

## RANGE ANALYSIS, SOCIO-ECONOMIC ACCESSIBILITY AND CONSUMPTION OF FIBRATES ON THE PHARMACEUTICAL MARKET OF UKRAINE DURING 2017-2020

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### Abstract

At present, statins are included in the first line of dyslipidemia therapy. Fibrates also take a certain place in the treatment of dyslipidemia. Given the above, it is advisable to study the pharmacoeconomic characteristics of fibrates presented on the pharmaceutical market of Ukraine.

The work aimed to explore the range, socio-economic accessibility, and consumption of fibrates in the pharmaceutical market of Ukraine during 2017-2020.

**Materials and methods.** A retrospective analysis of the range, prices, accessibility, and consumption of fibrates in Ukraine was conducted using the data of the analytical system "PharmXplorer" by information retrieval company "Morion" and the Compendium system. The assessment of economic accessibility was carried out on the indicator of solvency adequacy (Ca.s.), consumption volumes - on the indicator of DDDs (number of defined daily doses (DDD)), and the number of sold packages during 2017-2020.

**Results and discussion.** During 2017-2020, only 3 trade names (TN) of foreign-produced fenofibrate were registered on the pharmaceutical market of Ukraine, the prices of which did not fluctuate significantly. The fenofibrate drug - Lipofen SR (Nobel, Turkey) capsules 250 mg No. 30 in a blister is highly available to Ukrainian consumers (Ca.s. less than 5.0%), and the drug Tricor® 145 mg (Abbott Products GmbH, Germany) film-coated tablets 145 mg No. 20 and No. 30 in a blister (Ca.s. more than 5.0%) - moderately available. The dynamics of growth in sales of fenofibrate packaging in 2019-2020 compared to 2017-2018 has been established due to growth in sales of the drug "Tricor®" (film-coated tablets 145 mg No. 20 in a blister). The dynamics of increasing the consumption of fibrates in terms of DDDs, which generally corresponds to the dynamics of sales in the number of packages have been identified, but consumption volumes are insignificant.

**Conclusions.** Consumption of fibrates in the Ukrainian pharmaceutical market is insignificant as determined by their clinical efficacy and place in antihyperlipidemic CVD therapy, where statins predominate today.

**Keywords:** *fibrates, price analysis, socio-economic accessibility, consumption.*

## Introduction

Atherosclerosis and atherothrombosis of blood vessels are leading factors in the development and progression of cardiovascular diseases (CVD), which occupy a prominent place in the structure of morbidity and mortality in Ukraine and around the world [1, 2, 3].

The basis of the development of atherosclerosis and atherothrombosis is dyslipidemia, which is essentially a violation of the function and/or composition of lipids and lipoproteins in the blood. The most important is the so-called "atherogenic lipid triad", which is characterized by an increase in the level of very-low-density lipoproteins (VLDL cholesterol) and the associated increase in triglycerides (TG) and "small dense particles" of low-density lipoprotein cholesterol (LDL) and reduction of high-density lipoprotein cholesterol (HDL cholesterol) [4]. However, chronic inflammation also plays a central role in the development and progression of atherosclerosis [5, 6].

According to the latest clinical recommendations of the European Society of Cardiology (ESC, 2019) and the European Atherosclerosis Society (EAS, 2019), statins, cholesterol absorption inhibitors, fibrates, bile acid sequestrants, omega-3 unsaturated bile acids, cholesteryl ester transfer protein (CETP) inhibitors, type 9 convertase inhibitors, mipomersen, polyamide and nicotinic acid [4].

