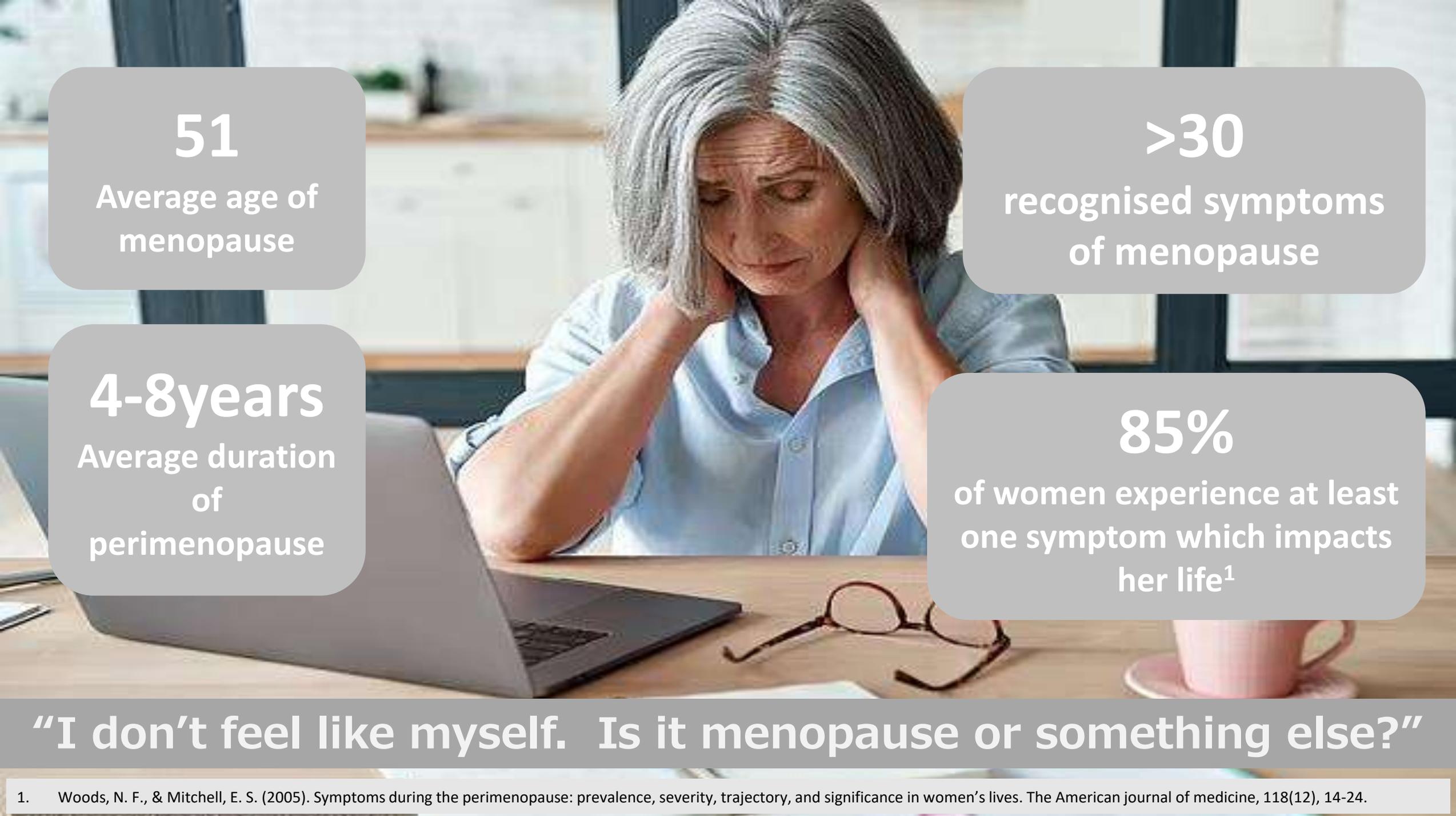


The Clearblue logo is located in the top left corner. It features the brand name "Clearblue" in a white, sans-serif font. Above the letter "i" in "Clear" is a stylized sunburst icon consisting of several short, radiating lines.

NEW Clearblue® Menopause Stage Indicator identifies a woman's likely menopause stage



51

Average age of
menopause

>30

recognised symptoms
of menopause

4-8years

Average duration
of
perimenopause

85%

of women experience at least
one symptom which impacts
her life¹

“I don’t feel like myself. Is it menopause or something else?”

