СОЦІАЛЬНИЙ МАРКЕТИНГ ТА ФАРМАКОЕКОНОМІЧНІ ДОСЛІДЖЕННЯ

UDC 615.322:615.454.1:339.138 https://doi.org/10.24959/sphhcj.19.170

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The study of the expediency of developing a new semi-solid drug based on the extract of *Scutellaria baicalensis*

Aim. To conduct the marketing analysis of the range of dermatological drugs with the antimicrobial and wound healing and / or anti-inflammatory effect for the complex treatment of wound superficial skin lesions (wounds, burns, scratches).

Materials and methods. Scientific and practical publications on the topic of the research were used. The State Register of Medicinal Products of Ukraine was used as an information source for research; the period of analysis was the IV quarter of 2019. In the segment studied the products with the specified pharmacological activities were included. According to the ATC-classification they belong to the following subgroups: D03A – preparations that promote healing (scarring) of wounds; D08A – Antiseptic and disinfectants. D06 subgroup products – antibiotics and chemotherapeutics for dermatological use were not subject to the analysis.

Results. The analysis of the range of dermatological drugs in Ukraine has been conducted, semi-solid medicines have been studied; it has been determined that the drugs presented are mostly of synthetic origin. Herbal medicines are represented by only a few names. The studies have also shown that these drugs possess a hydrophobic base, which has its disadvantages. In this regard, a promising dosage form is an emulgel, which combines the softening properties of a semi-solid dosage form due to the presence of the oil phase.

Conclusions. According to the results of the study, the nomenclature of dermatological drugs has been studied, and the expediency of creating a new drug in the form of an emulgel based on the dry extract of *Scutellaria* has been substantiated. The new drug will provide an effective therapeutic effect on the second and third phases of the wound-healing process since it promotes complete release of the active substances and their penetration into the tissues, prevents the secondary infections, protects the granulation tissue from mechanical damages, as well as activates the course of the wound process, reduces microbial contamination of wounds and creates conditions for epithelialization of the wound surface.

Key words: Ukrainian market; semisolid dosage form; emulgel; antibacterial.

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Дослідження доцільності розробки нового м'якого лікарського засобу на основі екстракту шоломниці байкальської

Мета: маркетинговий аналіз номенклатури дерматологічних лікарських засобів, що чинять антимікробну та ранозагоювальну і / або протизапальну дію та показані для комплексного лікування ранових поверхневих уражень шкіри (ран, опіків, подряпин).

Матеріали та методи: використано науково-практичні публікації стосовно теми дослідження; як інформаційне джерело – Державний реєстр лікарських засобів України; період проведення аналізу – IV квартал 2019 року. До досліджуваного сегмента були включені засоби із зазначеними фармакологічними активностями, які, згідно з АТС-класифікацією, належать до підгруп: D03A – Препарати, які сприяють загоєнню (рубцюванню) ран; D08A – Антисептичні та дезінфекційні засоби. Не підлягали аналізу лікарські препарати з підгрупи D06 – Антибіотики та хіміотерапевтичні препарати для застосування у дерматології.

Результати дослідження. Проведено аналіз асортименту дерматологічних препаратів України, досліджено м'які лікарські препарати й установлено, що представлені препарати переважно синтетичного походження. Препарати рослинного походження представлено лише кількома найменуваннями. Дослідження також показали, що представлені препарати мають гідрофобну основу, в якої є свої недоліки. Тому перспективною лікарською формою є емульгель, який поєднує у собі пом'якшувальні властивості м'якої лікарської форми завдяки наявності олійної фази.

Висновки. За результатами дослідження вивчено номенклатуру дерматологічних препаратів та обґрунтовано доцільність створення нового препарату у вигляді емульгелю на основі сухого екстракту шоломниці байкальської, який дозволить забезпечити ефективний лікувальний вплив на рановий процес у другій і третій фазах, сприятиме повному вивільненню із засобу та проникненню у тканини активних діючих речовин, попереджатиме вторинні інфекції; захищатиме грануляційну тканину від механічних ушкоджень, а також активізуватиме перебіг ранового процесу, знижуватиме мікробну забрудненість ран і створюватиме умови для епітелізації поверхні рани.

Ключові слова: український ринок; м'яка лікарська форма; емульгель; антибактеріальний.

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Исследования целесообразности разработки нового мягкого лекарственного средства на основе экстракта шлемника байкальского

Цель: маркетинговый анализ номенклатуры дерматологических лекарственных средств, оказывающих антимикробное и ранозаживляющее и / или противовоспалительное действие для комплексного лечения раневых поверхностных поражений кожи (ран, ожогов, царапин).

