

SECTION 4. PHARMACY

4.1 Analysis of the pharmaceutical market of diclofenac preparations

According to the WHO classification, pain is the main and most common reason for patients to see a doctor and then prescribe drugs (algae) - acute or chronic. According to WHO experts, 90% of all diseases are related to pain [275]. A recent study shows that approximately 1.71 billion people worldwide suffer from musculoskeletal pain and diseases [276]. Although the prevalence of disease varies with age and diagnosis, it affects people of all ages around the world [277].

As a result, about 30% of the world's population seeks medical attention. Pain is always subjective, and its perception depends on the intensity, nature and location of the injury, the nature of the injury, the circumstances in which the injury occurred, the psychological state of the person, his individual life experience and social status, etc. [278].

Depending on the clinical picture, pain is divided into somatic and visceral. Somatic pain is caused by irritation of pain receptors in the bones, joints and skin. In the case of visceral pain, various pathological mechanisms (mechanical damage, inflammation, X-rays, toxic substances) irritate pain receptors in the tissues of internal organs. These differences between visceral and somatic pain are not always clear, and different models of pain may involve several mechanisms [279, 280].

Leading position among all pain syndromes is back pain. Acute back pain of varying intensity during life is observed at least once in almost every person, in 15-20% of people it is transformed into prolonged (up to 2 months), and in 8-10% - in chronic pain, which causes long-term disability [281]. Next are pain in the joints, muscles of the shoulder girdle [282].

Comprehensive and routine therapy includes treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) and analgesics. Paracetamol has gained wide popularity [283]. The ratio of efficiency and safety has allowed it to gain the popularity of doctors around the world. The main advantage of paracetamol is that it can be prescribed to

patients with peptic ulcer, bronchial asthma, hemophilia, in the postoperative period. Compared to other NSAIDs, paracetamol has a less pronounced anti-inflammatory effect. Another known drug diclofenac has a pronounced anti-inflammatory effect and good analgesic effect. Discovered in the early 1970s, diclofenac is rightly considered the "gold standard" among NSAIDs for the relationship between clinical efficacy and frequency of adverse reactions. It is still the most popular drug among NSAIDs and ranks 8th in the top-10 best-selling drugs [279].

Diclofenac (Voltaren, Dicloberl, Olfen) is a derivative of phenylacetic acid and is one of the most potent inhibitors of COX-2. In the form of sodium or potassium salt, it is a crystalline powder from yellowish-white to light beige. Well soluble in methanol, soluble in ethanol, practically insoluble in chloroform, sodium and potassium salts are soluble in water, and diclofenac diethylamine is well soluble in ointment bases. Due to these physical and chemical properties, these compounds (Fig. 1-3) are used as active substances in drugs. In addition, such forms help to completely release diclofenac from the dosage form in the human body, ensuring the speed of therapeutic effect and its completeness [284].

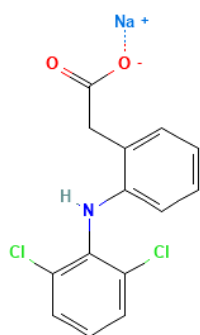


Figure 1. Diclofenac sodium

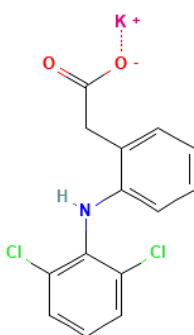


Figure 2. Diclofenac potassium

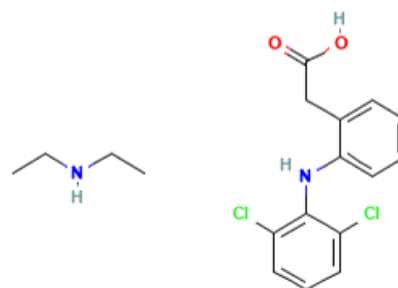


Figure 3. Diclofenac diethylamine

Diclofenac has anti-inflammatory, analgesic and antipyretic effects by inhibiting prostaglandin synthesis and thus reducing all manifestations of inflammation (pain, edema, local hyperthermia). According to the ATC-classification, it is placed in the means affecting the musculoskeletal system, namely under the code M01A B05 [284].

Diclofenac sodium was first synthesized in 1964 and since 1974 has been widely used by physicians around the world. Since the registration of the drug, more than 1 billion people have received treatment with diclofenac. Initially, diclofenac was used mainly in the treatment of rheumatological diseases requiring a pronounced anti-inflammatory and effective analgesic effect, but later the scope of diclofenac expanded significantly. In addition to prostaglandin inhibition, other mechanisms of action of diclofenac have been identified. It has been shown that diclofenac sodium can significantly inhibit the migration of leukocytes into the site of inflammation, affect the balance of cytokines (interleukin-6 and interleukin-10), which helps to slow the secretion of anti-inflammatory factors. Reduction of free radical production under the influence of diclofenac sodium may also help reduce the activity of the inflammatory process and limit its harmful effects on tissues. Doctors, in case of detection of pain of varying severity in the patient, for short-term use prescribe primarily diclofenac in various dosage forms [285].

