Marketing Analysis and Availability of Drugs with ATC Code N07BB: Current Trends

Valentyn Shapovalov (Doctor of Pharmaceutical Sciences, Professor, Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law", Ukraine)
Anatolii Derkach (Candidate of Pharmaceutical Sciences, Associate Professor, Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law", Ukraine)
Corresponding author: Anatolii Derkach

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Abstract. Marketing analysis was conducted and the availability of drugs for the treatment of alcohol addiction under the ATX code N07BB was assessed. The study covers three main clinical and pharmacological groups: Disulfiram (N07BB01), Naltrexone (N07BB04) and other drugs (N07BB10). The features of the release forms (tablets, granules, powders), availability and release regimens were analyzed. Disulfiram and Naltrexone drugs are available by prescription, while combined drugs are available without a prescription. The data obtained indicate a high potential for the use of these drugs for individualized and affordable therapy of alcohol addiction.

A thorough marketing assessment was undertaken to evaluate the availability of medications under ATX code N07BB, focusing on their role in alcohol addiction treatment. The analysis covered three principal clinical and pharmacological categories: Disulfiram (N07BB01), Naltrexone (N07BB04), and an additional subgroup of products (N07BB10). Researchers examined various dosage forms – including tablets, granules, and powders – alongside their accessibility and distribution requirements. Disulfiram and Naltrexone both require a physician's authorization, while certain combination therapies can be purchased without a prescription. Based on these data, there is clear evidence of a robust potential for these therapies to be used in personalized and cost-effective interventions for alcohol dependence. Moreover, their availability in multiple formats caters to patients' individual preferences and clinical needs, potentially enhancing adherence and treatment success. By offering a wide variety of administration possibilities, these medications are poised to improve outcomes in different healthcare settings. Research into dosing schedules and side effects can guide clinicians in refining therapeutic approaches. Healthcare professionals may consider these agents as part of a strategy, incorporating psychosocial support and other interventions that address the nature of alcohol dependence.

Keywords: marketing analysis, availability, alcohol addiction, pharmacotherapy, Disulfiram, Naltrexone, combined drugs, dispensing regimen.

Introduction. The problem of irrational use and addiction to psychoactive substances of various clinical-pharmacological, classification-legal, nomenclature-legal groups has become global. The development of addiction to psychoactive substances is rapidly developing among different segments of the population, especially among young people and minors. Clinical pharmacology and clinical pharmacy are engaged in the search for new accessible, effective, socially oriented schemes of pharmacotherapy of addiction, considering the characteristics of the course of the disease, the patient's age, etc.

A review of scientific sources shows that the simultaneous or sequential use of several psychoactive substances, alcohol, tobacco, psychoactive drugs (narcotics, psychotropic) is gaining momentum in countries such as Great Britain, France. Austria, England, Hungary, the Czech Republic, the USA, Portugal, Kazakhstan, Tajikistan, and others. Beer addiction is particularly dangerous, as beer contains a combination of several psychoactive substances, which leads to a faster development of addiction and complicates its pharmacotherapy [1-11].

The situation is aggravated by the fact that in Ukraine there is also an active spread of addiction, among young people, who often use combinations of alcohol, beer, wine, tobacco against the background of concomitant disorders. In view of this, addiction poses a significant threat not only to the health of individual individuals, but also to the socio-economic development of the state, as it

affects demographic security, productivity, educational level, and spiritual state of the population [12-17].

The problem of addiction is a multi-stage process that requires a comprehensive approach to treatment. As noted in the review, for effective therapy it is necessary to use both drug and non-drug methods, considering the stages of addiction development. This requires not only an appropriate medical and pharmaceutical infrastructure, but also an improvement in the regulatory framework to ensure preventive and treatment programs [17-21]. Given the complexity of combating the spread of addiction, it is important that state policy be focused on protecting public health, supporting young people, and strengthening international cooperation in the fight against illicit trafficking in psychoactive substances. Solving this problem requires comprehensive measures, including research into the market of psychoactive drugs to develop effective addiction pharmacotherapy regimens, prevention, and rehabilitation measures, and improving legislation to reduce negative social, mental, legal, and medical and pharmaceutical consequences for society [22-27].

The purpose of the study was to research the marketing analysis and availability of drugs (medicines) by ATC code N07BB.