Fibrates show a pronounced hypotriglyceridemic effect and the greatest effectiveness in the correction of dyslipidemias characterized by high levels of TG with low levels of HDL cholesterol [2, 7, 8]. By the mechanism of action fibrates are the nuclear  $\alpha$ -receptor agonists activated by peroxisome proliferators (PPAR- $\alpha$ ), which acting through transcription factors, regulate various stages of lipid and lipoprotein metabolism, including fatty acid oxidation, glucose metabolism, adipogenesis, and cell differentiation [9, 10, 11]. This causes a high efficiency of fibrates in reducing the level of both fasting and postprandial TG, as well as TG-rich lipoproteins. The ability of fibrates to reduce insulin secretion and increase tissue sensitivity to it, improve glucose tolerance, have anti-inflammatory effects, reduce platelet aggregation induced by adenosine diphosphate, arachidonic acid and

epinephrine has also been established [12, 13]. It has been found that under the influence of fibrates extravascular cholesterol deposits (xanthoma tendinosum et tuberosum) can disappear [11]. In the world pharmaceutical market, fibrates are represented by the following international non-proprietary names (INN): pemafibrate, gemfibrozil, bezafibrate, ciprofibrate, and fenofibrate [4].

The work aimed to explore the range, socio-economic accessibility, and consumption of fibrates in the pharmaceutical market of Ukraine during 2017-2020.

## Methods

Based on the data of the analytical system "PharmXplorer" by information retrieval company "Morion" [14] and information retrieval system Compendium online [15] a retrospective analysis of the range, prices, socio-economic affordability, and consumption of fibrates registered in the pharmaceutical market of Ukraine in 2017-2020 was conducted.

To assess economic affordability, the solvency adequacy ratio (Ca.s.) was calculated by the formula  $Ca.s. = (P / Wa.w.) \times 100\%$  [16, 17], where Ca.s. - solvency adequacy ratio; Wa.w - the average monthly salary of an average Ukrainian for 2017 (7105 UAH), 2018 (7810 UAH), 2019 (9205 UAH), 2020 (10687) [18]; P - the average retail price of a monthly course of treatment with the drug. It is believed that drugs that have Ca.s. less than 5% are highly accessible, from 5% to 15% - moderately accessible and more than 15% - poorly accessible [16]. The cost of a monthly course of dyslipidemia correction was calculated based on the administration of 1 tablet of the drug per day.

To calculate the consumption of medicinal products the DDDs indicator was used [17]. DDDs is the number of defined average daily doses (DDD) consumed by patients in Ukraine per year. In this study, calculations were performed for each year for 3 years according to formula 1:

$DDDs = \text{number of medicinal product sold in a year (mg)} / DDD(\text{mg})$

Information on the value of DDD is available on the WHO website [19].

## Results and Discussion

The analysis of the range of fibrates in the pharmaceutical market of Ukraine during 2017-2020 shows that this group of hypolipidemic drugs was represented by only one international non-proprietary name (INN) - fenofibrate (table. 1), represented by 3 trade names (TN): Lipofen SR (Nobel, Turkey), capsules 250 mg No. 30 in a blister (in 2017 and 2018) and Tricor® 145 mg (Abbott Products GmbH, Germany), film-coated tablets 145 mg No. 20 and No. 30 in a blister (from 2017 to 2020) [20]. Both registered drugs are foreign-made and are presented in solid dosage form: capsules and tablets. It should be noted that from 2019 the supply of Lipofen SR capsules (Nobel, Turkey) to the pharmaceutical market of Ukraine has been suspended.

Analysis of the price dynamics of registered representatives of fibrates indicates insignificant fluctuations in the cost of individual TN of fenofibrate during the study period (2017-2020).

Assessment of socio-economic accessibility among TN of fenofibrate has allowed establishing that during 2017 and 2018 Lipofen SR (caps. 250 mg No. 30 in a blister) was highly affordable to the population because Ca.s. was 4.54 and 4.61%, respectively. Tricor® 145 mg Abbott Products GmbH (Germany) film-coated tablets 145 mg No. 20 and No. 30 in a blister with Ca.s. more than 5% can be characterized as moderately available for all years studied (Table. 2).

The data in Table 3 show that the total sales of fibrates in 2017 were 10658.68 thousand packages, and in 2018, 2019, and 2020, respectively, 12750.32, 25712.46, and 25888.77 thousand packages. The dynamics of growth in sales of fenofibrate packages in 2019-2020 relative to 2017-2018 is traced due to the growth of sales of the drug Tricor® 145 mg (Abbott Products GmbH, Germany) film-coated tablets

145 mg No. 20 in a blister. In terms of consumption, this drug is the leader (table. 3).