Therefore, given the above, the aim of this work was to analyse the range of pharmaceutical market of diclofenac drugs in 2022 in Ukraine of domestic and foreign production by number of trade names (TN), dosage forms (DF), manufacturers of substances for the production of drugs and determine the main drugs in combination with diclofenac.

Information web resources such as the State Register of Medicinal Preparations of Ukraine [286] and Compendium-online [284] were used to study the range of the market for diclofenac drugs of domestic and foreign production. The obtained data were processed by methods of systematization, marketing analysis, comparison and generalization of the received information.

According to the State Register of Medicinal Preparations of Ukraine, the pharmaceutical market of Ukraine in 2022 is represented by 95 names of drugs with the active substance diclofenac, which is presented in such dosage forms as gels, tablets, suppositories, solutions for injection, capsules, patches, sprays (Table 1, Figure 4).

Table 1.

Comparative analysis of the range of diclofenac drugs in the pharmaceutical market
of Ukraine in 2022

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
1.	ALMIRAL (АЛМІРАЛ)	75 mg/3 ml	injection solution	Cyprus Medokemi LTD (Ampoule injection plant)	
2.	ALGOSAN (АЛГОЗАН®)	35 g in a tube (1 g of gel contains diclofenac diethylamine in terms of 100% of the substance - 15 mg)	gel		PJSC "Chervona zirka"
3.	ARGETT DUO (АРГЕТТ ДУО)	75 mg	capsules	Germany (Dragenopharm Apothecary Pushl GmbH) (primary and secondary packaging), Swiss Caps GmbH (primary and secondary packaging, series release); Ireland Temmler Ireland Limited (Bulk Production, Quality Control)	
4.	ARGETT RAPID (АРГЕТТ РАПІД)	75 mg	capsules	Germany (Dragenopharm Apothecary Pushl GmbH) (primary and secondary packaging), Swiss Caps GmbH (primary and secondary packaging, series release); Ireland Temmler Ireland Limited (Bulk Production, Quality Control)	
5.	ARGETT SPRAY	40 mg/g	skin spray	Germany (Farbil Waltrop GmbH)	

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
	(АРГЕТТ СПРЕЙ)				
6.	VOLTAREN EMULGEL (ВОЛЬТАРЕН ЕМУЛЬГЕЛЬ)	1 % (1 g of emulgel contains diclofenac diethylamine 11.6 mg, corresponding to 10 mg of diclofenac sodium)	emulgel	Switzerland (GSK Consumer Helsker S.A.)	
7.	VOLTAREN FORTE (ВОЛЬТАРЕ Н ФОРТЕ)	2,32 % (1 g of emulgel contains diclofenac diethylamine 23.2 mg, corresponding to 20 mg of diclofenac sodium)	emulgel		
8.	VOLTAREN (ВОЛЬТАРЕН)	75 mg/3 ml	injection solution	Switzerland (Novartis Pharma Shtein AG), Slovenia (Lek Pharmaceuticals)	
9.		100 mg	suppositories	France (Delpharm Huning SAS)	
10		25 mg	suppositories		
11		50 mg	suppositories		
12		25 mg	tablets	Italy (Novartis Pharma S.P.A.); Turkey (Novartis Saglik, Gida ve Tarim Urunleri San Ve Tik. A.S.)	
13		50 mg	tablets		

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
14	VOLTAREN® PATCH 24 HOURS	15 mg	transdermal plaster	Japan (Dojin Iyaku-Kako Co., Ltd.) (manufacturer of GLZ, primary packaging, quality control, secondary packaging, batch release); Greece (Famar AVE - Avlon plant of the 48th km of the Athens-Lamia State Road) (secondary packaging, series production)	
15	(ВОЛЬТАРЕН® ПЛАСТИР 24 ГОДИНИ)	30 mg			
16	VOLTAREN® RAPID	25 mg	tablets	Turkey (Novartis Saglik, Gida ve Tarim Urunleri San Ve Tik. A.S.)	
17	(ВОЛЬТАРЕН® РАПІД)	50 mg			
18	DICLAC® (ДИКЛАК®)	75 mg/3 ml	injection solution	Slovenia (Lek Pharmaceutical Company5)	
19	DICLAC® GEL (ДИКЛАК® ГЕЛЬ)	5 % (1 g of gel contains diclofenac sodium 50 mg)	gel	Germany (Salutas Pharma GmbH)	
20	DICLAC® LIPOGEL (ДИКЛАК® ЛІПОГЕЛЬ)	1 % (1 g of gel contains diclofenac sodium 10 mg)	gel		
21	DICLAC® ID (ДИКЛАК® ID)	150 mg	tablets	Germany (Salutas Pharma GmbH (production in bulk, packaging, series production)); Poland (Lek SA (packaging, release series))	
22	DICLAC® ID (ДИКЛАК® ID)	75 mg	tablets	Germany (Salutas Pharma GmbH)	