Materials and methods. The current research was carried out using the system approach during January 2024-September 2024.

Materials: regulatory and legal framework, medicinal products with codeine, instructions for medical use, and other local documents. The clinical and pharmacological groups of medicines were distributed according to the ATC classification [28].

Methods of the research. Administration, organizational and legal, normative, documentary, clinical and pharmacological, comparative, classification and legal, nomenclature and legal, marketing, technological, graphic analysis were used in the study.

The research of the article is a fragment of research works of Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law" on the topic "Multidisciplinary research of post-traumatic stress disorders during war among patients (primarily combatants)" (state registration number 0124U002540, implementation period 2024-2029).

Results and discussion. A review of scientific sources indicates a significant spread of addiction among young people, who are one of the most vulnerable groups of the population. According to international studies, young people are becoming the main target audience for the influence of psychoactive substances, since this stage of life is associated with increased emotional instability, the influence of social factors, experiments with self-expression and social risks. The tendency to early onset of alcohol, tobacco, illicit psychoactive substances, psychoactive drugs, and psychostimulants is especially threatening [12, 13, 29]. In the international ATC classification, drugs for the pharmacotherapy of alcohol addiction were assigned to a separate group "Means used in addictive health disorders" – ATC code N07BB [29]. According to ICD-10, the development of alcohol addiction corresponds to code F-10 “Mental and behavioral health disorders due to alcohol use” and, in ICD-11, code 6C40 “Alcohol use disorders” [9, 10].

The list of psychoactive substances, the abuse of which leads to addiction, is constantly expanding. The most common psychoactive substance abused among different segments of the population is alcohol. Alcohol is consumed alone and in combination with medications and tobacco [6, 30, 31].

Alcohol (ethanol) is a central nervous system depressant and has a wide range of concentrations in various drinks - from 1.5% to 60%. Its use is associated with the risk of developing alcohol dependence, withdrawal syndrome and numerous diseases, such as cirrhosis of the liver, oncological diseases of the gastrointestinal tract, pancreatitis, etc. [15, 16].

In addition to its direct impact on physical health, the psychoactive substance alcohol also causes alcohol-induced mental disorders, alcoholic psychosis, dementia, and neurocognitive disorders. The social aspect is also important – alcohol often leads to aggressive behavior and other destructive actions, which harms the consumer and his environment [32, 33]. In the pharmacotherapy of alcohol addiction, drugs of various clinical and pharmacological, classification and legal, and

nomenclature and legal groups are used. According to the ATC codes, the drugs belong to the clinical-pharmacological group "Methods used in alcohol dependence" and have the ATC code N07BB.

