

## deprexis Instructions for Use

These Instructions for Use are intended to ensure that deprexis is used correctly. Please read this information carefully and follow the instructions below. In addition, should you have any queries, the deprexis support team is there to help you during the usual office hours.

### INTENDED USE

#### EU, Switzerland, United Kingdom:

deprexis is intended to provide therapeutic methods and exercises based on evidence-based psychological and psychotherapeutic therapies for patients with unipolar depression or depressive disorders, to help them managing their depression or depressive disorder. deprexis is intended as a self-application supplemental to care-as-usual for patients 18 years of age or older. deprexis can be used for a period of 90 days. deprexis is neither intended to replace treatment provided by a health care provider nor to provide information which is used to take decisions with diagnosis or therapeutic purposes.

#### USA:

deprexis is web application indicated for the adjunctive treatment of chronic or recurrent depression or depressive disorders as a primary or secondary diagnosis (e.g. as a comorbidity in multiple sclerosis or epilepsy) for patients 18 years of age or older who are experiencing a depressive episode.

deprexis as an interactive online program can be accessed via any internet access. In order to use deprexis, the patient will receive an access key. This access key entitles the patient to use deprexis for 90 days after the first registration.

### HOW IT WORKS

deprexis is an interactive online program intended to be used independently by patients with unipolar depression or depressive disorders. It consists mainly of recognised treatment elements from cognitive behavioural therapy.

deprexis contains exercises and techniques for dealing with your condition. It also provides information on how to maintain a healthy lifestyle, and support with putting this into practice. deprexis provides you continuously with a choice of responses which you can select in order to align the content with your needs and preferences. At your request, deprexis will send you regular emails and text messages to help you delve deeper into the content of the exercises and integrate them in your daily routine.

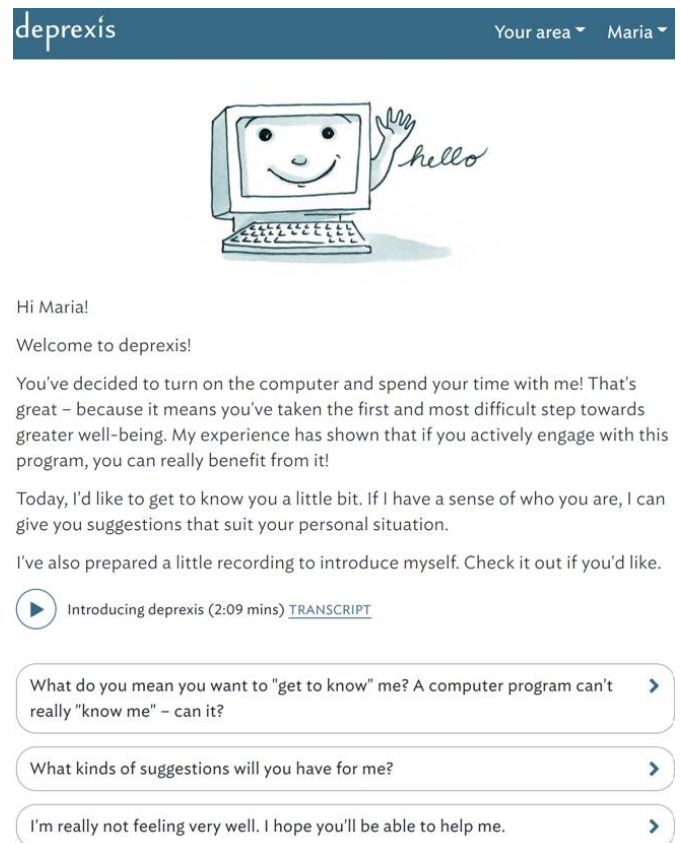


Fig.1: Example of a dialogue in deprexis.

In order to register with deprexis, you need an access key. The normal usage period for each access key is 90 calendar days after initial registration. If you have received the access key through a doctor's prescription, the period of use may differ. Once you have registered, deprexis is password-protected and you can access it any time via the internet provided that you have a compatible browser.

All processing of personal data is in accordance with the EU General Data Protection and the Health Insurance Portability and Accountability Act in USA. You can find further information on personal data protection in the privacy policy.