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
23	DICLO-F (ДИКЛО-Ф)	0,1 % (1 ml of solution contains diclofenac sodium 1.0 mg)	eye drops	India (Sentiss Pharma PVT Ltd.)	
24	DICLOBERL [®]	100 mg	suppositories	Germany (Berlin-Chemi AG)	
25	(ДИКЛОБЕРЛ [®])	50 mg			
26	DICLOBERL [®] RETARD (ДИКЛОБЕРЛ [®] РЕТАРД)	100 mg	capsules	Germany (Berlin-Chemi AG (final packaging, series release), Menarini-von Hayden GmbH (final packaging, batch control))	
27	DICLOBERL [®] N75 (ДИКЛОБЕРЛ [®] N75)	75 mg /3 ml	injection solution	Italy (A. Menarini Manufacturing Logistics and Services S.R.L. (production of the drug "in bulk", primary and secondary packaging, control and batch release), Alfasigma S.P.A. (production of the drug "in bulk", primary packaging) and series control))	
28	DICLODEV [®] (ДИКЛОДЕВ [®])	25 mg/ml	injection solution	Greece (DEMO S.A. Pharmaceutical Industry)	
29	DICLOSAN (ДИКЛОСАН)	40 g in a tube (1 g of gel contains: diclofenac sodium 10 mg)	gel		JSC "Lubnypharm"
30	DICLORAN [®] PLUS (ДИКЛОРАН [®] ПЛЮС)	30 g in a tube (1 g of gel contains diclofenac diethylamine	gel	India (Unique Pharmaceutical Laboratories (a division of J.B.	

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
		11.6 mg, equivalent to diclofenac sodium 10 mg)		Chemicals and Pharmaceuticals Ltd.)	
31	DICLOFEN GEL (ДИКЛОФЕ Н-ГЕЛЬ)	25 g in a tube (1 g of the drug contains diclofenac sodium 30 mg)	gel		PJSC SIC “Borshchahivsk iy CPP”
32	DICLOFENAC (ДИКЛОФЕНА К)	5% in the tube (1 g of gel contains diclofenac sodium 50 mg)	gel		PJSC Pharmaceutical factory "Viola"
33		50 mg/g gel			PJSC "Chervona zirka"
34		10 mg/g gel			
35		0,1 g in bulk: № 1000	suppositorie s		PJSC "Lekhim- Kharkiv"
36		0,1 g			
37		0,05 g	tablets		PJSC "Chervona zirka"
38	DICLOFENAC EURO (ДИКЛОФЕНА К ЄВРО)	50 mg	tablets	India (Unique Pharmaceutical Laboratories (a division of J.B. Chemicals and Pharmaceuticals Ltd.)	
39	DICLOFENAC	10 mg/g gel	gel		JSC "Farmak"
40	SODIUM (ДИКЛОФЕНА К НАТРИЮ)	25 mg	capsules		Kharkiv Pharmaceutical Enterprise "Health of the People" Ltd.

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
41		2,5 % (75 mg)	injection solution		JSC "Lubnypharm"
42		25 mg/ml (75 mg)	injection solution		PJSC "Lekhim- Kharkiv"
43		50 mg	suppositorie s		PJSC "Monpharm"
44	DICLOFENAC -BIOLIC (ДИКЛОФЕН АК-БІОЛІК)	25 мг/мл (75 mg)	injection solution		JSC "Biolik"
45	DICLOFENAC -VIOLA (ДИКЛОФЕН АК-ВІОЛА)	1 % (1 g of gel contains 10 mg of diclofenac sodium)	gel		PJSC Pharmaceutical factory "Viola"
46	DICLOFENAC -DARNYTSYA (ДИКЛОФЕН АК- ДАРНИЦЯ)	25 мг/мл (75 мг)	injection solution		PJSC "Pharmaceutical firm" Darnitsa"
47		25 mg	tablets		
48	DICLOFENAC - ZDOROV'YA (ДИКЛОФЕН АК- ЗДОРОВ'Я)	1 % (1 g of gel contains diclofenac sodium 10 mg)	gel		"Pharmaceutical company «Zdorovyе»" Ltd.
49		25 mg/ml (75 mg)	injection solution		
50	DICLOFENAC - ZDOROV'YA ULTRA (ДИКЛОФЕН АК-ЗДОРОВ'Я УЛЬТРА)	50 mg/g gel	gel		
51	DICLOFENAC - ZDOROV'YA FORTE (ДИКЛОФЕН АК-ЗДОРОВ'Я)	30 mg/g gel	gel		
52		40 mg/g gel	gel		