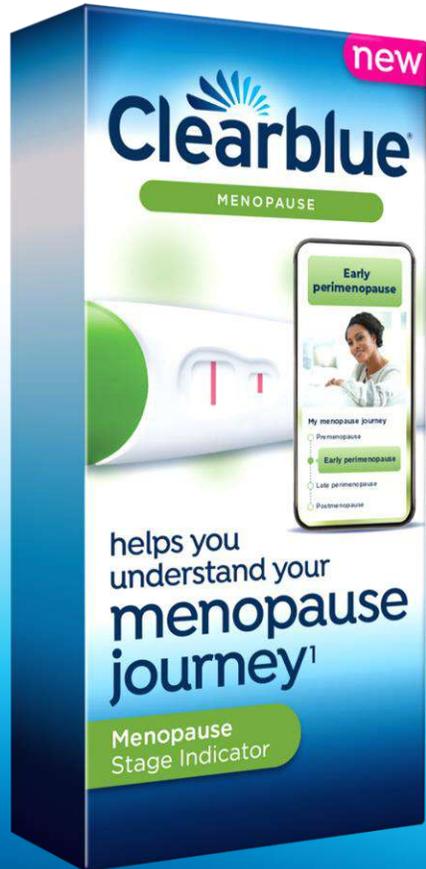
Research Tells Us

More than 2 in 3 women feel unprepared for the menopause journey¹

<10% of women (age 35-60) track their cycles/symptoms²

1. Marlatt KL, Beyl RA, Redman LM. A qualitative assessment of health behaviors and experiences during menopause: A cross-sectional, observational study. *Maturitas*. 2018 Oct;116:36-42.
2. Survey of perimenopause symptom prevalence and tracking – importance for the patient and clinician. Poster Presentation P13. The Menopause Society Annual Meeting. 2023. https://menopause.org/docs/default-source/agm/nams23_regular-lb_abstracts.pdf

Introducing Clearblue® Menopause Stage Indicator



Clearblue® Menopause Stage Indicator uses FSH measurements combined with cycle information and age in an app, to indicate her likely stage on the menopause journey¹

- Premenopause
- Early perimenopause
- Late perimenopause
- Postmenopause

The Clearblue® Menopause Stage Indicator is in line with Stages of Reproductive Aging Workshop (STRAW+10) criteria



1. A confirmed menopause stage diagnosis can only be made by a healthcare professional after all clinical and laboratory findings have been evaluated

STRAW+10

Recognized framework for reproductive aging

MENARCHE (FIRST PERIOD)



MENOPAUSE*



Stage	REPRODUCTIVE			PERIMENOPAUSE		POSTMENOPAUSE		
	Early	Peak	Late	Early	Late	Early		Late
Duration	Variable			Variable	1-3 years	2 years	3-6 years	Remaining lifespan
PRINCIPAL CRITERIA								
Menstrual cycle	Variable	Regular	Regular	Subtle changes in flow/length	Variable length persistent ≥ 7 -day difference in length of consecutive cycles	Cycle length ≥ 60 -day		
SUPPORTIVE CRITERIA								
<i>Hormone levels</i>								
FSH			Normal	Variable	\uparrow^b Variable	≥ 25 mIU/mL ^c	\uparrow^b Variable	Stabilizes
AMH			Low	Low	Low	Low	Low	Very low
Inhibin B			Low	Low	Low	Low	Low	Very low
DESCRIPTIVE CHARACTERISTICS								
Symptoms						Vasomotor symptoms likely	Vasomotor symptoms most likely	Increasing symptoms of urogenital atrophy

* Menopause is defined as 12 months since last period.

^b \uparrow = elevated (blood draw on cycle days 2-5).

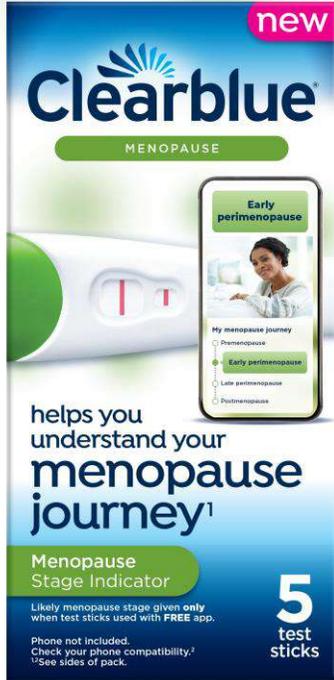
How can Clearblue® Menopause Stage Indicator facilitate patient discussions?

