or vaginal infections, localised lesions, or other undiagnosed symptoms of the vagina or labia**
- Have severe atrophic vaginitis or a very dry, itchy or sore vagina**
- Have a problem with manual dexterity and/or would have difficulty inserting tampons because of the size or shape of your vagina**

** If you have any of the above, do not use Pelviva® and we strongly recommend contacting your Doctor or healthcare professional for further advice.

⚠️ PRECAUTIONS

- If you have a history of heart problems or high/low blood pressure, consult your Doctor before using Pelviva®
- If you have epilepsy, consult your Doctor before using Pelviva®
- Pelviva® is not recommended for use in women under the age of 18
- Overuse – using more than one Pelviva® in 24 hours may cause muscle fatigue and can lead to an increase in the severity of the bladder leakage
- Once the Pelviva® wrapper has been opened use immediately, do not store unwrapped

⚠️ WARNINGS

DO NOT RE-USE PELVIVA®. Re-use could lead to vaginal irritation or infection.

DO NOT ATTEMPT TO RE-INSERT PELVIVA®. Re-insertion could lead to vaginal irritation or infection.

DO NOT USE PELVIVA® AFTER THE 'USE BY' DATE – see pack for details.

NO MODIFICATION OF PELVIVA® IS ALLOWED.

THE BATTERY INSIDE PELVIVA® IS NOT RECHARGEABLE.



WARNINGS

DO NOT USE PELVIVA® IF THE PACKAGING IS OPENED OR THE PELVIVA® OR PACKAGE IS DAMAGED.

PELVIVA® CAUSES PHYSIOLOGICAL CHANGE.

Do not use Pelviva® if you are engaging in any activity that could put the Pelviva® in contact with water such as taking a bath, showering or swimming as this may stop them working.

Do not use Pelviva® whilst in close proximity to any shortwave or microwave medical equipment as this may produce instability to the output of the Pelviva®.

Do not operate a vehicle or machinery whilst using Pelviva®.

Do not use Pelviva® during your period.

Do not use more than one Pelviva® at a time.

Pelviva® should only be used in the vagina.

Keep out of reach and sight of children.

Once removed the 'pull tab' represents a choking hazard if placed in mouth.

Do not put a Pelviva® in your mouth as this could lead to asphyxiation.

Only use Pelviva® with the OptiLube™ lubricating jelly supplied.

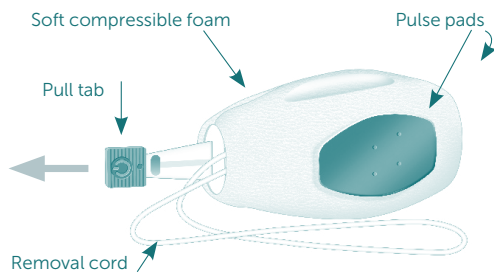
Stop using the product immediately and contact your Doctor or Healthcare professional if you:

- Feel any pain
- Notice any abnormal vaginal discharge, irritation or vaginal bleeding not associated with the usual menstrual cycle
- Experience a burning sensation when you urinate or other symptoms associated with a urinary infection
- Develop any sore areas or broken skin around the vaginal opening

You can also find helpful information in the Frequently asked questions (FAQ) section on the website