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
53	DICLOFENAC - ZDOROV'YA ULTRA (ДИКЛОФЕН АК- ЗДОРОВ'Я УЛЬТРА)	40 mg/ml	skin spray		
54	DICLOFENAC -TEVA (ДИКЛОФЕН АК-ТЕВА)	75 mg/3 ml	injection solution	Germany (Merkle GmbH) (production of bulk products, primary and secondary packaging, batch approval; quality control))	
55	DICLOFENAC -TEVA FORTE (ДИКЛОФЕН АК-ТЕВА ФОРТЕ)	2 % (1 g of gel contains diclofenac diethylamine 23.2 mg, equivalent to diclofenac sodium 20 mg)	gel	Germany (Merkle GmbH) (full cycle production), Transform Logistics GmbH (secondary packaging))	
56	DICLOFENAC -PHARMEX (ДИКЛОФЕН АК- ФАРМЕКС)	100 mg	suppositorie s		LLC "Farmex Group"
57		100 mg in bulk № 1160	suppositorie s		
58	DICLOSEYF® (ДІКЛОСЕЙФ®)	1,16 % (1 г гелю містить 11,6 мг диклофенаку діетиламіну у перерахуванні на диклофенак натрію 10 мг)	gel	India (Kusum Healthhker PVT Ltd.)	
59		100 mg	suppositorie s		
60		50 mg	suppositorie s		
61		2,32 % (1 g of gel contains 23.2	gel		

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
	(ДІКЛОСЕЙФ [®] ФОРТЕ)	mg of diclofenac diethylamine in terms of diclofenac sodium 20 mg)			
62	DIPHADOL (ДІФАДОЛ)	1 mg/ml	eye drops	Poland (Warsaw Pharmaceutical Plant Polfa JSC)	
63	DOLAREN [®] (ДОЛАРЕН [®])	50 mg	tablets	India (Nabros Farma Pvt. Ltd.)	
64		20 g or 50 g in a tube (1 g of gel contains diclofenac diethylamine in terms of diclofenac sodium 10 mg)	gel		
65	DOLOKS RETARD (ДОЛОКС РЕТАРД)	100 mg	tablets	India (Unique Pharmaceutical Laboratories)	
66	EVINOPON (ЕВІНОПОН)	25 mg/ml 3 ml (75 mg)	injection solution	Greece (Bros Ltd.)	
67	CLODYPHEN E (КЛОДИФЕН)	10 mg/g	gel	Romania (K.O. Slavia Farm S.R.L.)	
68		50 mg/g	gel		
69		1 mg/ml	eye drops	Romania (K.O. Rompharm Company S.R.L.)	
70		25 mg/ml (75 mg)	injection solution	Turkey (Mefar Ilach San. A.Sh.)	
71	MOVEX [®] ACTIVE (МОВЕКС [®] АКТИВ)	50 mg potassium diclofenac	tablets	India (Sava Helskea Ltd) Hungary (Meditop Pharmaceutical Co., Ltd.)	

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
72	NACLOPHE N (НАКЛОФЕ Н)	75 mg/3 ml	injection solution	Slovenia (KRKA, dd, Novo mesto (production "in bulk", primary and secondary packaging, control and release of the series))	
73		50 mg	suppositorie s	Slovenia (KRKA, Novo mesto)	
74		50 mg	tablets		
75	NACLOPHE N DUO (НАКЛОФЕ Н ДУО)	75 mg	capsules		
76	NACLOPHE N RETARD (НАКЛОФЕ Н РЕТАРД)	100 mg	tablets	Slovenia (KRKA, Novo mesto) (primary and secondary packaging, batch control and release) Germany (Hennig Arzneimittel GmbH & Co. KG (production in bulk))	
77	SODIUM DICLOFENAC -KV (НАТРИУ ДИКЛОФЕНА К-КВ)	25 mg	capsules		JSC “Kyiv Vitamin Plant”
78	NEURODYC LOVITE (НЕЙРО- ДИКЛОВІТ)	50 mg	capsules	Austria (G.L. Pharma GmbH)	
79	OLFEN [®] (ОЛФЕН [®])	140 mg / 12 hours per 140 cm ²	plaster	Japan (Teika Pharmaceutical Co., Ltd. (manufacturer responsible for the production of bulk product; primary and secondary packaging, batch control)) Germany	