- Personalized report
 - Details her likely **menopause stage** and how it was determined
 - At-a-glance **symptom tracking of 19 most commonly recognized symptoms** associated with menopause
- Improved patient **engagement**
- It provides women with a tool to educate, engage, and empower them on their menopause journey

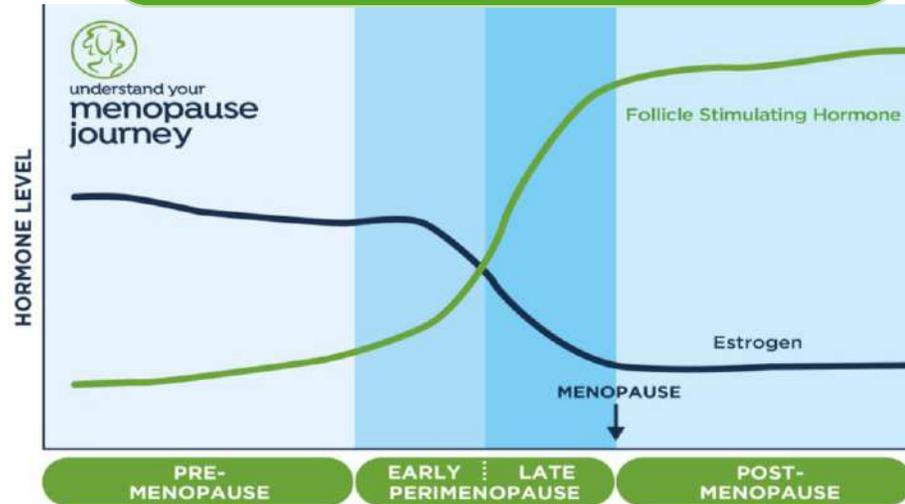
This product is not intended to replace the care provided by healthcare professionals

Clearblue® Menopause Stage Indicator – Product Overview

Clearblue® Menopause Stage Indicator

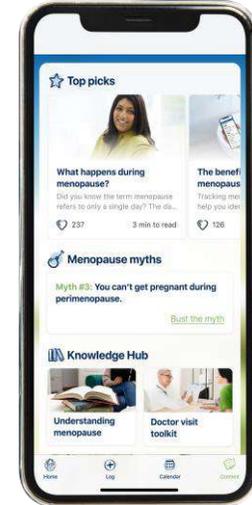


Hormone changes around menopause transition



Hormone changes in the years around the menopause transition. Adapted from: Randolph JF Jr, Zheng H, Sowers MR, et al. *J Clin Endocrinol Metab.* 2011;96(3):746-754.

In app content



Educational content & articles to help her learn more about her menopause journey

How it Works



She downloads Free Clearblue me App (iOS or Android)



She takes 5 Urine Tests over 10 days (every other day)



Indicates her likely Menopause Stage based on FSH results, age & cycle history

- Premenopause
- Early perimenopause
- Late perimenopause
- Postmenopause



She can Log & Track symptoms & cycles



Download a personalized report to share with her Healthcare Professional

Who is it for?

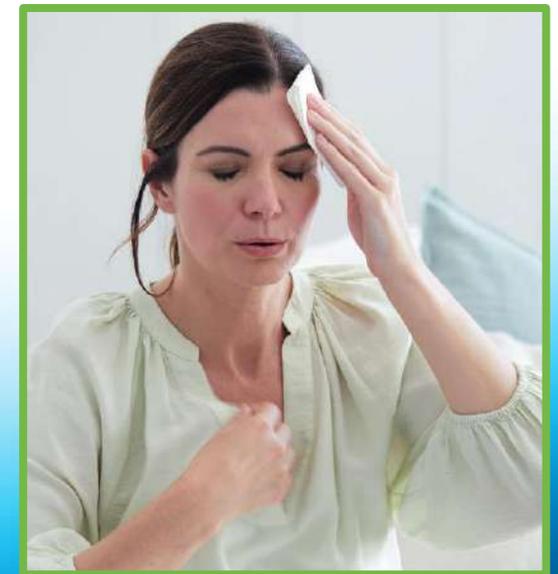
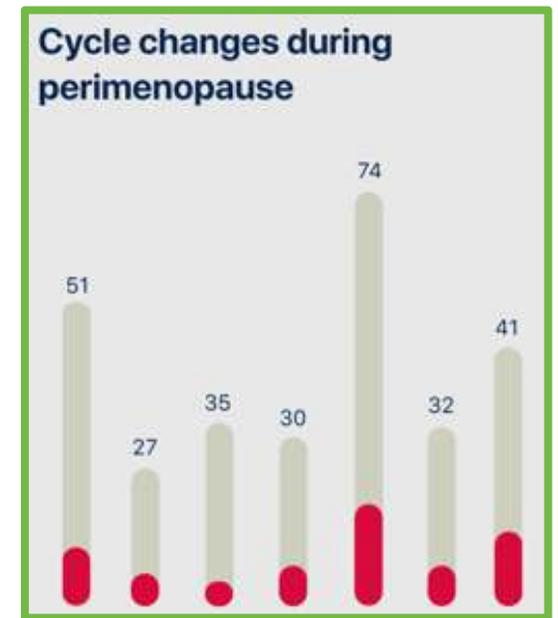
This product may benefit women who:

