

## Instructions For Use

### CARE for Major Depressive Disorder (CARE for MDD) Digital Therapeutic Software

These Instructions For Use are intended to ensure that CARE for MDD is used correctly. Please read this information carefully and follow the instructions below.

#### Intended Use

CARE for MDD is a digital therapeutic intended for the treatment of Major Depressive Disorder (MDD) in adults. It is intended to be used alongside standard of care and supported by a Healthcare Professional.

#### How It Works

CARE for MDD provides treatment composed of three parts: Therapeutic Lessons, Brain Exercises, and Personalised Reminders and Messages.

#### Frequency of Use

CARE for MDD comprises of an active treatment period involving 6 weeks of alternating Therapeutic Lessons and Brain Exercises followed by a 4-week extension period during which you will have open access to the Therapeutic Lessons (10 weeks total). After the 10-week period has ended, you will no longer be able to access CARE for MDD.

Core Feature	Typical Duration*	Frequency
Therapeutic Lessons**	3 - 4 minutes	3 times per week for 6 weeks
Brain Exercises	11 - 26 minutes	3 times per week for 6 weeks
Personalised Reminders and Messages	Less than 1 minute	Regularly for 10 weeks

\*In a clinical study of CARE for MDD, the majority of Brain Exercises were completed in this time frame. Duration will vary by individual user.

\*\*Once the 6-week treatment period is over, Therapeutic Lessons are available to be revisited for an additional 4 weeks.

#### Intended Patient Population

The intended patient population is 18 years and older with MDD.

## **Important Safety Information:**

To access CARE for MDD you will require an access code. This will enable your participation in the treatment program using the smartphone application (app).

CARE for MDD is not a replacement or substitute for your current medical or mental health care treatments. You should continue with your treatment as directed by your Healthcare Professional. CARE for MDD is intended to be used alongside standard of care as a treatment for MDD. Talk to your Healthcare Professional for additional information about MDD treatments that may be right for you.

CARE for MDD cannot send alerts or warnings to your Healthcare Professional. If you feel that your depressive symptoms are worsening or if you have feelings or thoughts of harming yourself or others, please contact your Healthcare Professional, dial 999 or go to the nearest Accident and Emergency Department immediately.

## **Operating Information**

CARE for MDD is intended for people who have access to a smartphone and are familiar with using a smartphone app.

Refer to the Apple App Store or Google Play Store on your smartphone to ensure compatibility to your specific smartphone and Operating System (OS) with an available internet connection. CARE for MDD supports the two most recent iOS and Android OS versions.

Ensure your smartphone is running an OS version matching those required. If not, update your smartphone software version before downloading and using CARE for MDD.

CARE for MDD is not currently compatible for use with computers or tablets.

Please log into CARE for MDD on your smartphone. This will make sure you do not miss any important reminders and will allow CARE for MDD to remember where you are in your treatment.

## **Security**

You are required to enter a username and password prior to using CARE for MDD. Please do not share your username or password with others.

Required updates will be installed on your smartphone automatically, if automatic updates are enabled, otherwise, you will need to visit the app store to manually install the update on your smartphone before you can proceed with your treatment.

If automatic updates are enabled on your smartphone, the update will occur automatically. Otherwise, you can manually update from the app store at your convenience.

## Getting Started

- CARE for MDD is intended for people with MDD who are comfortable with written and spoken English.
- Your Healthcare Professional must recommend CARE for MDD and provide you with instructions on how to obtain an access code in order to use CARE for MDD.
- An internet connection is required to download CARE for MDD on your smartphone. CARE for MDD is available for download from the Apple App Store and Google Play Store. The app can be found by searching for CARE for MDD.
- When you open the CARE for MDD app for the first time, you will need to enter the access code into the app.
- Next, you need to set a password that is at least 8 characters in length, and includes at least one uppercase letter, one lowercase letter, and one number.
- You will need to verify your email address and mobile phone number.
- Once your email address and mobile phone number are verified, you can begin your treatment with CARE for MDD. This includes completing brief Therapeutic Lessons and Brain Exercises. You will also start receiving reminders and personalised messages.
- During the 10 weeks period, you should continue with your current medical or mental health care treatment. Please discuss with your Healthcare Professionals to review your treatment progress.

## Terms and Conditions and Privacy Policy

During account creation, you will be asked to agree to the “Terms and Conditions” and “Privacy Policy”. The “Terms and Conditions” and “Privacy Policy” are accessible by clicking on “Important Information” on the app landing page.