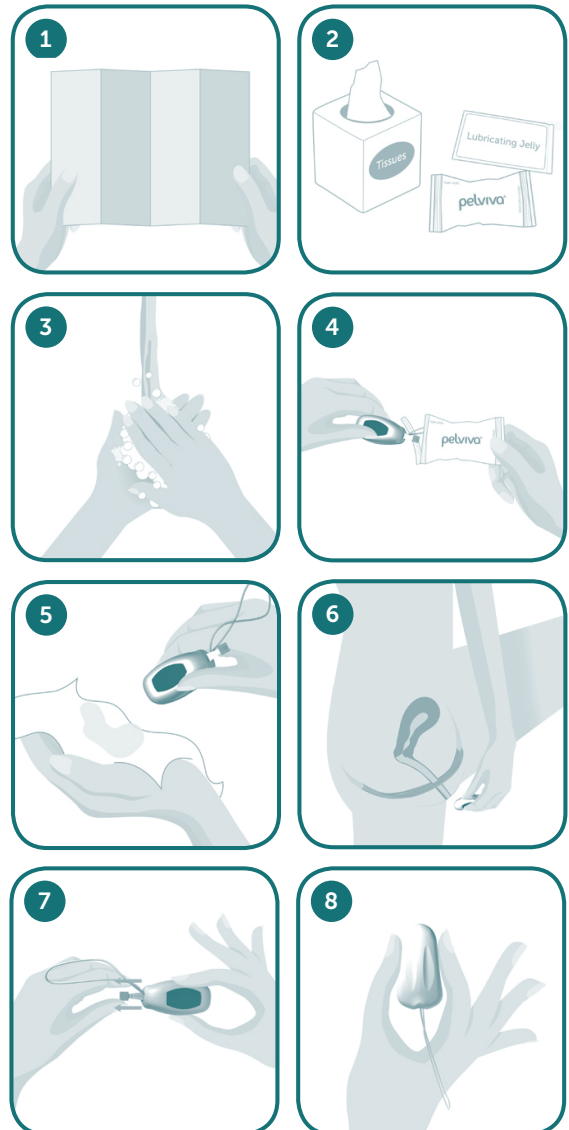
www.pelviva.com.

HOW TO USE PELVIVA®

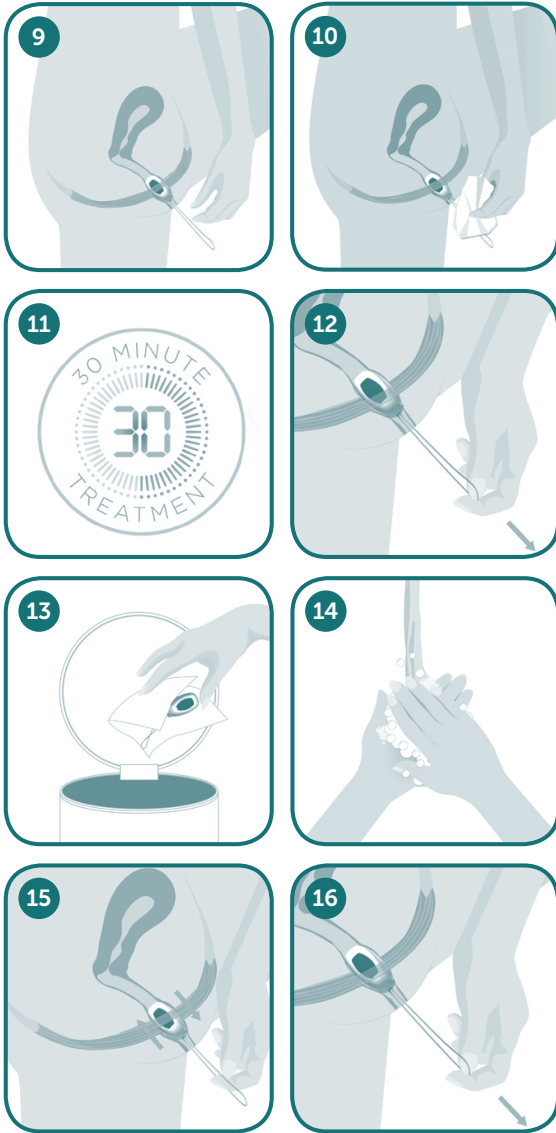


1. Read the Contraindications and Warnings prior to use.
2. Open the box and remove one Pelviva® and one sachet of OptiLube™ Lubricating Jelly. You will also need a clean tissue.
3. Empty your bladder, wash your hands thoroughly and dry.
4. Tear the wrapper where it says 'Tear Here' and take out the Pelviva®.
5. Tear open the OptiLube™ sachet and squeeze the entire contents on to a clean tissue. Take hold of the Pelviva® at the cord end and transfer all the gel onto the other end of the Pelviva® (a scooping action helps).
6. Decide on the most comfortable position where you can relax to insert the Pelviva®, for example, raising one leg onto a small stool or toilet seat, or lying on your back, with your head supported and your knees bent.

