Virtual/Augmented Reality Software in Medical Rehabilitation: Key Legal Issues

Oprogramowanie do tworzenia rzeczywistości wirtualnej/rozszerzonej w rehabilitacji medycznej: kluczowe kwestie prawne

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SUMMARY

Introduction: Vast majority of new IT technologies are primarily used in entertainment, vivid example of that is virtual reality and augmented reality. But this technologies are also widely used in medicine. One of the most perspective spheres for medical implementation of virtual reality and augmented reality technologies is medical rehabilitation. According to the prognosis of the research and consulting company IndustryARC, by 2020 the global market for virtual and augmented reality in healthcare will reach $ 2.54 billion. They will be used mainly for training doctors and rehabilitation of patients. Therefore, virtual reality and augmented reality is a widely known technologies in entertainment (and especially gaming) but relatively new phenomenon in medicine. Moreover, the problem of defining the legal regulation for hardware and software parts of such technologies is an "open book" nevertheless they rapidly redrafting the healthcare industry landscape and are thus poised to become a hive of legal activity in the years ahead. Some key legal aspects and perspectives of virtual reality and augmented reality devises' software that are using with medical rehabilitation aim will be a scope of this study.

Material and Methods: This study is based on EU, US, Japan and Ukrainian technical regulation acts, documents provided by an international voluntary group of medical device regulators, scientific researches and opinions of progressive-minded people in this sphere. The article is based on dialectical, comparative, analytic, synthetic and comprehensive methods.

Review: The legal regulation of software, which is used for medical purpose in Ukraine, is limited to one single normative definition. In European Union (EU), United States of America (US) and Japan there were developed and applied special guidelines that help developers, manufactures and end users to differ software on types by medical purpose criteria. Although there is no special rules for virtual reality and augmented reality devises' software that are using with medical rehabilitation aim, analyzing its legal nature it would be possible to admit that making some analogy with existing law regulation model of stand-alone medical devices' software is a right way for now. However, prospect evolution in technology may demand appropriate legal adjustment.

Conclusions: We can admit that there is already some existing legal base for regulation of virtual reality and augmented reality devices software that is used with medical rehabilitation aim. But there's also a big question of divergence between those group of virtual reality and augmented reality devices' software that is "more gaming than medical" and those examples of virtual reality and augmented reality devices' software, that really could be classified as medical device as standalone software. Using of already existing and commercially-available virtual reality and augmented reality technology to provide therapies for neurological disorders, rehabilitation etc. should significantly reduce costs for consumers – patients (by ability to carry out therapy at home) and for specialized medical institutions (because of ability to adapt existing technology for new kinds of therapy thus saving costs). However, not fully defined state of virtual reality and augmented reality software for medical rehabilitation from legal point of view definitely need some adjustment for avoidance of potential collisions in future.

Key words: medical rehabilitation, Virtual Reality devices' software, Augmented Reality devices' software, stand-alone software, medical purpose, medical devices.

STRESZCZENIE

Wstęp: Zdecydowana większość nowych technologii IT jest wykorzystywana przede wszystkim w rozrywce, czego przykładem jest rzeczywistość wirtualna i rzeczywistość rozszerzona. Ale technologie te są również szeroko stosowane w medycynie. Jedną z najbardziej perspektywicznych sfer, w których możliwa jest implementacja technologii rzeczywistości wirtualnej i rzeczywistości rozszerzonej jest rehabilitacja medyczna.

Materiał i metody: Zgodnie z prognozami firmy badawczo-konsultingowej IndustryARC do 2020 roku światowy rynek wirtualnej i rozszerzonej rzeczywistości w opiece zdrowotnej osiągnie wartość 2,54 mld USD. Będą one wykorzystywane głównie do szkolenia lekarzy i rehabilitacji pacjentów. Niemniej jednak rzeczywistość wirtualna i rzeczywistość rozszerzona to szeroko znane technologie w sferze rozrywki (zwłaszcza w świecie gier), ale stosunkowo nowe zjawisko w medycynie. Co więcej, problem zdefiniowania regulacji prawnej dla elementów sprzętowych i oprogramowania tych technologii jest nadal „otwartą księgą". Jednak szybko zmieniają one krajobraz sektora opieki zdrowotnej, przez co staną

się prężną gałęzią legalnej działalności w nadchodzących latach. Celem tej pracy jest omówienie niektórych kluczowych aspektów prawnych i perspektyw technologii rzeczywistości wirtualnej i rzeczywistości rozszerzonej, które wykorzystuje się do celów rehabilitacji medycznej.