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
				(Merkle GmbH (manufacturer responsible for batch control; manufacturer responsible for batch release))	
80	OLFEN® HYDROGEL (ОЛФЕН® ГІДРОГЕЛІЬ)	1 % (1 g of gel contains diclofenac sodium 10 mg)	gel	Germany (Merkle GmbH) (manufacturer responsible for in bulk production, primary packaging, secondary packaging, batch control; batch manufacturer)	
81	OLFEN®-100 SR DEPOCAPS (ОЛФЕН®- 100 СР ДЕПОКАПС)	100 mg	capsules	Switzerland (Acino Pharma AG (full cycle production; production of bulk products, quality control, batch approval; primary and secondary packaging)) Germany (Unterzuhungsinstitut e Heppeler GmbH (additional laboratory involved in batch control))	
82	OLFEN®-50 LACTAB (ОЛФЕН®-50 ЛАКТАБ)	50 mg	tablets		
83	ORTOFEN (ОРТОФЕН)	25 mg	tablets		JSC "Vitamins"
84		25 mg	tablets		PJSC «Technolog»
85		25 mg in bulk: 9,000 or 16000 tablets	tablets		
86	ORTOFEN- ZDOROV'YA (ОРТОФЕН- ЗДОРОВ'Я)	25 mg	tablets		"Pharmaceutical company «Zdorovye»" Ltd.
87	ORTOFEN- ZDOROV'YA FORTE	50 mg	tablets		"Pharmaceutical company «Zdorovye»" Ltd. ((all stages

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
	(ОРТОФЕН- ЗДОРОВ'Я ФОРТЕ)				of production, quality control, series release)); LLC "Farmex Group" (all stages of production, quality control)
88	PROTECON FAST® (ПРОТЕКОН ФАСТ®)	50 mg potassium diclofenac	tablets	India (Evertogen Life Sciences Limited)	
89	RAPTEN (РАПТЕН)	25 mg/ml in 53 ml (75 mg)	injection solution	Serbia ("Hemopharm" JSC)	
90	RAPTEN RETARD (РАПТЕН РЕТАРД)	100 mg	tablets		
91	RAPTEN GEL (РАПТЕН ГЕЛЬ)	1 % (1 g of gel contains diclofenac diethylamine 11.6 mg (corresponding to 10 mg of diclofenac sodium))	gel	Serbia ("Hemofarm" JSC, Vrsac, department production site Sabac (manufacturer of finished drug, primary, secondary packaging, batch control), "Hemopharm" JSC (manufacturer responsible for the release of the series))	
92	SOLAKUTAN (СОЛАКУТАН)	30 мг/г (1 г гелю містить 30 мг диклофенаку натрію)	gel	Germany (Mibe GmbH Arzneimittel)	
93	FANIGAN® FAST (ФАНИГАН® ФАСТ)	gel in bulk (1 g of gel contains diclofenac diethylamine in terms of	gel	India (Kusum Healthcare PVT Ltd.)	

№	Trade name (Ukrainian name)	Dosage	Dosage form	Manufacturer	
				foreign (country, name)	Ukrainian (name)
		diclofenac sodium 10 mg)			
94	FANIGAN (ФАНИГАН)	50 mg	tablets	India (Kusum Healthcare PVT Ltd.)	Kusum Pharm LLC
95	FLAMIDES GEL ФЛАМІДЕЗ ГЕЛЬ	20 g, 30 g, 40 g or 100 g (1 g of gel contains diclofenac diethylamine 11.6 mg (equivalent to diclofenac sodium 10 mg))	gel	India (Encube Ethicals Private Limited)	

According to Table 1 and Figure 1, the leading positions among DF are gels (30%) and tablets (27%) for 27 and 24 names of tradenames, followed by solutions for injection (15 TN) - 17%, suppositories (11 TN) - 12%, then capsules (8 TN) - 9%, plasters (3 TN) - 3%, sprays (2 TN) - 2% and eye drops (2 TN) - 2%. These DF of diclofenac present the potential for therapeutic action for both external and internal use.

The analysis of the first three leading LF by producer countries in the pharmaceutical market of Ukraine is as follows. For (emul)gels, the main producing countries are India (Unique Pharmaceutical Laboratories, Kusum Healthkker PVT Ltd., Nabros Pharma Ltd., Encube Ethicals Private Limited), Germany (Merkle GmbH, Transform Logistics GmbH, Mibe GmbH Artsneimittel), Serbia ("Hemopharm" JSC, Vršac), Romania (K.O. Slavia Pharm S.R.L.), Switzerland (GSK Consumer Helsker S.A.). The tablet form is produced in Italy (Novartis Pharma S.P.A.), Turkey (Novartis Saglik, Gida ve Tarim Urunleri San. Ve Tik. A.S.), Germany (Salutas Pharma GmbH, Hennig Arzneimittel GmbH & Co. KG, Unterzuhungsinstitut Heppeler GmbH), Poland (Lek S.A.), India (Unique Pharmaceutical Laboratories, Nabros Pharma Pvt. Ltd., Sava Helskea Ltd., Evertogen Life Science Limited, Kusum Heltti Leltgttdt),