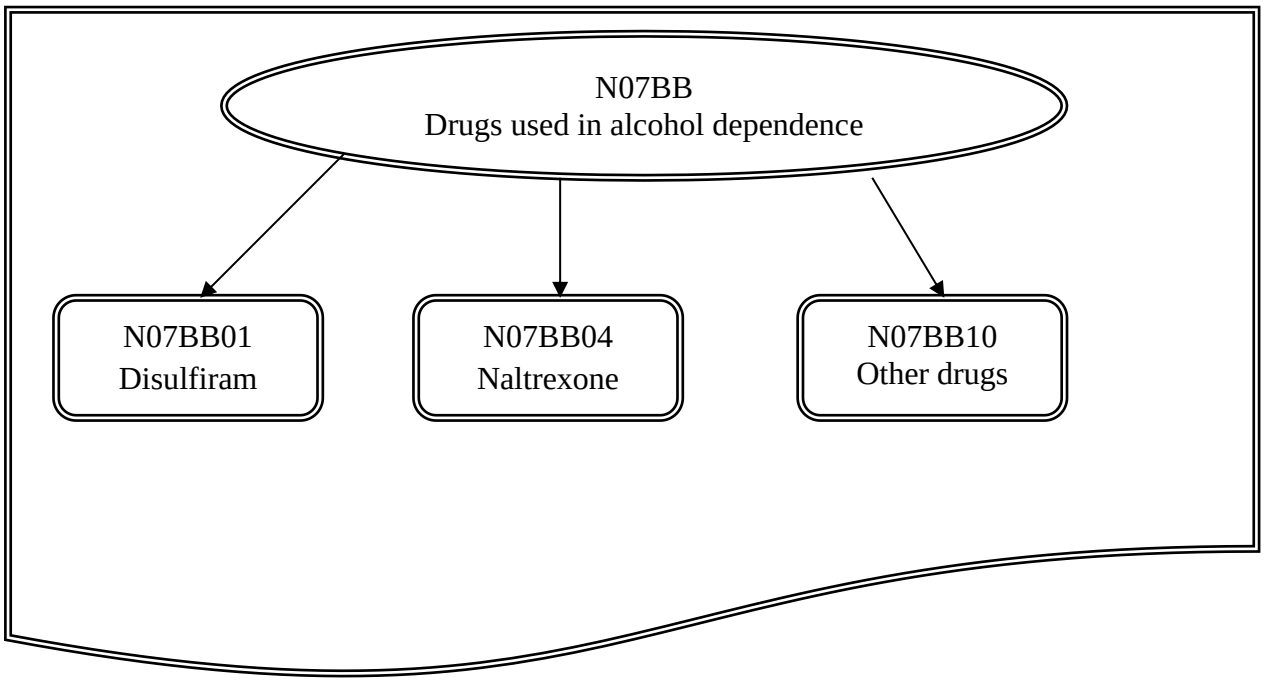

Fig. 1. Distribution of drugs for pharmacotherapy of alcohol addiction according to the ATC classification [29].

As can be seen from Fig. 1, the clinical-pharmacological group “Drugs used in alcohol addiction” includes 3 clinical-pharmacological groups:

- code N07BB01 – drugs with the INN Disulfiram;
- code N07BB04 – drugs with the INN Naltrexone;
- code N07BB10 – other drugs.

The list of drugs registered in Ukraine, as well as substances containing the active substance Disulfiram, is given in Table 1.

Table 1. Drugs and substances with the ATC code N07BB01 with the INN Disulfiram.

No.	Trade name	Manufacturer	Warehouse	Form of issue	Registration certificate
1.	Teturam	Public Joint-Stock Company "Scientific and Production Center "Borshchagiv Chemical and Pharmaceutical Plant", Ukraine	1 tablet contains disulfiram (calculated on 100% and dry substance) – 150 mg	tablets of 150 mg, 10 tablets in a blister; 1 or 5 blisters in a cardboard pack	UA/6325/01/01 unlimited from 19.05.2017
2.	Esperal	Sofarimex - Industria Kimica e Pharmaceutica, S.A., Portugal	1 tablet contains disulfiram 500 mg	tablets of 500 mg; No. 20: 20 tablets in a bottle, 1 bottle	UA/5332/01/01 unlimited from 01.10.2021

				in a cardboard box	
3.	Disulfiram	Unidrag Innovations Pharma Technologies Ltd., India	Disulfiram not less than 98.5% and not more than 101.0%, in terms of dry matter	powder (substance) in double polyethylene bags for pharmaceutical use	UA/17480/01/01 unlimited from 29.04.2024

Table 1 includes drugs and substances for the pharmacotherapy of alcohol addiction. All drugs contain the active substance Disulfiram, which belongs to the group N07BB01.

Disulfiram drugs are presented in two forms: tablet and powder. Tableted forms of drugs make up 66.7% of the total (Table 1). Presented in doses of 150 mg and 500 mg per tablet. Allows you to adapt pharmacotherapy depending on the individual needs of the patient. Disulfiram tablets are available in packages of 10 or 20 pieces, which is convenient for long-term administration in the pharmacotherapy of alcohol addiction. The powder form of Disulfiram is 33.3% and is intended for pharmaceutical use in the form of a substance, with a concentration of Disulfiram in the range from 98.5% to 101.0%. This form allows you to use the drug Disulfiram as part of various pharmaceutical products or for individual prescriptions.

Regarding the geography of production, 33.3% of Disulfiram drugs are manufactured by Ukrainian companies. PJSC "Scientific and Production Center "Borshchagov Chemical and Pharmaceutical Plant", which produces one of the drugs in tablet form. Another 33.3% of the products are supplied from Portugal. In particular, the manufacturer of Sofarimex – Industria Kimika is Pharmaceutica. The last 33.3% are produced in India, by the company Unidrag Inovets Pharma Technologies, which specializes in the supply of substances.

