



„Pharmaceutical composition containing roxithromycin, its preparation and medical use”

Product description

Roxithromycin is an antibiotic from the group of semi-synthetic macrolides. It is a 10-oxy-ether derivative of erythromycin with increased acid resistance and better pharmacokinetic parameters. It is a lipid type of compound. It is used orally in the treatment of Gram-positive infections, less often Gram-negative infections. Its mechanism of action consists of blocking the biosynthesis of bacterial proteins. In addition to the typically antimicrobial activity, roxithromycin also inhibits the production of proinflammatory compounds by bacteria that contribute to the development of acne. There have also been reports of roxithromycin inhibition of free radical formation in neutrophils and inhibition of keratinocyte apoptosis.

An innovative pharmaceutical composition containing roxithromycin has been developed which can be used for example for the treatment of androgenetic alopecia and/or acne vulgaris. In order to produce the proposed preparation, lipid micro- and nanoparticles were used as carriers of roxithromycin for hair follicles.

The available data show that roxithromycin has not yet been incorporated into micro and nano-sized lipids. There are no registered preparations with this antibiotic for external use yet worldwide.

Key words

Roxithromycin, lipid microparticles, lipid nanoparticles, androgenetic alopecia, acne vulgaris

Legal status of the product

Polish Patent Office:

PL 222631 B „Pharmaceutical composition containing roxithromycin, its preparation and medical use of the composition and a medicinal product containing the composition” – reported to Polish Patent Office on 14 November 2012 and labeled with No. P.401625, decision to grant a patent from 1 October 2015 – Medical University of Gdańsk the sole authorized entity to patent.

Subject of offer

The subject of the offer is a pharmaceutical composition containing roxithromycin, its preparation method, and the medical use of this composition for the manufacture of a medicinal product for the treatment of androgenetic alopecia and/or acne vulgaris.



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Product research funding to date

The project was funded from the resources of N N405 674740 "Micro- and nanoparticles lipids as roxytomycin carriers for hair follicles"

Analysis of market competition

Treatment of acne vulgaris and androgenetic alopecia is a difficult and long-lasting process. In the treatment of androgenogenic alopecia, the only approved formulation for topical use by the Food and Drug Administration is 2% and 5% Minoxidil. On the other hand, Finasteride is suitable for oral therapy, but it is associated with serious side effects and only men can be treated with it. There are no alternative pharmacological agents typically applied in the therapy for alopecia. Acne vulgaris is one of the most common dermatoses and despite the fact that many pharmaceuticals are available in the pharmaceutical market to combat it, more effective and innovative solutions are still sought after.

The use of roxithromycin in the technology of drug production for external use in the treatment of acne vulgaris and androgenetic alopecia is a novel approach and an important one for the needs of modern society.

Advantages of the proposed product

The etiology of both androgenic alopecia and acne vulgaris is related to the skin hair follicle unit. In these cases, targeted treatment of the follicle becomes a key element of the therapy. In the hair and sebaceous system, there are several places where it is possible and desirable to target the substance for therapeutic purposes. These are, among others, sebaceous glands, whose ducts come to light of hair follicles, the site of the development of bacteria *Propionibacterium acnes*, causing acne.

In vitro studies on human hair follicles have shown that roxithromycin inhibits hair transitions in the catagene phase by inhibiting keratinocyte apoptosis and thereby causing hair length increase. Within *in vivo* conditions, however, after using an external 0.5% roxithromycin solution for 24 weeks, restoration of hair growth was noted in more than half patients affected by androgenetic alopecia.

Lipid micro and nanoparticles, as medicine carriers, are a suitable matrix for the incorporation of roxithromycin because of its lipophilic nature. The carriers are characterized by low toxicity and are biodegradable. Their crucial advantage is also the protection of the drug incorporated in them from chemical degradation. It has been shown that they effectively reach the human hair follicles, and by accumulating there form a reservoir of drug incorporated in them, and provide extended release and action for up to 10 days.



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Both acne vulgaris and androgenetic alopecia are socially-afflicted diseases, which greatly affect the self-esteem and the well-being of the patients. Nowadays, when the external appearance plays such an important role, new ways of treating these ailments cannot be overestimated.