### REQUIREMENTS FOR USE

You will need a computer, a laptop, a smartphone or a tablet with internet access, as well as an up-to-date version of one of the following browsers: Google Chrome, Mozilla Firefox, Edge or Safari. A minimum (logical) resolution of 320 x 568 pixels is recommended. You will also need an email address and, as an option, a mobile number for the text message service. For audio files, a bandwidth of 192 kBit/s is recommended.

No special computer skills are required, as deprexis guides you through the program in an interactive dialogue.

### INDICATION

deprexis is used in the supportive treatment of patients with unipolar depression or depressive disorders.

### WHEN SHOULD deprexis NOT BE USED (CONTRAINDICATIONS)?



deprexis should not be used by patients with bipolar disorder, psychotic disorder (e.g. schizophrenia) or by patients with suicidal risk.

#### Explanation

A patient is considered at risk of suicide if they have harboured serious intent to commit suicide during the past 90 days (regardless of whether there was a concrete plan to do so). Patients who have attempted suicide during the past 12 months are also considered at risk.

### FREQUENCY OF USE

Experience has shown that deprexis should ideally be used 1-2 times a week for at least half an hour for each session.

### AGE RESTRICTION

18 years. No data is available for patients under 18 years of age.

### SIDE EFFECTS AND SAFETY INFORMATION



deprexis is not a substitute for clinical care administered by a qualified healthcare professional.

Current medication and/or treatments must never be changed without first consulting your doctor or psychotherapist. You should contact your doctor or psychotherapist if your mood or condition has not improved after a prolonged period of time (more than several days or weeks), or becomes suddenly worse.

It is possible that not every patient will benefit from using this program; this may in some circumstances trigger feelings of disappointment.

Not every exercise or every recommendation is equally suitable for every patient. If working with the program becomes too stressful for you, or if an exercise or recommendation is too difficult, makes you feel uncomfortable, causes you problems or exacerbates your complaints, you should take a break from using the program and talk to your doctor or psychotherapist about this.

Should you experience any side effects associated with your use of deprexis, please inform your doctor or psychotherapist immediately or send an email to [info@deprexis.com](mailto:info@deprexis.com).

All serious incidents that occur in connection with this product should be reported to the manufacturer and to the competent authority in the EU country in which you are resident.

You can find further contact details in the deprexis legal notice under the menu item "Help".

To date there are no known interactions.

### INFORMATION FOR EMERGENCIES

In case of an emergency (e.g. a crisis or deterioration in your state of health), you should contact your attending doctor/psychotherapist immediately or call the telephone number for emergency services in your country. Here are some examples

Germany:

- General emergency calls: 112
- Emergency services: 112
- Police: 110
- Counselling: 0800 111 0 111, 0800 111 0 222

Switzerland:

- General emergency calls: 112
- Ambulance: 144
- Police: 117
- Counselling helpline: 143

France:

- General emergency calls: 112
- Emergency services: 15
- Police: 17
- Counselling: 0147077777
- Suicide prevention hotline: 0145394000

## Italy:

- General emergency calls: 112
- Emergency services: 118
- Police: 113
- Counselling: 199284284
- Suicide prevention hotline: 800860022, 0633777740

## Spain:

- General emergency calls: 112
- Ambulance: 061
- Police: 091
- Counselling: 902500002
- Suicide prevention hotline: 717 003 717

## UK:

- General emergency calls: 999
- Emergency services: 999
- Police: 999
- Counselling: 111
- Suicide prevention hotline: 116 123

## USA:

- General emergency calls: 911
- Emergency services: 911
- Police: 911
- Counselling: 1-800-784-2433
- Suicide prevention hotline: 1-800-273-8255

If you cannot reach anyone or get help using these telephone numbers, please check if they have changed.

**MANUFACTURER**

GAIA AG  
Hans-Henny-Jahnn-Weg 53  
22085 Hamburg  
Germany  
www.gaia-group.com

**SOFTWARE VERSION**

Please refer to the deprexis legal notice under the menu item "Help" for details of the current software version.

**INFORMATION CURRENT AS OF**

2021-11-24

**FURTHER INFORMATION**

For technical questions, please email the support team at [info@deprexis.com](mailto:info@deprexis.com). If you would like a complimentary printed copy of these Instructions for Use, please send your request to the support email address mentioned above. We will send you the printed copy within 7 business days.

**EXPLANATION OF SYMBOLS**

- Caution



- Manufacturer



- Medical Device



- Consult electronic instructions for use



- The authorised representative in Switzerland