Slovenia (KRKA, dd, Novo mesto), Switzerland (Acino Pharma AG). Manufacturers of injectable solutions are Cyprus (Medokemi Ltd.), Switzerland (Novartis Pharma Stein AG), Slovenia (Lek Pharmaceuticals), Italy (A. Menarini Manufacturing Logistics and Services S.R.L., Alfasigma S.P.A.), Greece (DEMO S.A. Pharmaceutical Industry, Bros LTD), Germany (Merkle GmbH), Turkey (Mefar Ilach San A.Sh.), Slovenia (KRKA, Novo mesto) and Serbia (Hemofarm AD).

The main dosage forms presented on the market by Ukrainian manufacturers are gels, tablets, solutions for injection, suppositories, capsules and sprays. According to the State Register of Medicinal Products, the manufacturers of drugs with the active substance diclofenac among domestic enterprises are as follows. Gels are produced by PJSC "Chervona zirka", JSC "Lubnypharm", PJSC SIC "Borshchahivskiy CPP", PJSC Pharmaceutical factory "Viola", JSC "Farmak" and "Pharmaceutical company «Zdorovye»" Ltd. Solutions for injections are produced by JSC "Lubnypharm", PJSC "Lekhim-Kharkiv", JSC "Biolik, PJSC "Pharmaceutical firm" Darnitsa" and "Pharmaceutical company «Zdorovye»" Ltd.

Kusum Pharm LLC, "Pharmaceutical company «Zdorovye»" Ltd., "Farmex Group" LLC, PJSC «Technolog», JSC "Vitamins", PJSC "Pharmaceutical firm" Darnitsa" and PJSC "Chervona zirka" produce such a dosage form of a tablet. Suppositories are produced by PJSC "Lekhim-Kharkiv", PJSC "Monpharm" and LLC "Pharmex Group". Capsules are produced at such Ukrainian enterprises as JSC "Kyiv Vitamin Plant" and Kharkiv Pharmaceutical Enterprise "Health of the People" Ltd. Dosage form spray is presented only by "Pharmaceutical company «Zdorovye»" Ltd.

Therefore, the leaders of the Ukrainian market of manufacturers are PJSC "Chervona zirka" (gels, solutions for injections, tablets) and "Pharmaceutical company «Zdorovye»" Ltd. (gels, solutions for injections, spray).

