

edupression.com® System

edupression.com® System contains the registered medical products edupression.com® Psychoeducation and edupression.com® Mood Chart.

INSTRUCTIONS FOR USE

These instructions for use will help you to use edupression.com® correctly. Therefore, please read this document carefully and follow the instructions contained therein as closely as possible. If you have any questions, please do not hesitate to contact the edupression.com® team in the supported forums or via the mail address kontakt@edupression.com during normal business hours.

INTENDED USE

The intended use of edupression.com® is based on those of the two medical devices it contains:

The online-based **psychoeducation** for unipolar depressive patients developed by edupression.com® is based on the goal-oriented and structured communication of preventive and disease-relevant information to patients with unipolar depression, combined with psychotherapeutic effective factors, largely derived from elements of cognitive behavioral therapy, with the aim of

- the reduction of depressive symptoms,
- the improvement of the course of disease in depressive patients,
- of improving the functional level of depressed patients,
- the improvement of treatment adherence,
- of improving remission rates of depressed patients,
- the reduction of the risk of relapse in mildly to moderately ill depressed patients,
- preventive effects in people with low symptom severity.

The edupression.com® **mood chart** is used for monitoring

- of depression symptoms,

- mood instability,
- residual symptoms of unipolar depressed patients,
- as well as in the presence of depressive "sub-threshold symptoms",

which gives the patient visual feedback on disease progression and therapy response.

In addition, the mood chart is used to monitor newly developing depressive symptoms in the context of relapse, thus supporting early detection of relapse or recurrence by the patient.

In addition, the edupression.com® mood diagram supports the patient's recognition of temporal relationships between depressive symptoms and factors that may have a positive or negative influence on the course of the disease or the response to therapy. Thus, the edupression.com® mood diagram supports desired behavioral changes by the patient.

FUNCTION

edupression.com® System offers help to people suffering from unipolar depression by educating them about diagnosis and treatment principles, providing therapy-relevant information (e.g., therapy methods, mechanisms of action, opportunities and risks), compensatory skills for specific, problem-related deficits (e.g., social skills), and supporting the patient in developing general self-management and coping skills (e.g., problem-solving strategies for dealing with relapses). This typically includes elements from cognitive behavioral therapy.

The therapy content is repeated in a playful manner and is thus internalized. To ensure the safety of the patients, technical safety precautions are in place (e.g., in case of suicidal thoughts, a warning is sent with a request to seek help) and professionally trained contact persons are available in the supervised forums. In addition, the patient has the option of doing the program together with a depression specialist (doctors, psychologists, psychotherapists).

The mood chart provides users with a graphical representation of their symptoms; this gives them the opportunity to monitor the course of

the disease during therapy, but also an early warning system that indicates possible deterioration after recovery ("remission").

Through the graphical feedback of the edupression.com® mood chart, you can immediately recognize changes in mood. In addition, you can make an intangible illness visible and tangible for yourself and his/her social environment. This possibly helps in dealing with work colleagues, friends and family and creates understanding for an illness that is still stigmatized.

CONDITION OF USE

You need a computer, a laptop, a smartphone or a tablet PC with Internet access as well as a browser in a current version (Google Chrome, Mozilla Firefox, Internet Explorer/Edge or Safari). Furthermore, you need an e-mail address. Special computer skills are not required.

Language skills in German or English are required.

AREA OF APPLICATION

edupression.com® system is suitable for all unipolar depressive disorders without psychotic symptoms, as well as for depressive moods that are below the diagnostic threshold of a depressive episode.

CONTRAINDICATION



Absolute contraindication:

F20 Schizophrenia; F22 Persistent delusional disorders; F25 Schizoaffective disorders; F31 Bipolar affective disorder

(with the exception of F31.3); F32.3 Severe depressive episode with psychotic symptoms; F33.3 Recurrent depressive disorder, current episode severe with psychotic symptoms; Suicidality.

Relative contraindication: F31.3 Bipolar affective disorder, current episode mild or moderate depression; F32.2 Severe depressive episode without psychotic symptoms; F33.2 Recurrent depressive disorder, current episode severe without psychotic symptoms.

This also applies to depressive patients who, for various reasons, are unable to follow the online

offer of psychoeducation (e.g. intelligence impairment, alcohol or drug intoxications, visual impairment, etc.). edupression.com® is also not suitable for patients who are unable to use a digital terminal such as a computer/tablet/smartphone or who do not have the necessary language skills. do not have the necessary language skills, which may apply to some geriatric patient groups or patients with a native language that is not available on edupression.com® or who lack foreign language skills.

METHOD AND DURATION OF APPLICATION

Access to edupression.com® is possible via a code to be entered during registration. The period of use per code covers the prescription period from initial registration.

During this period, users are given access to the Activity Feed (Home). Personalized therapy sessions are played out via this feed. Many playful elements (videos, quizzes, ...) and emails encourage users to actively engage with the information and exercises and to integrate them into their everyday lives.

NOTES

A medical examination should always be carried out at the beginning of treatment for unipolar depressive disorder in order to exclude physical causes (e.g., thyroid disease). Any change in existing medication and/or treatment should not be made without consulting your doctor/psychotherapist. Furthermore, we recommend contacting your doctor or your therapist if your mood and condition do not improve for a longer period of time (several days/weeks) or if they even worsen acutely.

Suicidal thoughts or thoughts of harming yourself can occur as a symptom of depression. If you experience these thoughts acutely, we strongly recommend that you consult your doctor or psycho-therapist, or the nearest hospital.

SOFY GmbH recommends the use of the edupression.com® system in consultation with the treating doctor, psychotherapist or psychologist. (These three professional groups are

often simplified at edupression.com® as "depression specialists").

FREQUENCY OF USE

Experience shows that edupression.com® should ideally be used 3–4 times a week for 10–15 minutes each time.

The mood chart should ideally be used daily, preferably in the evening before going to bed.

MINIMUM AGE

edupression.com® system is suitable for patients aged 18 and over.

SIDE EFFECTS

Not all patients may be able to benefit from program use. This can potentially trigger feelings of disappointment.

You may find that dealing with upsetting issues is stressful for you. If dealing with the program is too stressful for you, you should take a break, suspend program use and talk to your doctor/psychotherapist about it.

Not every exercise is equally suitable for every patient. If an exercise causes you difficulty, feels uncomfortable, or affects you, do not continue to perform that exercise. Consult your physician/psychotherapist if necessary.

If any side effects occur in connection with the use of edupression.com®, report them immediately to your doctor or psychotherapist or contact us by e-mail at kontakt@edupression.com.

INTERACTIONS

We are not aware of any interactions.

EMERGENCY INFORMATION

In case of emergencies (e.g., crises, suicide risk), contact your attending physician/psychotherapist, or a hospital in your area immediately. Alternatively, please dial the emergency numbers applicable to your country.

MANUFACTURER



SOFY GmbH, Am Renninger 8, 3400
Klosterneuburg, Austria

STATE OF THE SOFTWARE

For the current software version of edupression.com® System, please refer to the imprint of the edupression.com homepage.

STATE OF INFORMATION

2023-08-11

FURTHER INFORMATION

For further questions, please contact us by e-mail kontakt@edupression.com.



System consisting of registered medical devices according to Article 12 MDD (EU Regulation 93/42/EEC as amended) or Article 22 MDR (EU Regulation 2017/745 as amended).