7. Pull the tab. After pulling the tab there is a 10-second delay before the programme starts to give you plenty of time to insert the Pelviva®.
8. For ease of insertion, the Pelviva® can be compressed by gently squeezing pulse pads together.
9. Insert the Pelviva®. Making sure that the pulse pads are parallel to your legs left and right, push the Pelviva® into your vagina. It should sit between the Pelvic Floor muscles, slightly below where a tampon fits. Once inserted, the Pelviva® should be at least 2 cm inside with only the cord showing.
10. After insertion wipe away any excess OptiLube™ from the skin.
11. Pelviva® will start a few seconds after you remove the pull tab and will work for 30 minutes then stop automatically.
12. To remove Pelviva® pull firmly on the removal cord.
13. Wrap the Pelviva® and dispose of as normal household waste.
14. Wash and dry your hands after use.
15. If you experience any discomfort during use, try adjusting the position of the Pelviva® by either pushing it further in with your finger or by pulling gently on the removal cord.
16. If you need to remove Pelviva® during use, pull firmly on the removal cord during a rest phase taking care not to touch the pulse pads.



HOW TO USE PELVIVA®



SAFE DISPOSAL

DO NOT FLUSH PELVIVA® DOWN THE TOILET

DO NOT INCINERATE PELVIVA®

DO NOT DISPOSE OF PELVIVA® IN A SANITARY BIN
IN A PUBLIC TOILET

As Pelviva® is used in the vagina it is not recyclable.
Please wrap and dispose of as normal household waste.

HOW DO YOU KNOW PELVIVA® IS WORKING?

When you're using Pelviva® with its reactive pulse technology, you'll feel a pulsing sensation that everyone experiences differently.

For example, new users may feel the pulse very strongly at first but less so after 3–4 Pelviva®, and some women may feel the pulse is greater on one side.

A pulsing sensation tells you that Pelviva® is working, however, some Pelviva® may feel stronger than others depending on their position in your vagina, the activity you are undertaking, the side of the cord, your own anatomy and even the time of the month.

With experience, you will learn how to use Pelviva® to suit your body to obtain your best Pelvic Floor workout. Longer term, you'll know that Pelviva® is having a positive effect as the leaks reduce and you begin to feel more in control.

POSSIBLE SIDE EFFECTS

Pelviva® has been tested to ensure safe use. However, if you do experience any unexpected reactions or technical difficulties whilst using Pelviva® you should stop using the product immediately and contact your Doctor or healthcare professional.

You can also find helpful information in the Frequently asked questions (FAQ) section on the website www.pelviva.com. You can report any unexpected reactions or technical difficulties to our helpline on 0800 681 6008.

Following initial exercise, your muscles may ache after use. Try resting for a few days and then start using Pelviva® again.

TOXIC SHOCK SYNDROME (TSS)

Always remove Pelviva® immediately after the programme finishes. Failure to remove Pelviva® immediately may increase the risk of Toxic Shock Syndrome.

- TSS is a rare infection principally associated with young women using high absorbency tampons during their menstrual period. In the event that Pelviva® has been used during menstruation or has been inadvertently left in the vagina for more than the programme cycle, you are at higher risk of suffering from TSS.
- If you have any sudden fever with vomiting, diarrhoea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn, seek medical attention immediately and stop using Pelviva®.

LOOKING AFTER YOUR PELVIC FLOOR HEALTH

Pelviva®, with its reactive pulse technology, will help you feel your Pelvic Floor muscles working and this can help you exercise them more effectively. There are two types of Pelvic Floor exercise:

1. Long slow contractions

Imagine that you are trying to stop yourself passing wind or urine. Start by tightening the muscles around the back passage, then squeeze and lift your Pelvic Floor muscles upwards and forwards. You may not feel that much is happening at first, but keep trying. Hold the squeeze for a few seconds and then relax for a few seconds. Don't hold your breath. Gradually, increase the hold time and the number of contractions you do until you can hold the squeeze for up to 10 seconds and repeat it up to 10 times.

2. Short strong contractions

Because it's important for your Pelvic Floor muscles to be able to react quickly to stop you leaking when you cough, sneeze, jump, laugh or shout, you need to do these contractions too. Tighten your muscles as quickly and strongly as you can, then relax. Do this up to 10 times each time.

When you're using Pelviva® and you can feel it working, try contracting your Pelvic Floor muscles at the same time and hold for 10 seconds. Do this 10 times, then let the pulses continue.