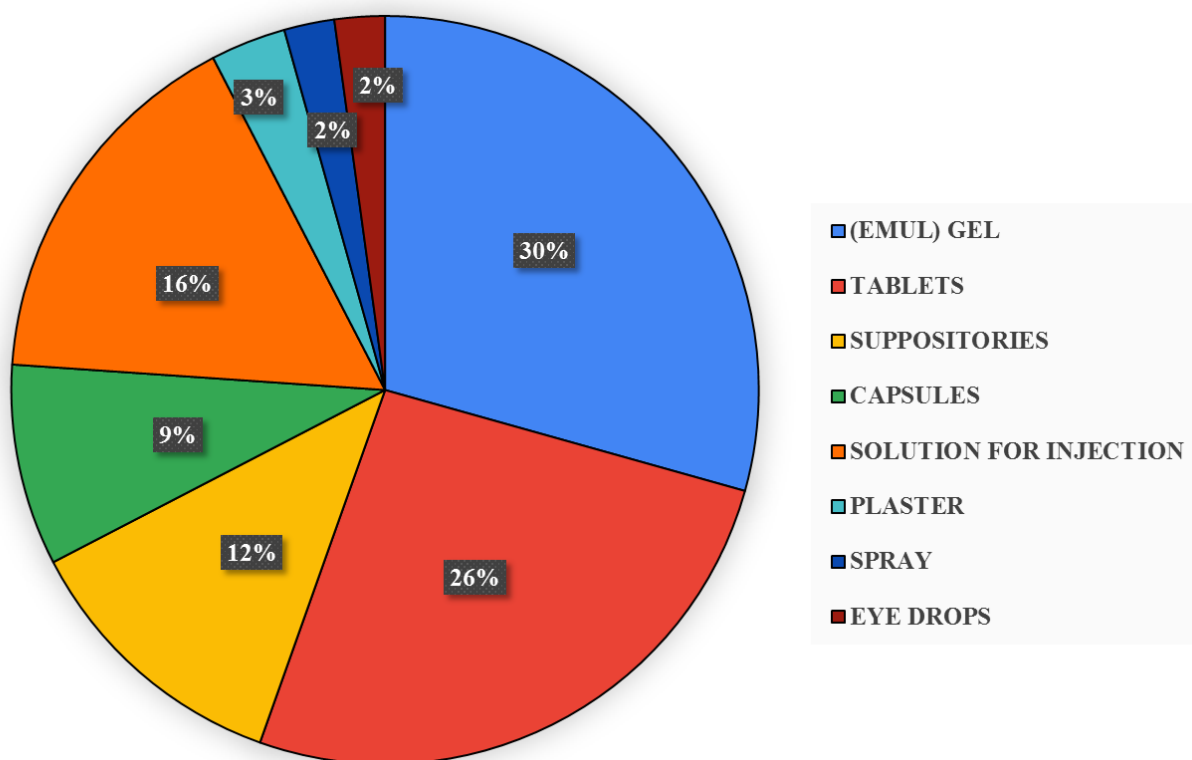


Figure 4. Percentage of each dosage form in the total amount of diclofenac drugs.

The detailed distribution of trade names by country of origin is shown in Figure 5. In addition, the analysis of data from the State Register of Medicinal Preparations of Ukraine showed that for some diclofenac drugs production is carried out in cooperation with different pharmaceutical manufacturers. In particular, this applies to the production of such drugs of foreign production as ARGETT DUO, ARGETT RAPID, VOLTAREN[®], VOLTAREN[®] PLASTER 24 HOURS, DIKLAK[®] ID, DICLOBERL RETARD, DICLOBERL[®] N75, DICLOFENAC-TEVA FORTE, NACLOFEN RETARD, OLFEN[®] plaster, OLFEN[®]-50 LACTAB, and domestic production ORTHOPHEN-ZDOROVYE FORTE.

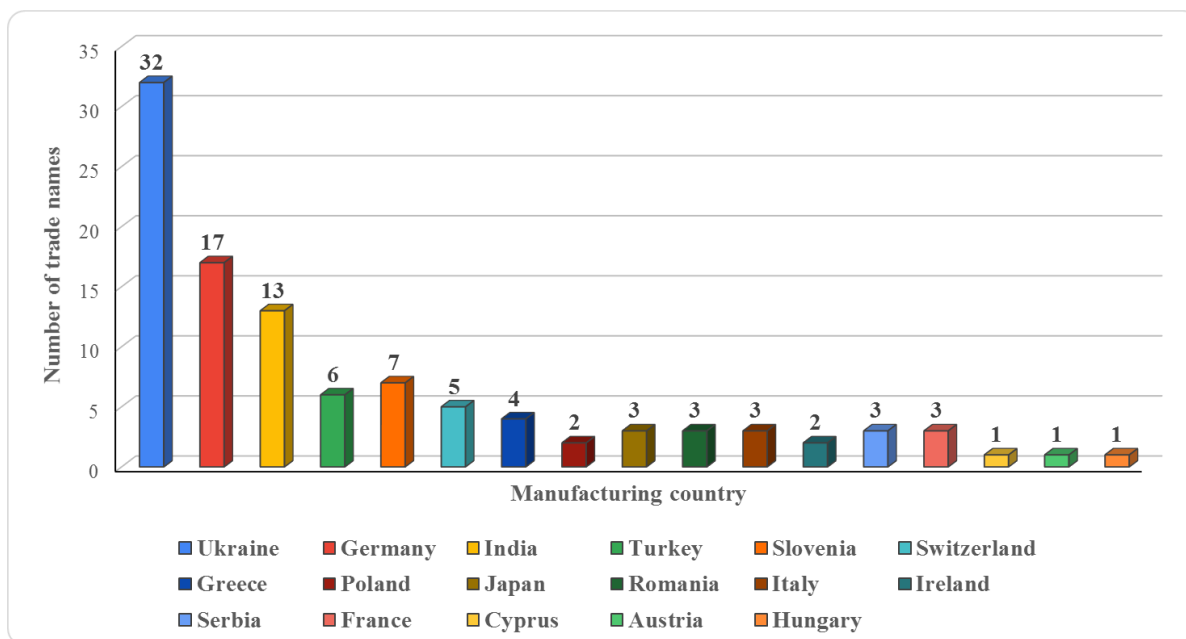


Figure 5. Quantitative ratio of trade names of diclofenac drugs by manufacturers.

An analysis of suppliers of diclofenac sodium/potassium/diethylamine substances for the manufacture of the above drugs revealed only 2 Indian companies Aarti Drags Limited and Amoli Organics Pvt., as well as 1 Chinese company Henan Duntai Pharm Co., Ltd. These companies supply Ukrainian pharmaceutical companies diclofenac sodium or diclofenac diethylamine in the form of a dry powder. Unfortunately, there are no manufacturers of these substances on the Ukrainian pharmaceutical market according to the State Register of Medicinal Preparations of Ukraine.