- Have noticed changes to their menstrual cycles
 - Changes in cycle length (more variability, longer, shorter)
 - Changes to periods (heavier, lighter, longer, shorter)

OR

- Have started to experience some symptoms

And who might be thinking **'Is this menopause?'**



Contraindications

This product is not suitable for women who:

- Are pregnant or breastfeeding
- Are taking hormonal birth control, hormone therapy, or medications affecting FSH
- Have PCOS
- Have had surgical procedures affecting their cycle (e.g. Hysterectomy, Bilateral oophorectomy, Endometrial Ablation)

It is not for contraceptive use.

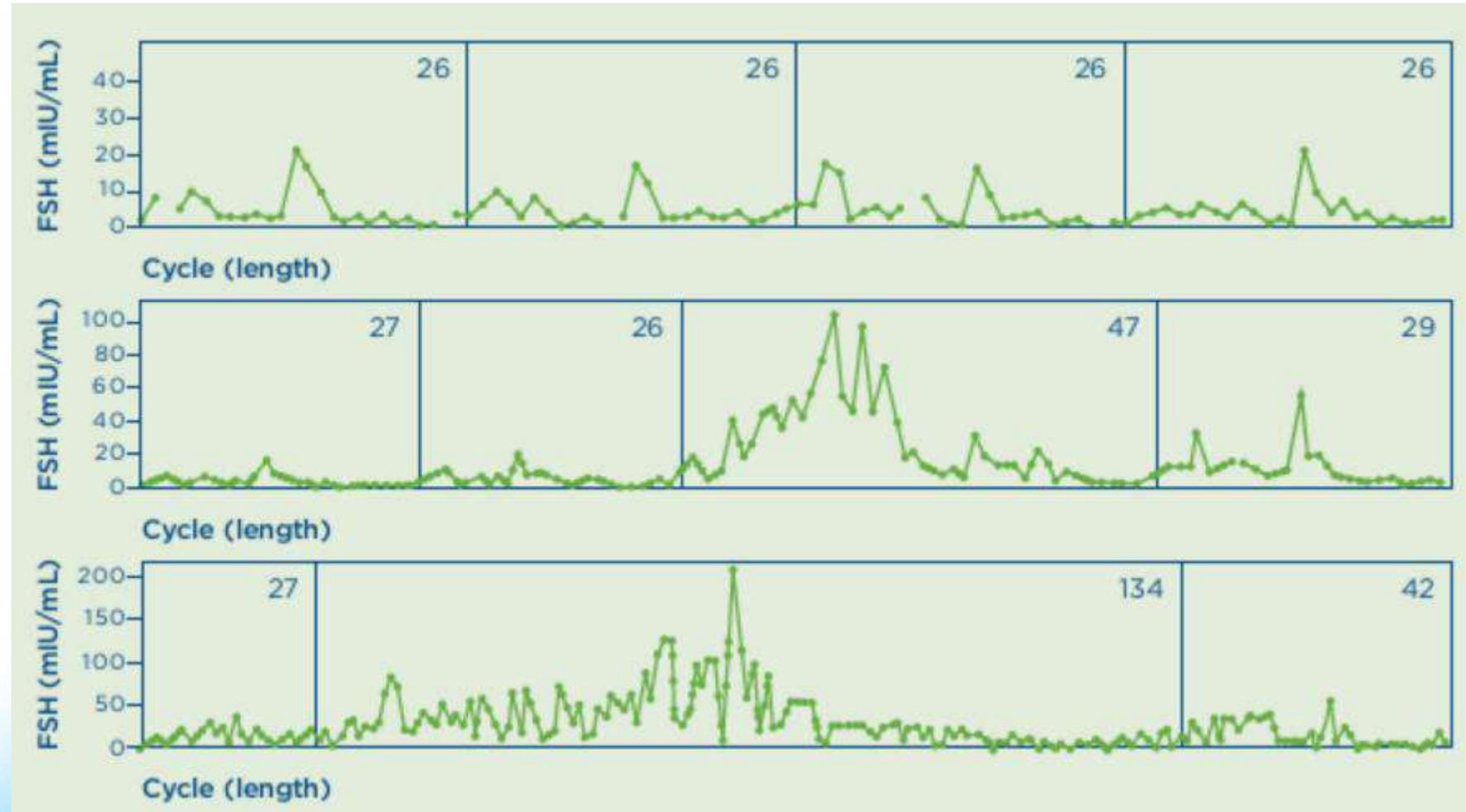
FSH in Reproductive Aging

FSH Clinical Data

FSH increased during reproductive aging.

- Premenopause
 - Consistent cycle length
 - FSH peaks at ovulation
- Early perimenopause
 - Irregular cycle length
 - Raised FSH
- Late perimenopause
 - Irregular, long cycles
 - Raised FSH

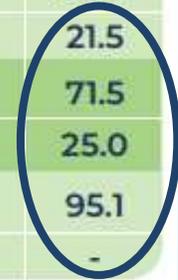
Schematic graph showing how FSH levels fluctuate throughout cycles. SPD Data on file.



Serial FSH tests vs. Single

- Women (n=108) 45-60years, daily urine samples for up to 90 days
- Stage defined by STRAW+10 cycle characteristics
- When testing on a single day, a similar percentage of cycles in the early perimenopause and late perimenopause group had one positive test (≥ 25 mIU/mL) (21.5% vs 25.0% cycles respectively)