Материалы и методы: использованы научно-практические публикации относительно темы исследования; как информационный источник – Государственный реестр лекарственных средств Украины; период проведения анализа – IV квартал 2019 года. В исследуемый сегмент были включены средства с указанными фармакологическими активностями, которые, согласно АТС-классификации, относятся к подгруппам: D03A – Препараты, которые способствуют заживлению (рубцеванию) ран; D08A – Антисептические и дезинфицирующие средства. Не подлежали анализу лекарственные препараты из подгруппы D06 – Антибиотики и препараты для применения в дерматологии.

Результаты исследования. Проведен анализ ассортимента дерматологических препаратов Украины, исследованы мягкие лекарственные препараты и установлено, что представленные препараты в основном синтетического происхождения. Препараты растительного происхождения представлены только несколькими наименованиями. Исследования также показали, что представленные препараты имеют гидрофобную основу, у которой есть свои недостатки. Перспективной лекарственной формой является эмульгель, который сочетает в себе смягчающие свойства мягкой лекарственной формы благодаря наличию масляной фазы.

Выводы. По результатам исследования изучена номенклатура дерматологических препаратов и обоснована целесообразность создания нового препарата в виде эмульгеля на основе сухого экстракта шлемника байкальского. Новый препарат позволит обеспечить эффективное лечебное действие на раневой процесс во второй и третьей фазах, будет способствовать полному высвобождению и проникновению в ткани активных действующих веществ, предупреждать вторичные инфекции; защищать грануляционную ткань от механических повреждений, а также активизировать течение раневого процесса, снижать микробную обсемененность ран и создаст условия для эпителизации раневой поверхности.

Ключевые слова: украинский рынок; мягкая лекарственная форма; эмульгель; антибактериальный.

Statement of the problem. The skin is often regarded as the single and largest organ in the human body, its main function is the barrier. The skin protects the body from various adverse environmental factors, including preventing it from entering pathogenic microorganisms. However, at the same time, the human skin is densely populated with microorganisms, among them the most frequent representatives are *Staphylococcus epidermidis*, *Staphylococcus saprophyticus* and fungi of the *Candida* genus. In the normal state of the skin its microflora does not cause the development of pathological conditions, but the situation changes in the case of damage to the integrity of the skin and dermatological diseases. In addition, pathogens can get into the injury site from the environment, traumatic agent, etc. Therefore, pharmacotherapy of wounded skin injuries should in any case include an antimicrobial (antibacterial and antifungal) component. The rational treatment of wounds should also be aimed at reducing the severity of the inflammatory process, stimulating the growth of granulation tissue and accelerating epithelialization (wound healing effect) [1-3].

Among the substances that can exhibit the antimicrobial action a great attention is drawn to herbal medicines, the resistance to which is developing very slowly. In addition, herbal medicines simultaneously affect several links of the pathological process, and it is their additional advantage, since in the composition of dermatological drugs, along with the antimicrobial activity, these agents have the anti-inflammatory and wound healing properties [4, 5].

Recently, there is a growing demand for natural products.

Sutellaria baicalensis is a source of useful and active compounds. The variety of pharmacological effects of *Scutellaria* root is due to a rich set of biologically active compounds, including coumarins, tannins, essential oils, flavonoids and many others. The most prominent is the group of phenolic compounds represented by flavones, flavanones, flavonols, chalcones and lignoflavonoids. Among the phenols of *Scutellaria*, flavones, in which baicalin dominates, are leaders. Therefore, our further studies were aimed at creating an emulgel based on the dry extract of *Scutellaria baicalensis* root.

Analysis of recent research and publications. Among the published scientific works closely related to the direction of our research the leading place is occupied by publications of such scientists as Kotvitska A. A. [6], Yakovleva L.V. [7], Simonyan L. S [8], Grom O.L. [9] et al., Shmatenko O.P. [10] et al., etc. The articles are mainly devoted to the analysis of antibacterial agents, mostly antibiotics, in different dosage forms.

Identification of aspects of the problem unsolved previously. Despite the large number of articles devoted to the study of the market of antimicrobial drugs, separate studies on herbal medicines with the antimicrobial action in the form of semisolid dosage forms have not been conducted.

Objective statement of the article. The aim of the article is the marketing analysis of the range of dermatological drugs with the antimicrobial and wound healing and / or anti-inflammatory effect for the complex treatment of wound superficial skin lesions (wounds, burns, scratches).

