MEDICAL UNIVERSITY OF GDAŃSK

www.mug.edu.pl
58 349 11 11
info@gumed.edu.pl
ul. M. Skłodowskiej-Curie 3a,
80-210 Gdańsk

Fundusze Europejskie Inteligentny Rozwój
Ministerstwo Nauki i Szkolnictwa Wyższego
INKUBATOR INNOWACYJNOŚCI+
Unia Europejska Europejski Fundusz Rozwoju Regionalnego

A pharmaceutical composition containing lipopeptide conjugate and its salts for use in the treatment of chronic wounds

Product description

A pharmaceutical composition containing lipopeptide conjugate and its salts can be used to produce a therapeutic preparation for chronic wounds. Tissue defects, involving the full thickness of the skin, represent a serious social problem with a high risk of mortality. The healing process of such wounds is particularly complex and requires interaction of many elements, activation and coordination of processes of biochemical or cellular nature. Growth factors that initiate the next stage of new tissue formation, the transition from the inflammatory phase to the proliferative phase, are of vital importance. The presented invention provides new lipopeptide conjugates or their pharmaceutically acceptable salts rich in Hyp residues located at positions AK3, AK4, which are mediators of tissue regeneration by stimulating proliferation and migration of fibroblasts and keratinocytes. The product formed using the proposed composition may be used to treat tissue defects involving the full thickness of the skin such as burn wounds, ulcers, bedsores or wounds resulting from metabolic disorders such as diabetic foot.

Key words

Lipopeptides, Lipopeptide conjugates, lipopeptide conjugate salts, chronic wounds, dressings.

Legal status of the product

– P.433169 “Lipopeptide conjugates and their salts, method of manufacture of lipopeptide conjugates and their salts, pharmaceutical composition comprising a lipopeptide conjugate and its salts for the treatment of chronic wounds” - application dated 06.03.2020, Medical University of Gdańsk, joint holder of the invention.
– EP21020127 “Lipopeptide conjugates and their salts, method of manufacture of lipopeptide conjugates and their salts, pharmaceutical composition comprising a lipopeptide conjugate and its salts for the treatment of chronic wounds” – application dated 04.03.2021, Medical University of Gdańsk, joint holder of the invention.

Object of the offer

The object of the invention is a pharmaceutical composition of a preparation for stimulation of proliferation and migration of fibroblasts and keratinocytes for the use in the treatment of chronic wounds.

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Product research funding to date

“Innovation Incubator +” project of the Ministry of Science and Higher Education "Support for management of scientific research and commercialization of R&D results in scientific units and enterprises" under the Operational Programme Intelligent Development 2014-2020 (Measure 4.4).

Analysis of competition in the market

Currently, in addition to transplantation, regenerative medicine and the development of tissue engineering are high hopes for the treatment of burn wounds (2nd/ 3rd degree), venous ulcers or diabetic foot. The first product approved by the FDA in 1996 for the treatment of burns is a non-living extracellular matrix composed of collagen and 6-chondroitin sulfate-Integra™. There is also a known method to produce a living bilayer allogeneic skin called Apligraf(Graftskin)™ based on a collagen matrix. In 1998, Apligraf(Graftskin)™ was registered and approved by the FDA for the use in the treatment of venous ulceration and diabetic foot. The high cost as well as other requirements of the therapies used require improvements and lead to a constant search for new treatment methods. Increasing attention is being given to the development of topical therapies involving biologically active compounds that are involved in promoting wound healing. Most therapeutic agents currently described for the treatment of chronic wounds include growth factors, cytokines, chemokines, collagen, and hyaluronic acid. For the treatment of neuropathic ulcers of the diabetic foot of lesser extent extending into the subcutaneous tissue, bekaplermin, a human platelet-derived growth factor BB that retains the activity of endogenous PDGF, manufactured by Johnson&Johnson, has been approved. These therapeutic agents, despite a number of advantages, have a high cost of obtaining, and their topical application causes burning and erythema as well as a short half-life and reduced stability. In addition, side effects of therapy using high concentrations of growth factors have also been observed, i.e., excessive cell growth, psoriasis, impaired skin function and cancer risk. Another important expectation related to the use of new substances is the methods of their delivery to the local site of action, which for the most part require large amounts of proteins for the biological effect. Ongoing attempts in recent years to create polymeric constructs that take into account their long-term release, improving the stability of the encapsulated proteins, still represent a challenge for the coming years.

Advantages of the proposed product

As part of the work on the invention, it was possible to develop a fast, effective, efficient and scalable synthesis method to obtain lipopeptide conjugates. The proposed method ensures high safety of lipopeptide conjugates and determines their high biological activity. Peptide structures (counting<10AK) show several advantages in development of new and effective therapy. The interest in peptide structures in wound therapy is due to their high specificity of action. Due to their lower molecular weight and degradability, they do not remain in the body for a long time, show a low toxicity profile and better tissue penetration. New high purity lipopeptide conjugates obtained can be used to produce various types of dressings depending on the manufacturer's needs, e.g. dressings in the form of aqueous solutions, suspension, cream, ointment, emulsion in an aerosol, three-dimensional patch or hydrogel in a tube.