Przegląd: Regulacje prawne dotyczące oprogramowania wykorzystywanego do celów medycznych na Ukrainie ograniczają się do jednej definicji normatywnej. W Unii Europejskiej (UE), Stanach Zjednoczonych (USA) i Japonii opracowano i zastosowano specjalne wytyczne, które pomagają programistom, producentom i użytkownikom końcowym w różnicowaniu oprogramowania na typy według przyjętych kryteriów zastosowania poszczególnych produktów w medycynie. Chociaż nie istnieją specjalne zasady dotyczące wyrobów wykorzystujących oprogramowanie tworzące rzeczywistość wirtualną i rzeczywistość rozszerzoną i mających zastosowanie w rehabilitacji medycznej, analizując ich prawny charakter, można uznać, że dokonanie pewnej analogii z istniejącym modelem regulacji prawnych dotyczącym oprogramowania samodzielnych wyrobów medycznych jest obecnie właściwą drogą. Jednakże, w dalszej perspektywie rozwoju technologii może okazać się konieczne wprowadzenie odpowiednich modyfikacji prawnych.

Podsumowanie: Możemy przyznać, że istnieje już pewna podstawa prawna do regulacji urządzeń posiadających oprogramowanie do rzeczywistości wirtualnej i rzeczywistości rozszerzonej i wykorzystywanych w celach rehabilitacji medycznej. Ale pojawia się również istotna kwestia dotycząca rozbieżności między tymi grupami urządzeń, które mają «bardziej charakter gier niż wyrobów medycznych» oraz urządzeniami, które naprawdę można zakwalifikować jako wyroby medyczne, takie jak samodzielne oprogramowanie. Wykorzystanie już istniejącej i dostępnej komercyjnie technologii rzeczywistości wirtualnej i rzeczywistości rozszerzonej w celu zapewnienia terapii zaburzeń neurologicznych, rehabilitacji itp. powinno znacznie obniżyć koszty dla konsumentów pacjentów (dzięki możliwości prowadzenia terapii w domu) oraz dla wyspecjalizowanych instytucji medycznych (z powodu umiejętności dostosowania istniejącej technologii do nowych rodzajów terapii, co pozwala obniżyć koszty). Jednak nie do końca określony stan prawny oprogramowania do rzeczywistości wirtualnej i rzeczywistości rozszerzonej wykorzystywanego w celach rehabilitacji medycznej zdecydowanie wymaga poprawy w celu uniknięcia potencjalnych problemów w przyszłości.

Słowa kluczowe: rehabilitacja medyczna, urządzenia wykorzystujące rzeczywistość wirtualną, urządzenia wykorzystujące rzeczywistość rozszerzoną, samodzielne oprogramowanie, przeznaczenie medyczne, urządzenie medyczne

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INTRODUCTION

Today, the vast majority of new IT technologies are primarily used in entertainment sphere, vivid example of that is virtual reality and augmented reality. Many games, entertaining mechanisms etc. are built on the base of abovementioned technologies nowadays. However, helmets and glasses that plunging us into other worlds could be useful not only for sophisticated games. For example, virtual reality technologies are widely used in medicine. One of the most perspective spheres for medical implementation of virtual reality and augmented reality technologies is medical rehabilitation [1].

According to the forecast of the research and consulting company IndustryARC, by 2020 the global market for virtual and augmented reality in healthcare will reach $ 2.54 billion [2]. They will be used mainly for training doctors and rehabilitation of patients.

The greatest experience in the use of virtual reality and augmented reality technologies has been accumulated in the field of restoring hand movements of the patients with the pathology of the Central Nervous System.

Software is becoming increasingly important and pervasive in healthcare. Given the availability of a multitude of technology platforms (e.g., personal computers, smart phones, network servers, etc.), as well as increasing ease of access and distribution (e.g., internet, cloud), software created for medical purposes (software used to make clinical decisions) and non-medical purpose (e.g., administrative, financial) are being used in healthcare [3].