- **Testing with 5 Serial FSH tests allows greater distinction** between early (39.2%) and late perimenopausal cycles (71.5%) showing 1 or more positive test(s)

Percentage of cycles with positive test		0		1		1 or more	
		N	%	N	%	N	%
Menopause stage	Testing						
Premenopausal	5 Consecutive days	850	79.1	122	11.4	224	20.9
	Single	163	90.6	17	9.4	17	9.4
Early perimenopausal	5 Consecutive days	557	60.8	86	9.4	359	39.2
	Single	113	78.5	31	21.5	31	21.5
Late perimenopausal	5 Consecutive days	734	28.5	176	6.8	1842	71.5
	Single	90	75	30	25	30	25.0
Postmenopausal	5 Consecutive days	38	4.9	70	9.0	740	95.1
	Single	-	-	-	-	-	-



Clearblue® FSH testing regimen

Our data shows...

- FSH testing can be done at any time in her cycle (vs STRAW+10 reco of day 3-5)

She does 5 urine tests every other day over a 10 day period

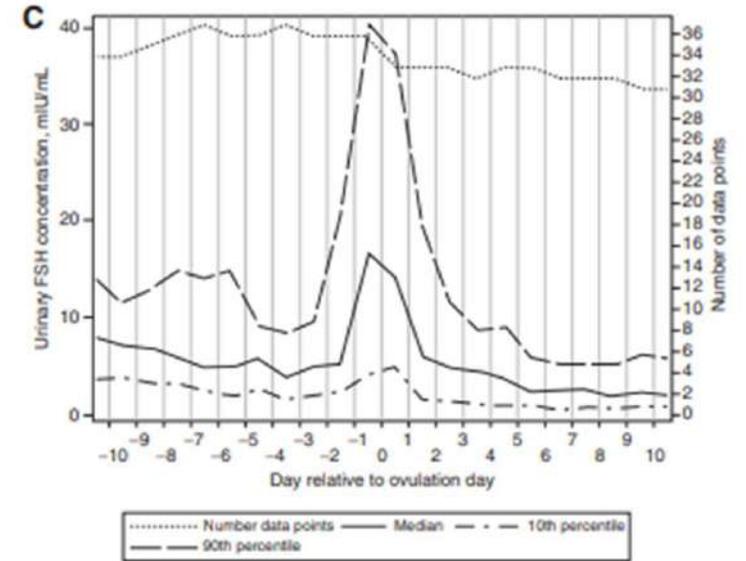
This allows the app to determine her 'overall' FSH level (high, low or variable) and accounts for mid-cycle FSH rise associated with ovulation

This means...

- She doesn't even have to wait until the start of her next cycle
- She doesn't have to test during her period

FSH is a supportive criteria to cycle length information as per STRAW+10.

The FSH results are combined with her age and cycle history to indicate her likely stage.