Materials and methods. Scientific and practical publications on the topic of the research were used. The State Register of Medicinal Products of Ukraine was used as an information source for research; the period of analysis was the IV quarter of 2019. In the segment studied the products with the specified pharmacological activities were included. According to the ATC-classification they belong to the following subgroups: D03A – preparations that promote healing (scarring) of wounds; D08A – Antiseptic and disinfectants. D06 subgroup products – antibiotics and chemotherapeutics for dermatological use were not subject to the analysis.

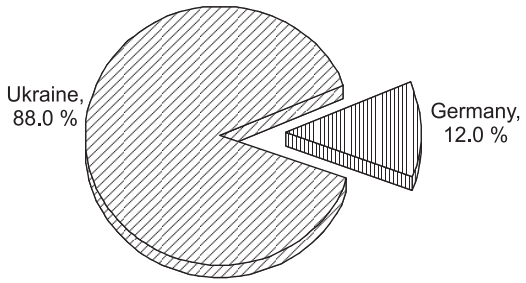

Fig. 1. Distribution of dermatological drugs of the segment studied by the manufacturer country

Presentation of the main material of the research. At the pharmaceutical market of Ukraine dermatological drugs that exhibit the complex antimicrobial and wound healing and / or anti-inflammatory effects are represented by 25 names (Table), the vast majority of them are domestic products. Imported medicines are represented by a small number of names of manufacturers from Germany (Fig. 1).

Distribution by dosage forms differs for synthetic, herbal products and combined drugs, which make up 48.0, 40.0 and 12.0 % of the segment studied, respectively. Thus, most synthetic drugs are made in the form of ointments and creams, while preparations with active ingredients of herbal origin are presented mainly in liquid dosage forms (tinctures) and hydrophobic ointments. In turn, the combined preparations, which combine the active substances of synthetic and plant origin, are available at the domestic pharmaceutical market in the form of aerosol, ointment and liniment (Fig. 2).

Thus, most of the dermatological drugs of plant origin are represented by liquid dosage forms (tinctures) and hydrophobic ointments. The consistency properties of semi-solid dosage forms give them some advantages over tinctures, including the ease of application to the skin and mucous membranes, the creation of a protective layer that remains on the skin and prevents re-infection of the lesion, reduction of the frequency of use due to the long release of drugs from the base, and also the absence of the irritant effect of ethanol, which is contained in tinctures in a considerable amount. However, hydrophobic ointments have also significant drawbacks, which include the patients' negative subjective sensations (stickiness, contamination of clothing and linen), as well as the occlusive or "greenhouse" effect – they impede the access of air to the lesion. In this

Table

THE NOMENCLATURE OF DERMATOLOGICAL DRUGS EXHIBITING THE COMPLEX ANTIMICROBIAL AND WOUND HEALING AND / OR ANTI-INFLAMMATORY ACTION PRESENTED AT THE PHARMACEUTICAL MARKET OF UKRAINE

Trade name	Dosage form	Active substances	Manufacturer	Pharmacological action
1	2	3	4	5
Synthetic drugs				
Levomecol	ointment	chloramphenicol, methyluracil	PJSC Pharmaceutical factory "Viola", Ukraine; JSC "Farmak", Ukraine; PJSC "Lubnyfarm", Ukraine; PJSC SIC "Borshchahivskiy CPP", Ukraine; PJSC "Red Star" Chemical Factory, Ukraine	antimicrobial, wound healing, anti-inflammatory
Pantestin-Darnitsa®	gel	dexpanthenol, miramistin	PJSC "Pharmaceutical Firm "Darnitsa", Ukraine	antimicrobial, wound healing, anti-inflammatory
Methyluracil with miramistin	ointment	methyluracil, miramistin	PJSC "Pharmaceutical Firm "Darnitsa", Ukraine	antimicrobial, wound healing, anti-inflammatory
Mefenate	ointment	sodium mefenamate salt, vinyl	JSC "Farmak", Ukraine	antimicrobial, anti-inflammatory, wound healing
Happyderm plus	cream	dexpanthenol, benzalkonium chloride, chlorhexidine digluconate solution	Pharmaceutical company "Zdorovye", Ltd., Ukraine	antimicrobial, wound healing, anti-inflammatory
Panthenol plus	cream	chlorhexidine dihydrochloride, dexpanthenol	LLC "Ternopharm", Ukraine	antimicrobial, wound healing, anti-inflammatory
Panthenol plus	spray	chlorhexidine dihydrochloride, dexpanthenol	Pharmaceutical company "Zdorovye", Ltd., Ukraine	antimicrobial, wound healing, anti-inflammatory
Rescue®	cream	dexpanthenol, chlorhexidine bigluconate 20 % solution	PJSC "Kyivmedpreparat", Ukraine	antimicrobial, wound healing, anti-inflammatory
Bepanthen® plus	cream	dexpanthenol, chlorhexidine dihydrochloride	GP Grenzach Productions GmbH, Germany	antimicrobial, wound healing, anti-inflammatory
Bepanthen® plus	spray	dexpanthenol, chlorhexidine dihydrochloride	Lichtenheldt GmbH GmbH Pharmaceutische Fabrik, Germany	antimicrobial, wound healing, anti-inflammatory
Ichthyol	ointment	ichthyol	PJSC "Red Star" Chemical Factory, Ukraine; PJSC "Lubnyfarm", Ukraine; PJSC "Monfarm", Ukraine; LLC "Ternopharm", Ukraine; PJSC Pharmaceutical factory "Viola", Ukraine; JSC "Fitofarm", Ukraine	antimicrobial, anti-inflammatory
Vinylin®	topical fluid	polyvinyl-butyl ether	PJSC "Vitamins", Ukraine	antimicrobial, wound healing, anti-inflammatory
Herbal medicines				
Calendula ointment	ointment	calendula tincture (1 : 10) (extractant – 70 % ethanol)	DKP Pharmaceutical Factory LLC, Ukraine; PJSC "Lubnyfarm", Ukraine; PJSC Pharmaceutical factory "Viola", Ukraine; JSC "Fitofarm", Ukraine; LLC "Ternopharm", Ukraine	antimicrobial, anti-inflammatory

