

KOPFSCHMERZWISSEN – THE APP: INSTRUCTIONS FOR USE

TRADE NAME

Kopfschmerzwissen

MEDICAL DEVICE CLASS

CE Risk class I medical device
as per Annex VIII of Regulation (EU) 2017/745

PRODUCT IDENTIFIER

UDI-DI: 04270005361918

REQUIREMENTS FOR USE

- iPhone with iOS 17 or later, or iPad with iPadOS 17 or later (displayed in iPhone format)
- Android smartphone or tablet with Android 13 or later
- Internet connection: required to activate the app (code or in-app purchase) and for the medication scanner
- Free storage space: at least 200 MB; languages: German, English, Arabic

CLINICAL BENEFIT

The 'Kopfschmerzwissen' mobile app is designed to reduce headache episodes by secondary and tertiary prevention in migraine (ICHD-3, 1) and tension-type headache (ICHD-3, 2) and by primary prevention of medication-overuse headache (ICHD-3, 8.2).

For this purpose, aspects of individual behaviour that are particularly relevant to the occurrence of headaches, medication intake and symptoms typical of these disorders are recorded, documented and analysed on the basis of user input. Users receive information and reminders, selected on the basis of their input, about factors that trigger headaches. Using the 10–20 rule, the app alerts users to impending medication overuse.

The app records and identifies features of migraine, tension-type headache and medication-overuse headache in accordance with the International Classification of Headache Disorders (ICHD-3), but does not make a diagnosis.

The app's analysis results allow headache triggers to be identified and monitored for each individual user, so that health-promoting measures can be derived with which users prevent headache attacks.

Using the app does not replace medical examination and advice. Users affected by headaches are advised to consult a doctor. Users can make the headache and medication information they have documented in the app available to their treating doctors separately, in the form of a medical report.

Target group
The main target group of the application is German-speaking people aged 18 and over.

Contraindications
No contraindications are known. Using the 'Kopfschmerzwissen' smartphone application is not associated with any specific risk; to date, no incidents in connection with the use of the app have become known.

Notes on use
The medical device is self-explanatory and can be used without any time limit.

The medical device gives recommendations on physical activity, food intake and fluid intake. If you have an underlying condition that requires a particular diet, a restricted fluid intake or restricted physical activity, you may only be able to use the app to a limited extent. In these cases, we recommend consulting a doctor before using the medical device.

Please report serious incidents in connection with the use of 'Kopfschmerzwissen' to the manufacturer and to the competent authority in your country.

Side effects
No side effects are known when the app is used as intended.

PRODUCT DESCRIPTION

Objectives
The 'Kopfschmerzwissen' mobile app is designed to:
- reduce the frequency and intensity of headache episodes; it is intended to promote individual health literacy and to support people aged 18 and over in preventing migraine, tension-type headache and medication-overuse headache competently and effectively in everyday life;
- draw attention to impending medication overuse;
- summarise headache episodes in line with the ICHD, in accordance with the medical requirements for headache documentation (headache attacks; medication intake).

How it works
With the app, users document headache-relevant aspects of their own behaviour, their medication intake and any headache symptoms that occur. The app analyses their entries, taking the current state of research into account.

Users receive personalised information, suggestions and recommendations for prevention, selected on the basis of their entries. 'Kopfschmerzwissen' prompts users to let the app remind them of preventive measures.

The app identifies features of migraine, tension-type headache and medication-overuse headache. To do so, it draws on the criteria of the International Classification of Headache Disorders (ICHD-3). It also makes it possible to monitor factors that trigger headaches particularly often.

On the start screen, users see the number of days on which they have taken medication during the last 30 days. From five days onwards, they receive a warning that medication should not be taken on more than ten out of 30 days. A barcode scanner integrated into the app makes it easier to record exactly which medication has been taken.

Users affected by headaches are advised to see a doctor. The information on headaches and medication collected with the app is passed on to the treating doctors in a clear summary (medical report).

Users are encouraged to integrate a progressive muscle relaxation exercise, which is available in the app, into their everyday lives.

Contents

The following are documented and analysed:

- Areas of behaviour: sleeping, eating, drinking, work (breaks, screen time, lighting conditions, noise exposure), perceived stress, physical activity, and alcohol and other stimulants.
- Headache features: in accordance with the criteria of the International Classification of Headache Disorders (ICHD-3).
- Medication intake: medication, time of intake, effect.

Users can add notes in their own words.

The medical report (PDF) contains all user entries on headaches and medication.
On the basis of their entries, users receive personalised messages with information, suggestions and recommendations on headache prevention. User interfaces and the texts behind the info buttons provide medically sound knowledge about headaches and how to prevent them.

Users can be reminded of preventive measures in the following areas: going to bed, meals, drinking, breaks, physical activity, relaxation.

The headache quick test developed by Prof. Göbel can be taken in the app.
Users can do a progressive muscle relaxation exercise.
Within the app, users can access the information portal prevent-headache.org.

Using the app

Users document their behaviour (including medication intake) and headache attacks every day and are shown personalised analysis results.

The app provides users with analysis results from the very first day of use and with personalised messages after the third day of use.

Users can generate and export the medical report at any time and pass it on to their doctor.

By using the reminder function, users receive push notifications that encourage preventive behaviour.

A relaxation exercise based on Jacobson's method allows users a short period of active relaxation.

In the 'Achievements' category, users can see where their behaviour already helps to prevent headaches, which keeps them motivated.

MANUFACTURER

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SUPPORT

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DATE OF ISSUE OF THE INSTRUCTIONS FOR USE

25 November 2026

You can request a paper copy of these instructions for use free of charge at info@zies-frankfurt.de or +49 (0) 69-9540717-0. It will be delivered within 7 calendar days at most. Older versions of these instructions for use are available from the manufacturer on request.