Clearblue FSH test stick



Urinary FSH concentrations correlate well with Serum¹

Qualitative FSH levels in urine

- FSH test result:
 - Positive if FSH \geq 25mIU/mL,
- >99% accurate results in lab conditions

In-app instructions guide her on how and when to test

Product Performance

Clinical Performance

The overall agreement between the Clearblue[®] Menopause Stage Indicator and STRAW+10 reference system for determining menopause stage was **97.5%** (95% CI: 92.9, 99.5)

Laboratory Analytical Performance

FSH test sticks passed >10 analytical performance studies*

FSH test is >99% accurate

Performance in women's hands

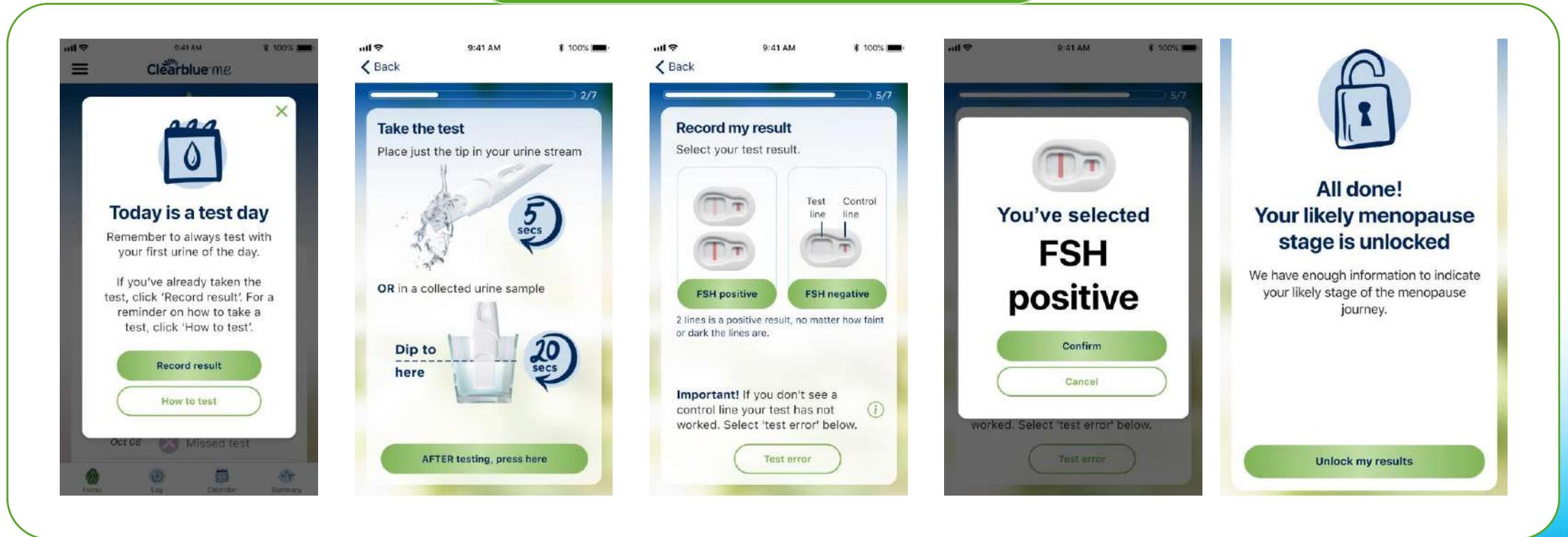
Studies with women representative of the intended user of the product

* Data on file

Clearblue® Menopause Stage Indicator – App Features

User Validated App

App – Guides her how to test



User can set reminders to test

After all tests are taken

User Validated App

App – Clearly displays result and how to generate HCP report

My menopause stage
Jan 12 2023

Early perimenopause

Your likely menopause stage is calculated by combining your FSH test results with other factors including information you provide on your menstrual cycle history and age.

You can't use this product if you're pregnant, breastfeeding, are taking hormonal birth control, hormone replacement therapy, medications affecting FSH, have PCOS, or after surgical procedures which affect your cycle. In such cases the likely menopause stage result may be misleading.

A confirmed menopause stage diagnosis can only be made by a healthcare professional after all clinical and laboratory findings have been evaluated. Always see your healthcare professional before changing or stopping any birth control or other medications.

Next steps?
You may wish to test again in the next few months, and/or see your doctor to confirm your stage.