Therefore, virtual reality and augmented reality are a widely known technologies in entertainment (and especially gaming) but relatively new phenomenon in medicine. Moreover, the problem of defining the legal regulation for hardware and software parts of such technologies is an "open book" nevertheless they rapidly redrafting the healthcare industry landscape and are thus poised to become a hive of legal activity in the years ahead [4]. Some key legal aspects and perspectives of virtual reality and augmented reality devices software that are using with medical rehabilitation aim will be a scope of this study.

MATERIAL AND METHODS

This study is based on EU, US and Ukrainian technical regulation acts, documents provided by an international voluntary group of medical device regulators, scientific researches and opinions of progressive-minded people in this sphere. The article is based on dialectical, comparative, analytic, synthetic and comprehensive methods.

REVIEW AND DISCUSSION

Bearing in mind novelty of Virtual Reality (VR) and Augmented Reality (AR) technologies at all and especially in medical sphere (including rehabilitation) we need to star from defining of them, using its natural and legal determinants. So:

Virtual Reality [5] – The computer-generated simulation of a three-dimensional image or environment that can be interacted with in a seemingly real or physical way by a person using special electronic equipment, such as a helmet with a screen inside or gloves fitted with sensors.

Augmented Reality [5] – A technology that superimposes a computer-generated image on a user's view of the real world, thus providing a composite view.

"Gamification" in areas such as science, medicine and healthcare is not an absolutely new approach, numerous clinical trials has been looking for such new form of rehabilitation for at least 10-15 last years. Finding the newer, cost-effective, user-friendly, user-oriented and innovative methods of treatment in medical rehabilitation drove us to VR/AR technologies [6, 7].

High level of effectiveness of VR/AR technologies in rehabilitation is obvious [8]: the process are effective as an conventional medical rehabilitation, the process is less boring and more joy able for patient, easily accessible for the majority and could be easily organized at home, however still usable for medical institutions. Development of movement-based consoles, such as the Wii, Xbox Kinect etc., alternative methods of treatment for different areas such as rehabilitation of stroke, treatment for patients with Cerebral Palsy, Parkinson's have become much more available and less complex. Wide use of virtual/augmented reality (VR/AR) therapy can provide increasing of motivation and positive feedback to the patient among medical rehabilitation. Many existing medical trials are proving it to be successful, showing better results than conventional occupational therapies in terms of recovery. New and new ideas and start-ups in this field are emerging literally every day, for example "FDA cleared the Yugo Microsoft ($MSFT) Kinect-based physical therapy system. Developed by Israeli startup Yugo, the device can be used to create a personalized physical therapy routine, which can be done at home following prompts from an Xbox or other computer that's connected to the Kinect. The Kinect camera records patient's movements and sends it to the cloud, enabling physiotherapists to keep tabs on their patients' rehabilitation from orthopedic injuries (or lack of therapy, in the case of those who are noncompliant)" [9].

Both technologies could be used in rehabilitative medical techniques but what about their software status, is it remains in entertainment sphere or must it be considered as part of medical sphere with appropriate law regulation? Could VR/AR software be considered as a medical device? Answers on questions are not so obvious and demand precise legal technique to avoid serious complications in future.

Ukrainian technical regulation of Medical devices states, that term "medical device" means any instrument, apparatus, appliance, **software**… **including the software intended by its manufacturer to be used specifically for** diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation, for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception - and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means [10]. Definition provided in Council Directive 93/42/EEC from 14 June 1993 concerning medical devices is equivalent [11]. The main factor of determining is purpose, but such limited scope of definitive characteristics is misleading in nowadays medical paradigm.

The first step in determining of VR/AR software place among medical devices is approach to determine its nature by analogy with existing legally regulated categories. Main medical device regulators in the US, Europe, Japan and other markets have begun addressing some of the challenges that arise when software and medical devices converge. In Europe, for example, regulators have suggested the following categories of software that functions as a medical device [12]: a) *Software that is a component and integral part of a medical device; b) Software as a medical device (also known as stand-alone software), including apps.*

First group looks obvious and software, which is a component of medical device, automatically is viewed as a medical device. Second group is slightly different (and such category must include VR/AR medical software in our view) and the difficultness ground on the fact that such software can be used for a large variety of medical purposes [13]. Standalone software can directly control an apparatus, can provide immediate decision triggering information, or can provide support for healthcare professionals, but wide variety of their groups demands to clarify some criteria for the qualification of stand-alone software as medical devices [14].