## User Introduction

After you complete your registration, you will be shown a set of screens that will guide you through your assigned activities and how to use the app. Tap the “NEXT” button at the bottom of each screen to navigate to the next screen. You can also tap the back arrow at the top to navigate to the previous screen.

There are six tasks per week, alternating between Therapeutic Lessons and Brain Exercises.

If you miss a day for any reason, **do not worry. You can catch up** by doing two tasks the next day to stay on your weekly schedule. You cannot do more than two tasks per day. At the end of each week, any remaining Therapeutic Lessons are unlocked so you can view them later, but the previous week’s Brain Exercises will not be available.

An example of the recommended treatment schedule is shown in Table 2 and an alternative schedule is shown in Table 3 below.

**Table 2: Recommended Treatment Schedule of Therapeutic Lessons and Brain Exercises**

	<b>Sunday</b>	<b>Monday</b>	<b>Tuesday</b>	<b>Wednesday</b>	<b>Thursday</b>	<b>Friday</b>	<b>Saturday</b>
<b>Week 1</b>	Lesson 1	Exercise 1	Lesson 2	Exercise 2	Lesson 3	Exercise 3	Rest
<b>Week 2</b>	Lesson 4	Exercise 4	Lesson 5	Exercise 5	Lesson 6	Exercise 6	Rest
<b>Week 3</b>	Lesson 7	Exercise 7	Lesson 8	Exercise 8	Lesson 9	Exercise 9	Rest
<b>Week 4</b>	Lesson 10	Exercise 10	Lesson 11	Exercise 11	Lesson 12	Exercise 12	Rest
<b>Week 5</b>	Lesson 13	Exercise 13	Lesson 14	Exercise 14	Lesson 15	Exercise 15	Rest
<b>Week 6</b>	Lesson 16	Exercise 16	Lesson 17	Exercise 17	Lesson 18	Exercise 18	Rest
<b>4 Weeks Continued Access</b>	Option to revisit Lessons 1-18 at any time						

Table 3 shows an example of an alternate treatment schedule where you start treatment in the middle of the week and ‘double up’ on tasks some days.

**Table 3: Alternate Treatment Schedule of Therapeutic Lessons and Brain Exercises (Example)**

	<b>Wednesday</b>	<b>Thursday</b>	<b>Friday</b>	<b>Saturday</b>	<b>Sunday</b>	<b>Monday</b>	<b>Tuesday</b>
<b>Week 1</b>	Lesson 1 Exercise 1			Lesson 2 Exercise 2	Lesson 3 Exercise 3		
<b>Week 2</b>		Lesson 4	Exercise 4	Lesson 5 Exercise 5	Lesson 6 Exercise 6		
<b>Week 3</b>		Lesson 7 Exercise 7		Lesson 8 Exercise 8		Lesson 9	Exercise 9
<b>Week 4</b>	Lesson 10	Exercise 10		Lesson 11		Exercise 11	Lesson 12 Exercise 12
<b>Week 5</b>				Lesson 13 Exercise 13	Lesson 14 Exercise 14	Lesson 15	Exercise 15
<b>Week 6</b>		Lesson 16 Exercise 16		Lesson 17 Exercise 17	Lesson 18 Exercise 18		
<b>4 Weeks Continued Access</b>	Option to revisit Lessons 1-18 at any time						

## Set a Reminder

You can choose to set a daily notification, which will remind you to do your daily task. If it is the first time you use CARE for MDD, you will be prompted to set up this notification. You can click on “Skip This” to continue without setting up these notifications.

You can add your reminder to your smartphone’s calendar to help you stay on track with your program. A prompt will display during the initial app set-up. You can click on “Add to Calendar” and follow the screen prompts. You can click “Skip This” to continue without setting up your calendar.

## Home Screen

Each time you re-open the app, you will be taken to the Home screen.

On the Home screen, you can:

- Monitor your weekly progress goal at the top of the screen in terms of percent completion.
- Start an available Therapeutic Lesson by tapping on “Start” under “Lesson.”
- Start an available Brain Exercise by tapping on “Start” under “Brain Exercise.”

## Patient Profile

You can access your profile by tapping on the “Profile” icon at the top of the Home screen.

### Support

Tapping “Support” under “Profile” will give you access to the number you can call for technical support or to report any side effects or quality complaints.