The calculation of fibrate consumption by DDDs generally corresponds to the dynamics of consumption in the number of packages.

An increase in the consumption of fenofibrate drugs in 2019-2020 compared to 2017-2018 has been established both in terms of the number of packages sold and in terms of the number of DDDs.

In general, it can be argued that fibrates are rarely prescribed by Ukrainian physicians, which is probably determined by their clinical efficacy and place in antihyperlipidemic CVD therapy, where statins predominate today.

## Conclusions

Among hypolipidemic drugs of the fibrate group in the pharmaceutical market of Ukraine in 2017-2020, only fenofibrate drugs were registered (3 TNs in 2017-2018 and 2 TNs in 2019-2020 of foreign production).

Insignificant fluctuations in the cost of individual TNs of fenofibrate during the study period were found. Assessment of socio-economic accessibility among TNs of fenofibrate shows that during 2017 and 2018, Lipofen SR (Nobel, Turkey) caps. 250 mg No. 30 in a blister was highly affordable to the population because Ca.s. was 4.54 and 4.61%, respectively. Tricor® 145 mg Abbott Products GmbH (Germany), film-coated tablets 145 mg No. 20 and No. 30 in a blister with Ca.s. more than 5.0% was moderately affordable for all years studied.

An increase in the consumption of fenofibrate drugs in 2019-2020 compared to 2017-2018 has been established both in terms of the number of packages sold and in terms of the number of DDDs.

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**Table 1.** The results of the analysis of the range and price characteristics of fenofibrate TN, which are presented on the pharmaceutical market of Ukraine from 2017 to 2020

Item No.	TN of fenofibrate	The cost of packaging of the drug, UAH			
		2017	2018	2019	2020
1.	Lipofen SR, Nobel (Turkey) capsules 250 mg No. 30 in a blister	322.22	360.4	-	-
2.	Tricor® 145 mg Abbott Products GmbH (Germany) film-coated tablets 145 mg No. 20 in a blister	399.30	412.47	392.98	409.20
3.	Tricor® 145 mg Abbott Products GmbH (Germany) film-coated tablets 145 mg No. 30 in a blister	568.42	579.27	583.55	604.11

**Table 2.** Solvency adequacy ratio (Ca.s., %) TNs of fenofibrate, which were presented on the pharmaceutical market of Ukraine from 2017 to 2020

Item No.	TN of fenofibrate	Solvency adequacy ratio (Ca.s., %)			
		2017	2018	2019	2020
1.	Lipofen SR, Nobel (Turkey) capsules 250 mg No. 30 in a blister	4.54	4.61	-	-
2.	Tricor® 145 mg Abbott Products GmbH (Germany) film-coated tablets 145 mg No. 20 in a blister	8.43	7.92	6.40	6.11
3.	Tricor® 145 mg Abbott Products GmbH (Germany) film-coated tablets 145 mg No. 30 in a blister	8.0	7.42	6.34	6.45

**Table 3.** Indicators of fenofibrate consumption in the pharmaceutical market of Ukraine in 2017-2020

INN Fenofibrate	DDDs (thousands)				Consumption (thousands of packages)			
	2017	2018	2019	2020	2017	2018	2019	2020
Lipofen SR, Nobel (Turkey), capsules 250 mg No. 30 in a blister	0.609	0.173	-	-	16.24	4.61	-	-
Tricor® 145 mg Abbott Products GmbH (Germany), film-coated tablets 145 mg No. 20 in a blister	147.68	175.54	366.07	384.32	10185.40	12105.91	25246.20	25504.82
Tricor® 145 mg Abbott Products GmbH (Germany), film-coated tablets 145 mg No. 30 in a blister	9.94	13.92	10.14	8.35	457.04	639.80	466.26	383.95
Total amount	158.24	18.96	376.21	392.67	10658.68	12750.32	25712.46	25888.77