Analysis of subgroup M02A A65 ** Diclofenac, combinations of group M02A Non-steroidal anti-inflammatory drugs for topical use showed that it is represented by only 7 trade names (3 of which are produced in Ukraine) exclusively in the form of gels, and 71% of diclofenac substance is used as diclofenac diethylamine (Table 2). At the same time, in group M01A Non-steroidal anti-inflammatory and anti-rheumatic drugs of subgroup M01A B55 Diclofenac, combinations in 87% of diclofenac are used in the form of sodium salt and in one case - potassium (Table 3). 75% of the DF are tablets. There are also 2 preparations in the form of capsules and solution for injection. Paracetamol is used as another active ingredient in 6 trade names of diclofenac combination drugs. Among the 8 trade names of the drugs, foreign manufacturers

predominate and only one DICLOCAINE is produced in Ukraine by "Pharmaceutical company «Zdorovye»" Ltd.

Table 2

Preparations of group M02A A65 ** Diclofenac, combinations

№	Trade name (Ukrainian name)	Diclofenac substance	Other active substances
1.	ALGOSAN® (АЛЬГОЗАН®)	diclofenac diethylamine	chestnut seed extract dry
2.	DICLORAN® PLUS (ДИКЛОРАН® ПЛЮС)	diclofenac diethylamine	methyl salicylate, menthol (levomenthol), linseed oil
3.	DICLOSAN (ДИКЛОСАН)	diclofenac sodium	nicotinic acid
4.	DICLOFEN GEL (ДИКЛОФЕН-ГЕЛЬ)	diclofenac sodium	levomenthol
5.	DOLAREN GEL (ДОЛАРЕН ГЕЛЬ)	diclofenac diethylamine	menthol, methyl salicylate
6.	FANIGAN® FAST (ФАНИГАН® ФАСТ)	diclofenac diethylamine	menthol, methyl salicylate, linseed oil
7.	FLAMIDES GEL (ФЛАМІДЕЗ ГЕЛЬ)	diclofenac diethylamine	methyl salicylate, levomenthol

Table 3

Preparations of group M01A B55 Diclofenac, combinations

№	Trade name, dosage form (Ukrainian name)	Diclofenac substance	Other active substances
1.	BOL-RAN®, tablets (БОЛ-РАН®)	diclofenac sodium	paracetamol
2.	DICLOCAINE, solution for injection (ДИКЛОКАЇН)	diclofenac sodium	lidocaine hydrochloride
3.	DOLAREN®, tablets (ДОЛАРЕН®)	diclofenac sodium	paracetamol
4.	DOLOXEN, tablets (ДОЛОКСЕН)	diclofenac sodium	paracetamol
5.	NEUODYCLOVITE, capsules (НЕЙРОДИКЛОВІТ)	diclofenac sodium	thiamine hydrochloride, pyridoxine hydrochloride, cyanocobalamin
6.	TILDA®, tablets (ТИЛДА®)	diclofenac sodium	paracetamol, chlorzoxazone
7.	FANIGAN, tablets (ФАНИГАН)	diclofenac sodium	paracetamol
8.	FLAMIDES®, tablets (ФЛАМІДЕЗ®)	diclofenac potassium	paracetamol, serratiopeptidase

Thus, the analysis of the range of drugs with the active substance diclofenac showed that the leading positions in the group M02A A15 among the dosage forms are gels for external use, as well as tablets and solutions for injection. Regarding the prospects of development, it should be noted that the market niches for the development and production of new tablets or gels are filled with a wide range. Therefore, it is worth paying attention to quite promising drugs such as sprays or plasters, which are very few on the market, but in the treatment of local pain, they are one of the convenient ways to use for the patient. However, it should be borne in mind that the use of the dosage form plaster is somewhat limited by the price of such a form for the average consumer (from 870.00 UAH for 5 pcs.) [287] and the range of trade names (only 3), which is represented exclusively by foreign manufacturers. It should be noted that the use of diclofenac as a spray is represented by only 2 trade names, among which is a Ukrainian manufacturer.

It is established that the leaders among the drug-producing countries in the M02A A15 group are Ukraine, Germany and India, with Ukrainian manufacturers significantly predominating. The leaders of the Ukrainian market of diclofenac drugs are "Pharmaceutical company «Zdorovye»" Ltd., PJSC "Chervona zirka".

The market range of diclofenac combinations in groups M02A A65 ** and M01A B55 is represented by a total of 15 trade names in the vast majority of foreign production. Moreover, in the first group all drugs are produced exclusively in the form of gels, and in the second group the tablet form predominates. Therefore, the niche of developing new combinations of diclofenac and their introduction into Ukrainian production is promising.