### Edit Profile

Tapping “Edit Profile” under “Profile” will allow you to change the following information:

- Name
- Password
- Phone number

### Reminders

Tapping “Reminder” under “Profile” will allow you to manage your daily notifications and make changes if desired.

### Important Information

Tapping “Important information” under “Profile” will give you access to the following information:

- Manufacturer
- UK Responsible Person
- App Version
- Intended Purpose
- Instructions for Use
- Terms and Conditions
- Privacy Policy
- Open Source Licenses

### Log Out

You can log out of the app by tapping on “Log out” at the bottom of the “Profile” page.

### Reset Password

Your Password can be reset by tapping on “Forgot Password” on the login page or by editing “Profile” on your “Profile” page.

## **My Plan**

Your plan progress or upcoming Therapeutic Lessons and Brain Exercises for the week can be accessed by tapping on “My Plan.”

## **Tasks**

Each week the CARE for MDD treatment includes six tasks: three Therapeutic Lessons and three Brain Exercises.

The Home screen will display your daily tasks. You will need to complete the Therapeutic Lesson before you can unlock the Brain Exercise.

### Therapeutic Lessons

To begin your assigned Therapeutic Lesson, go to the Home screen in the app and tap “Start” which can be found in the Therapeutic Lessons box. Follow the instructions in the app to complete the Therapeutic Lesson.

When you complete the Therapeutic Lesson, tap “Done” and you will return to the Home screen to start your next task.

You can go back to finish Therapeutic Lessons any time from the “Learn” tab on the menu bar at the bottom of your screen.

### Learn Library

There are a total of 18 Therapeutic Lessons. The Therapeutic Lessons are stored in the learn library and can be accessed by tapping “Learn.”

### Toolkit

After the Therapeutic Lessons are completed, they will be added to the “Toolkit.” You can revisit and practice completed Therapeutic Lessons by tapping on “Toolkit.”

### Brain Exercise

The Brain Exercises are designed to activate the parts of your brain that are more responsible for emotion recognition and memory. Activating these two parts of the brain at the same time is believed to help strengthen the connection between them. This may help the brain better process emotions and improve symptoms of depression.

The app will give you directions on how to complete the Brain Exercises. This may feel difficult at times, but that is normal. You will have as much time as needed to complete the Brain Exercise once you begin; however, if you start a Brain Exercise and are then interrupted for 15 minutes or more, the app will restart your Brain Exercise session for the day. It’s not about speed or accuracy. The point is to keep your brain challenged and engaged.

There are a total of 18 Brain Exercises. To begin your assigned Brain Exercise, go to the “Home” screen in the app and tap “Start” which can be found in the Brain Exercise box.

When you complete the Brain Exercise, tap “Done” and you will return to the “Home” screen.

### Messages/Reminders

CARE for MDD includes reminders to help keep you on schedule such as SMS text messages that reinforce the skills taught in the lessons and are meant to encourage completion of the program. Personalised SMS text messages also reinforce concepts and skills acquired during the lessons.

### Continued Access

The 6-week treatment course is followed by a 4-week lesson review period where you will have continued access to the Therapeutic Lessons only. Brain Exercises will no longer be available. After the 10-week time period (6-week treatment period plus 4-week lesson review period) has ended, you will no longer be able to access CARE for MDD.

## **Manufacturer:**

Otsuka America Pharmaceutical Inc. 2440 Research Blvd, Rockville, MD 200850

## **UK Responsible Person:**

Otsuka Pharmaceutical Europe Ltd. 2 Windsor Dials, Arthur Road, Windsor, SL4 1RS, United Kingdom

To get Care for MDD support or report Care for MDD side effects or quality complaints, contact Otsuka Pharmaceutical Europe Ltd. at +44 (0) 2033758575.

Available: Monday–Friday (excluding National Holidays)

Hours of Operation: 9 AM to 5 PM

Website: [www.careformdd.co.uk](http://www.careformdd.co.uk)

## **Emergency**

Call 999 or go to the nearest Accident and Emergency Department if you are experiencing a medical emergency or you are in immediate danger of suicide.

If you have any questions about your depression, please contact your Healthcare Professional, or call 111.

## **SOFTWARE VERSION**

Please refer to the “Important Information” section in the Patient Profile section of CARE for MDD for details of the current software version.

Date of issue of the instructions for use: **25-MAR-2024**