My menopause journey

- Premenopause
- **Early perimenopause**
Your FSH test results and other factors indicate you are most likely in early perimenopause.
- Late perimenopause
- Postmenopause

What does early perimenopause mean?

Perimenopause means 'around menopause' and is when your menstrual cycles and hormones levels start to change. Early perimenopause means you may experience irregular cycles with 7 days or more difference in length between one cycle and the next on at least 2 occasions. You may also find your periods change, becoming heavier or lighter; or longer or shorter.

You may find you have some menopausal symptoms like hot flashes, night sweats or sleep problems. See your doctor if your symptoms interfere with daily life, or if you have any health concerns.

My FSH test results

A regularly raised level of FSH can be an indication that you are approaching or in menopause, when combined with other factors like age and cycle variability. It's not unusual for FSH levels to vary day to day. That's why several tests are needed to indicate if your overall FSH level is high or low.

Date	Result
Feb 7	Missed test
Feb 9	Positive
Feb 11	Positive
Feb 13	Test error
Feb 15	Test error
Feb 17	Negative

A mixture of positive and negative FSH tests indicates your FSH level is variable.

Save

Period flow

You may wish to see your healthcare professional if you log symptoms as 'high' and/or experience other issues such as unusual bleeding.

light medium heavy extra heavy

Spotting

low medium high

Anxiety

low medium high

Brain fog

low medium high

Breast tenderness

Download your personalized report

Only a healthcare professional can confirm your menopause stage. You may wish to share this report with your healthcare professional to give them information about your likely menopause stage.

You can download your report as often as you wish and it will update your symptoms logged in the last 6 weeks, for you to share your most recent data with your healthcare professional.

Please note, on downloading the report you assume all control and liability of disclosure of the report information.

PDF
File size: Aprox. 500KB

Download

Personalized Report to Share with Healthcare Professional



- 1 **Cycle history**
Has she seen irregular cycle length (varying by 7 days or more) or long cycles (60 days or longer) in the last 12 months
- 2 **FSH results**
Number of Positive ($\geq 25\text{mIU/ml}$) and Negative ($< 25\text{mIU/ml}$) test results
- 3 **Likely menopause stage¹**
The result this woman received from Clearblue® Menopause Stage Indicator
- 4 **Symptoms logged**
Symptom type and frequency logged in the last 6 weeks

Clearblue
Menopause Stage Indicator

Result given on Oct 8

Premenopause
 Early perimenopause 3
 Late perimenopause
 Postmenopause

Details 1

Username: Mary Smith
 DOB: Mar 14 1978
Menstrual cycle over last 12 months: On at least TWO occasions, has seen 7 days or more difference in length between one cycle and the next.
 Has NOT had a cycle of 60 days or more.

Further Information for Healthcare Professionals
 The Clearblue Menopause Stage Indicator algorithm combines 5 serial urine FSH results with age and cycle information (classified based on the Stages of Reproductive Aging Workshop (STRAW+10) criteria) to indicate likely menopause stage. See: Harlow SD, et al. *Executive summary of the Stages of Reproductive Aging Workshop + 10.* J Clin Endocrinol Metab. 2012;97(4):1159-1168.

FSH test results 2

As Follicle Stimulating Hormone (FSH) levels can vary across the menstrual cycle, serial testing (where positive is $\geq 25\text{mIU/ml}$ and negative is $< 25\text{mIU/ml}$ FSH), is used to normalize and indicate if the overall FSH level is high, low, or variable.

5		
4		
3		
2		
1		
0		
	Positive	Negative

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Symptom diary: report downloaded Nov 12

Tracking your symptoms using the Clearblue® me app can help you and your healthcare professional better understand your menopause journey. Please note that at this time symptoms are not included in the algorithm to determine menopause stage.