When you're not using Pelviva®, we recommend that you continue to do exercises 1 and 2 to help maintain the health and strength of your Pelvic Floor.

OPTILUBE™ AND USE

INDICATIONS FOR USE

OptiLube™ is a water soluble, sterile lubricating jelly used to aid the smooth insertion of medical devices in procedures including:

- Insertion of catheters • Endoscopy • Gynaecological examinations • Rectal examinations • Cystoscopy

OptiLube™ is harmless to human tissue.
Contains: Purified water, PEG, Glycerine, Sodium Hydroxide, 4 – Hydroxybenzoic acid ester.

OPTILUBE™ AND USE

WARNINGS: Do not use if product is damaged or seal broken. Do not use if sensitive to any ingredients contained in OptiLube™. If irritation occurs, discontinue use and consult a doctor. Keep out of the reach of children. Sterile until opened.


HOW TO STORE PELVIVA®

Store within a temperature range of 0–35 degrees Celsius. Store in its original packaging in order to protect from moisture.

Do not use this device after the USE BY date which is stated on the box.

PELVIVA® MANUFACTURERS DECLARATION

Electromagnetic Emissions		
Pelviva® is intended for use in all establishments including domestic establishments		
Emissions Test	Compliance	Electromagnetic Environment
RF Emissions CISPR 11	Group 1 Class B	Pelviva® uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
Harmonic emissions IEC 61000-3-2	Not Applicable	Battery Powered 3 volts internal

Pelviva® Electromagnetic Immunity and Guidance			
Pelviva® is intended for use in the electromagnetic environment specified below and the user should ensure it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-8	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial, hospital, or domestic environment
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	See guidance below
<p>Portable and mobile RF communications equipment should be used no closer to Pelviva® than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as follows:</p> <p>Recommended separation distance: $d = 1.2 \sqrt{P}$ for 80MHz to 800MHz $d = 2.3 \sqrt{P}$ for 800MHz to 2.5GHz P = output power rating in watts d = separation distance in metres</p> <p>Interference to Pelviva® may occur in the vicinity of equipment marked with the following symbol </p>			

PELVIVA® TECHNICAL SPECIFICATION



















Pelviva® is operated by battery only, is started 10 seconds after the tab is pulled and ceases automatically after 30 minutes.

- Waveform: asymmetrical modified bi-phasic
- Frequency 2–125 Hz
- Pulse duration: 250 micro seconds
- Max output: 36 (+/- 20%) milliamps
- Rated Output

Load	100 Ohms	1000 ohms
Volts	11.7v (117mA)	26v (26mA)
DC	41.5%	80.2%
Volts RMS max	3.8v	7.3v

DC component may cause slight skin irritation. See 'possible side effects' for advice.

SYMBOL MEANINGS

	PART NUMBER		SERIAL NUMBER
	SEE INSTRUCTIONS FOR USE		BATCH NUMBER
	TYPE BF APPLIED PART		DO NOT USE IF PACK IS DAMAGED
	SINGLE-USE ONLY		USE BY
IP24	INGRESS PROTECTION: • PROTECTED AGAINST FINGERS OR OTHER SOLID OBJECTS OF 12.5MM DIAMETER AND ABOVE • PROTECTED AGAINST WATER SPLASHED FROM ALL DIRECTIONS NOTE 'WARNINGS' PELVIVA® SHOULD BE KEPT DRY. CONTACT WITH WATER MAY RESULT IN MALFUNCTION.		
	STORAGE TEMPERATURE LIMITS		
	HUMIDITY LIMITATION		ATMOSPHERIC PRESSURE
	KEEP AWAY FROM SUNLIGHT AND/OR HEAT		KEEP DRY
	CAUTION		FRAGILE HANDLE WITH CARE
	PELVIVA® IS A REGISTERED TRADEMARK OF FEMEDA		
	MANUFACTURER Pelviva® Femeda Ltd. Unit 9, Network Centre, Colbourne Avenue, Nelson Park, Cramlington, Northumberland NE23 1WD, UK For Order, Enquiries & Advice Tel: 0800 681 6008		
	OptiLube™ Optimum Medical Solutions First Floor, Unit 5, Armley Court, Armley Road, Leeds, LS12 2LB UK. Tel: 08456 435 479		