EU in terms of defining standalone healthcare software has **EC`s Guidelines on the qualification and classification of standalone software** published in January 2012. The document gives some guidance regarding process of qualifying standalone software as medical device. **Step 1:** if the stand-alone software is a computer program, then it may be a medical device. If the software is not a computer program, then it is a digital document and therefore not a medical device. **Step 2:** if the software is incorporated into a medical device rather than standalone software, it must be considered as part of that medical device in the regulatory process of that device. If it is standalone software, proceed to decision step 3. **Step 3:** if the software does not perform an action on data, or performs an action limited to storage, archival, communication, 'simple search' or lossless compression (*i.e.* using a compression procedure that allows the exact reconstruction of the original data) it is not a medical device. **Step 4:** an example of software for the benefit of individual patients is software intended to be used for the evaluation of patient data to support or influence the medical care provided to that patient. Examples of software which are not considered as being for the benefit of individual patients are those which aggregate population data, provide generic diagnostic or treatment pathways, scientific literature, medical atlases, models and templates as well as software for epidemiologic studies or registers. **Step 5:** if the manufacturer specifically intends the software to be used for any of the purposes listed in Article 1(2) a of Directive 93/42/EEC, then the software shall be qualified as a medical device (if only a non-medical purpose, such as invoicing or staff planning, is intended by the manufacturer – it is not a medical device). **Step 6:** if the software is an accessory to a medical device, it is not a medical device, but it falls under Directive 93/42/EEC.

The legal definition of 'putting into service' requires that a device is made available to the final user/operator as being ready for use on the Community market. Software made available to the user over the internet (directly or via download) or via *in vitro* diagnostic commercial services, which is qualified as a medical device, is subject to the medical devices directives [14].

USA has the same document named **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices** (issued on May 11, 2005). This guidance stands for Food and Drug Administration's (FDA's) current position on this topic and is intended to provide information to industry regarding the documentation that is recommended to include in premarket submissions for software devices, including standalone software applications and hardware-based devices that incorporate software [15].

Qualification of Medical Device Software in Japan grounds on Japanese Pharmaceutical Affairs Law, that has been revised as "PMD Act" and it has been in effect since Nov. 25, 2014. One of the significant points of the revision was the implementation of revised GHTF Essential Principles (2012) which led to the introduction of standalone medical device software into the Japanese regulatory system [16].

The intended use of the medical device software is based on the definition of the medical device, installed in general-purpose PC or handheld terminals. Qualification of Medical Device Software: 1) Software which creates indices, images, charts for diagnosis or treatment by means of processing data from medical devices; 2) Software which supports the decision of treatment plan or treatment method (including simulation software). General concept of regulation in many aspects is comparable with US regulations [15].

Some help at this point comes from International Medical Device Regulators Forum (a voluntary group of medical device regulators), that produced document which provide regulators with the fundamental building blocks and a common understanding of the many kinds and importance of software for medical purposes in advancing public health [17].

Narrowing the scope of medical devices' software there are group of EU standards, among main of them [12]:

The IEC 60601 family of standards. The third edition of IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*, published in 2005, was a major revision of the standard, and included most of the content of IEC 60601-1-4 as clause 14, IEC 60601-1-4 could be withdrawn now.

IEC 62304 for stand-alone and component medical device software. IEC 62304 *Medical device software - Software life cycle processes* was published in 2006, covering both software as a component of a medical device and standalone software (a medical device in its own right). IEC 62304 is the only international standard for medical software that has been recognized in many jurisdictions.