Continuation of Table

1	2	3	4	5
Woundeheal	ointment	propolis tincture (1 : 10) (extractant – 80 % ethanol), carophylene, Japanese Sophora tincture (1 : 2) (extractant – 48 % ethanol), tormentil tincture (1 : 5) (extractant – 70 % ethanol), yarrow tincture (1 : 5) (extractant – 70 % ethanol)	LLC "Scientific and Production Pharmaceutical Company "AIM", Ukraine	antimicrobial, wound healing, anti-inflammatory
Ilon®	ointment	larch turpentine, turpentine oil, eucalyptus oil	Zessra Artzneimittel GmbH & Co. KG, Germany	antimicrobial, anti-inflammatory
Propolis tincture	tincture	propolis tincture (1 : 10) (extractant – 80 % ethanol), 25 ml	LLC "Ternopharm", Ukraine; PJSC "Vitamins", Ukraine	antimicrobial, wound healing, anti-inflammatory
Calendula tincture	tincture	Calendula flower tincture (1 : 10) (extractant – 70 % ethanol)	DKP Pharmaceutical Factory LLC, Ukraine; State Enterprise "Experimental Plant of Medicinal Products of the Institute of Bioorganic Chemistry and Petrochemistry of the NAS of Ukraine", Ukraine; Kilaff PE, Ukraine; Biolik PJSC, Ukraine; MEDLEV LLC, Ukraine; PJSC "Lubnyfarm", Ukraine; PJSC Pharmaceutical factory "Viola", Ukraine; JSC "Fitofarm", Ukraine; LLC "Ternopharm", Ukraine	antimicrobial, anti-inflammatory
Sage tincture	tincture	sage leaf tincture (1 : 5) (extractant – 70 % ethanol)	DKP Pharmaceutical Factory LLC, Ukraine	antimicrobial, anti-inflammatory
Sophora tincture	tincture	tincture of Japanese Sophora (1 : 2) (extractant – 48 % ethanol)	PJSC Pharmaceutical factory "Viola", Ukraine; JSC "Fitofarm", Ukraine; DKP Pharmaceutical Factory LLC, Ukraine	antimicrobial, anti-inflammatory
Antiseptol n	tincture	chamomile liquid extract (6 : 10, extractant – 50 % ethanol), 96 % ethanol	Pharmaceutical company "Zdorovye", Ltd., Ukraine	antimicrobial, anti-inflammatory
Elecaphyt-viola	blend	tripartite bur-marigold herb, chamomile flower, liquorice root, sage leaves, eucalyptus leaves, Calendula flowers	PJSC Pharmaceutical factory "Viola", Ukraine	antimicrobial, wound healing, anti-inflammatory
Elecasol	blend	tripartite bur-marigold herb; chamomile flower; liquorice root; sage leaves; eucalyptus rod-shaped leaves; marigold flowers	JSC "Liktravy", Ukraine	antimicrobial, wound healing, anti-inflammatory
Combined drugs				
Balsamic liniment (by Vishnevsky)	liniment	birch tar, xeroform	JSC "Fitofarm", Ukraine	antimicrobial, wound healing
Olasol®	aerosol	Sea buckthorn oil, chloramphenicol, benzocaine, boric acid	JSC "Stoma", Ukraine	antimicrobial, wound healing, anti-inflammatory
Altan ointment	ointment	altan (ellagitanins), dimethyl sulfoxide	PJSC SIC "Borshchahivskiy CPP", Ukraine; PJSC "Lubnyfarm", Ukraine; PJSC Pharmaceutical factory "Viola", Ukraine; DKP Pharmaceutical Factory LLC, Ukraine	antimicrobial, wound healing, anti-inflammatory