Symptom Frequency: 1-2 days, 3-4 days, 5+ days

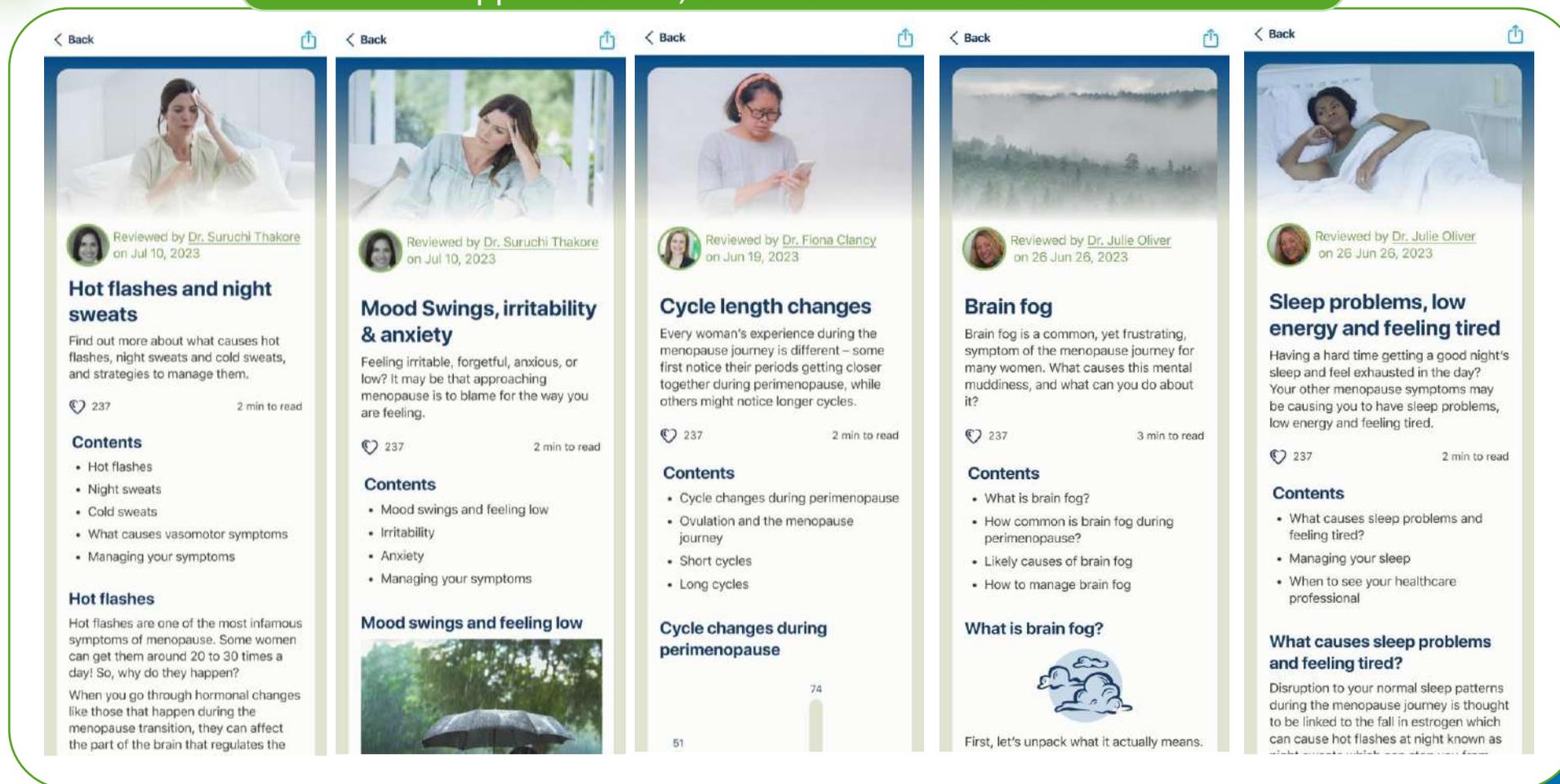
Symptom	Nov 6 - Nov 12	Oct 30 - Nov 5	Oct 23 - Oct 29	Oct 16 - Oct 22	Oct 9 - Oct 15	Oct 2 - Oct 8
Vasomotor						
Hot flashes	3-4 days	3-4 days	3-4 days	3-4 days	3-4 days	3-4 days
Night sweats			3-4 days	3-4 days		
Cold sweats	3-4 days				3-4 days	
Psychological						
Anxiety	3-4 days					
Irritability			3-4 days	3-4 days		
Mood swings						
Low mood						
Forgetfulness						
Brain fog						
Physical						
Spotting	3-4 days	3-4 days	3-4 days	3-4 days		
Tiredness	3-4 days	3-4 days	3-4 days	3-4 days		
Sleep problems						
Headaches			3-4 days	3-4 days		
Joint pain						
Weight gain						
Heart palpitations						
Breast tenderness			3-4 days	3-4 days		
Sexual						
Loss of sex drive						
Vaginal dryness						

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User Validated App

App – Relevant, Credible Educational Content



Where can women find it?

Women can find this product at many retailers and online

Please check <https://www.clearblue.com/buy-now> to find a stockist

Thank you!

For more information visit:

<https://www.clearblue.com/menopause/stage-indicator>

 Clearblue