IEC 82304: A dedicated health software system standard. The scope of IEC 82304-1 intersects the scope of IEC 62304 but is not identical. It includes different types of software and different steps of the software lifecycle. IEC 82304-1 deals with health software, defining .HEALTH SOFTWARE assoftware intended to be used specifically for maintaining or improving health of individual persons, or the delivery of care. It is completed with the definition of health software product in the section 3.7 of the standard; HEALTH SOFTWARE PRODUCT as combination of HEALTH SOFTWARE and ACCOMPANYING DOCUMENTS; MEDICAL DEVICE SOFTWARE as SOFTWARE SYSTEM that has been developed for the purpose of being incorporated into the MEDICAL DEVICE being developed or that is intended for use as a MEDICAL DEVICE

Much deeper analysis on this matter could be found in our previous papers, devoted to defining legal and natural aspects of standalone software as medical device [18, 19].

Returning to the first point we must admit that VR/AR software could be/could be not defined as a medical devices' software according to it designation and impact on human's health. In addition, key difference between both definitions is the purpose of use. IEC 62304 – for medical intended use, whereas IEC 82304-1 – for any kind of software, which directly or indirectly has an effect on health. The scope of IEC 82304-1 is broader than the scope of IEC 62304. The following types of software are in the scope of IEC 82304-1 but not IEC 62304: Radiology Information Systems (RIS), Prescription Management Systems (PMS), Laboratory Information Management Systems (LIMS), Mobile Apps, which are not Mobile Medical Apps, according to the FDA Guidance on this subject, Software, which are not qualified as medical devices, according to the MEDDEV 2.1/6 EU Guidance. Thus, IEC 82304-1 includes in its scope standalone software, which are not regulated as medical devices [20].

US legislation categorize medical software by Draft Guidance dividing them on three groups: 1) apps that "are an extension of one or more medical devices by connecting to such a device for purposes of controlling the device or displaying, storing, analyzing, or transmitting patient-specific medical-device data."; 2) apps that "transform a mobile platform into a medical device by using attachments, display screens, or sensors, or by including functionalities similar to those of currently regulated medical devices."; 3) apps that "allow the user to input patient-specific information and — using formulae or processing algorithms — output a patient-specific result, diagnosis, or treatment recommendation to be used in clinical practice." The FDA proposes to regulate apps that fall into any of these three categories as medical devices. As such, they will be subject to the regulatory process discussed here [21]. Japanese approach are more or less the same with that in US.

Therefore, we can admit, that there is already some legal base for regulation of VR/AR devices' software, which is used with medical rehabilitation aim. A lot of similar characteristics with "classic" stand-alone software shed some light on this point. However, there is also a big question of divergence between those groups of VR/AR devices software that is "more gaming than medical" and those examples of

VR/AR devices software, which really could be classified as medical device as standalone software and that is used for medical rehabilitation after various diseases. So, there is a huge question of how they will be controlled, which kind of regulation must be established. Nevertheless, there is no current strict and understandable guidance for VR/AR devices' software ("games") being used as treatment for medical rehabilitation per se, existing from 2012 the European Commission's "MEDDEV 2.1/6 – Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices" – give us a way to define them as "standalone software" (which is used for medical and healthcare applications but was not incorporated into a medical device at launch). According to abovementioned guidance, the hardware device (gaming/specialized console, manipulator etc.) would likely be classified as an "accessory" for the device – VR/AR device & VR/AR software itself – potentially would be classed according to its use and category of risk to the patient in the same way as standard medical devices, using abovementioned characteristics.

Taking into account that devices with AR/VR software for medical rehabilitation could be used not only in medical institutions (clinics, rehabilitation centers etc.) but also at home, there must be clear defining of all parameters for premarket control, responsible person and strict demands for accuracy, informativeness, potential threats, effectiveness of instructions, that came with such devices.

Using of already existing and commercially-available VR/AR technology to provide therapies for neurological disorders, rehabilitation etc. should significantly reduce costs for consumers – patients (by ability to carry out therapy at home) and for specialized medical institutions (because of ability to adapt existing technology for new kinds of therapy thus saving costs). However, not fully defined state of AR/VR software for medical rehabilitation from legal point of view definitely need some adjustment for avoidance of potential collisions in future.