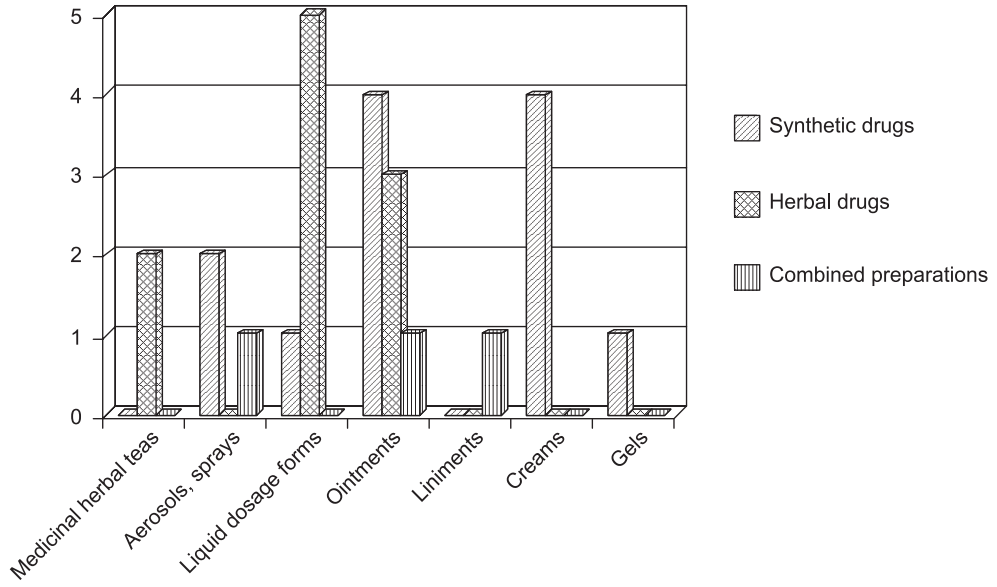

Fig. 2. Distribution of synthetic, herbal and combined drugs of the segment studied by dosage forms

regard, a promising dosage form is a cream that combines the softening properties of an ointment due to the presence of the oil phase, but does not create a "greenhouse" effect due to a less viscous texture and a higher content of the hydrophilic phase. An emulgel, which, like all creams, consists of oil and hydrophilic phases, can be considered a kind of a cream.

Therefore, in view of the absence of herbal dermatological drugs with the antimicrobial and anti-inflammatory and / or wound healing effect in the form of a cream, gel or emulgel at the pharmaceutical market of Ukraine, a promising task of modern domestic pharmacy is their development and introduction into clinical practice.

The development of the emulgel based on the dry extract of *Scutellaria baicalensis* will allow to launch a new topical medicinal product with the marked wound-healing and antimicrobial effects due to the presence of biologically active substances (in particular, macro- and microelements) contained in the gel.

Conclusions

1. The nomenclature of dermatological drugs with the antimicrobial and wound healing and / or anti-inflammatory action at the market of Ukraine has been studied; it has been found that their number is 25 items.

2. The analysis of the distribution of drugs by the manufacturer country has shown that most of them are made in Ukraine – 88 %, and 12 % in Germany.

3. The analysis by dosage forms has shown that among the trade names studied the semi-solid dosage forms (a total of 14 names) dominate, most of them are ointments (8 names) and creams (4). APIs of synthetic origin have been found to be 65 %, while those of natural origin 35 %. It confirms the relevance of creating a semi-solid dosage form based on the dry extract of *Scutellaria baicalensis*.

Prospects for further research. Based on the studies conducted the expediency of developing a new drug in the form of an emulgel based on the dry extract of *Scutellaria* and its introduction into the production by the enterprises of Ukraine have been substantiated. This drug is a single-component product and exhibits the marked reparative and antimicrobial effects.

Conflict of interest: authors have no conflict of interests to declare.

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Надійшла до редакції 05.10.2019 р.