CONCLUSIONS

Software becomes more and more incorporated into medical devices, virtual reality and augmented reality, as was mentioned before, are a widely known technologies in entertainment (and especially gaming) but relatively new phenomenon in medicine. Using of them opens new horizons in medical rehabilitation sphere because of their high level of effectiveness, attractiveness for patient, new progressive mechanics and cost-saving approach of using "old and existing" technology for "new opportunities". But existing low level of legal definition accompanied with uncertainty about the criteria of dividing software on medical device software and not medical device software may give grounds for legal collisions, corruption abuses, slowing of technical progress in this field. To prevent such consequences, it is necessary to develop and adopt the legislative norms that will intend to define the criteria for the qualification of medical device software and the application of the classification criteria to such software, define the status of VR/AR devices software in their medical rehabilitative context. Considering the trend of convergence of Ukrainian legislation with EU Law seem appropriate to use EC`s Guidelines and practical expirience on the qualification and classification of standalone software including software of VR/AR in medical sphere.

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Informacja prasowa

Solanki z Zabłocia

Według Światowej Organizacji Zdrowia i wielu ekspertów w zakresie medycyny, niedobór jodu to problem ogólnoświatowy, który bezpośrednio wpływa na rozwój chorób tarczycy. Najłatwiejszym rozwiązaniem pozwalającym na dostarczenie do organizmu odpowiedniej porcji jodu jest stosowanie oryginalnej Solanki z Zabłocia.
Naturalna solanka z Zabłocia o mineralizacji ogólnej 46g/l (4,6%) zawiera największą na świecie zawartość jodu, dochodzącą do 139 mg w litrze solanki. Okazuje się, że niedobór jodu dotyka prawie 90% powierzchni naszego kraju, a chorobami tarczycy zagrożone jest prawie 8 milionów osób.
Solanka z Zabłocia wydobywana jest od ponad 120 lat w miejscowości uzdrowiskowej Zabłocie-Solanka z odwiertów „KORONA" oraz „TADEUSZ". Dzięki swoim właściwościom jest w stanie wytworzyć mikroklimat morski pozwalający na wyjątkowy relaks, a co najważniejsze, poprawę stanu zdrowia.
Jod jest ważny dla prawidłowego fizycznego i psychicznego rozwoju każdego z nas, już od początku naszego życia. Niewystarczająca ilość jodu u dorosłych może być przyczyną zwolnienia reakcji, pogorszenia pamięci, apatii, depresji, powiększenia tarczycy. Jod jest mikroelementem niezbędnym dla prawidłowego funkcjonowania tarczycy, reguluje przemiany energetyczne w organizmie, natomiast brom ma działanie uspokajające, łagodzi napięcie nerwowe oraz łagodzi stres.

Inhalacje solankowe

Inhalacja jest metodą zapobiegania i wspomagania leczenia wielu schorzeń dróg oddechowych, polega na wdychaniu rozcieńczonej solanki rozpylonej w postaci aerozolu. Wdychanie aerozolu solankowego powoduje nawilżenie dróg oddechowych, rozrzedzenie śluzu i łatwiejsze odkrztuszanie.
Podczas takiej kuracji następuje wchłanianie jodu, powodujące dłużej trwający wzrost poziomu jodu we krwi i jego przenikanie do tkanek organizmu, szczególnie do układu nerwowego.
Inhalacje solankowe wspomagają komfort oddychania, zwalczanie i hamowanie stanów zapalnych, nawilżanie śluzówki. Inhalacje pomagają w profilaktyce następujących schorzeń: przewlekły nieżyt nosa, gardła, krtani i oskrzeli, stany wyczerpania głosowego, alergiczne choroby górnych dróg oddechowych.
Solanka z dodatkiem naturalnego oleju lawendowego służy do wzbogacania organizmu w mikroelementy poprzez wdychanie aerozolu solankowego lub kąpiele aromaterapuetyczne. Naturalny olej lawendowy wykazuje właściwości antybakteryjne, przez co jest wspaniałym naturalnym środkiem łagodzącym objawy przeziębienia. Stosowany do inhalacji łagodzi kaszel, katar i nieżyt górnych dróg oddechowych. Ponadto posiada działanie uspokajające - zmniejsza objawy stanów lękowych, depresji, złego nastroju, stanów podenerwowania, a co za tym idzie ułatwia zasypianie.
(www.solanka.pl)