All Disulfiram drugs have unlimited registration certificates, which indicates their long-term permission for use and effectiveness in the treatment of alcohol addiction.

Drugs and substances with INN Naltrexone belong to the clinical and pharmacological group with ATS code N07BB04, which are registered in Ukraine are given in Table 2.

Table 2. Drugs and substances ATC code N07BB04 INN Naltrexone.

No.	Trade name	Manufacturer	Warehouse	Form of issue	Registration certificate
1.	Naltrexone hydrochloride	Sanofi Chemie, France	Naltrexone hydrochloride not less than 98.0% and not more than 102.0% in terms of anhydrous and solvent-free substance	powder (substance) in a polyethylene bag for pharmaceutical use	UA/17952/01/01 25.02.2020 25.02.2025
2.	Naltrexone hydrochloride	Rusan Pharma Ltd., India	not less than 98.0% and not more than 102.0% of 17-(cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxy-morphinan-6-one hydrochloride, calculated on the	powder (substance) in polyethylene double bags for pharmaceutical use	UA/17690/01/01 unlimited from 29.04.2024

			anhydrous basis substance		

Table 2 contains data on the drugs and substances INN Naltrexone used in the pharmacotherapy of alcohol addiction with the code N07BB04. Table 2 presents Naltrexone drugs in powder form, which are used as substances for pharmaceutical use. Both drugs have a Naltrexone concentration in the range of 98.0% – 102.0% in terms of anhydrous substance, which guarantees their high purity and efficacy. 100% of the Naltrexone drugs presented in Table 2 are in the form of a powder for pharmaceutical use, which provides flexibility in their use in the manufacture of final pharmaceutical products. Regarding the geographical distribution of Naltrexone manufacturers, 50% of the substances are manufactured in France by Sanofi Chemie, and the other 50% in India by the manufacturer Rusan Pharma Ltd. Both INN Naltrexone drugs are supplied in double polyethylene bags to ensure safety and quality during transportation and storage. The registration certificates of these substances INN Naltrexone have different validity periods: one of the drugs manufactured in France has a registration from 02/25/2020 to 02/25/2025, and the Indian drug has an unlimited registration, which came into force on 04/29/2024.

Table 2 demonstrates the use of INN Naltrexone as an active substance for pharmaceutical production, ensuring high quality and availability of drugs for the treatment of alcohol addiction.

The clinical and pharmacological group “Other drugs” with ATC code N07BB10 includes drugs with various active substances INN. They are used not only in the pharmacotherapy of alcohol addiction, but also to relieve hangover symptoms. It is of great importance in relieving withdrawal syndrome and improving the quality of life of alcoholics. Drugs of the group N07BB10 “Other drugs” are given in Table 3.

Table 3. Other drugs for the pharmacotherapy of alcohol addiction from group N07BB10.

No.	Trade name	Manufacturer	Warehouse	Form of issue	Registration certificate
1.	Proproten-100	CJSC Santonika, Lithuania	1 tablet contains antibodies to the brain-specific protein S-100 affinity purified C1000 – 3 mg	tablets, 20 tablets in a blister; 1 or 2 blisters in a cardboard box	UA/3646/01/01 unlimited from 22.07.2019
2.	Medikhronal-Darnytsya	PJSC "Darnytsia Pharmaceutical Firm", Ukraine	package No. 1: 1 package contains: glucose monohydrate 17.5 g; package No. 2: 1 package contains: glycine 7 g; sodium formate 3.5 g	granules, package No. 1 and pack No. 2 in a pack; 7 packs No. 1 and 7 packs No. 2 in a pack; 21 pack No. 1 and 21 pack No. 2 in a pack	UA/6504/01/01 unlimited from 12.06.2017

Table 3 presents two drugs with different compositions and forms of release.

- Tablets make up 50% of the drugs on the pharmaceutical market. The first drug Proproten-100 is produced in Lithuania by JSC Santonica, contains 3 mg of antibodies to the brain-specific protein S-100. These tablets are available in blisters of 20 pieces, with the possibility of packing one or two blisters in a cardboard box. The drug Proproten-100 has an unlimited

registration certificate since 22.07.2019.

- Granules make up the other 50% of the drugs. The second drug Medikhronal-Darnytsya is produced by PrJSC "Pharmaceutical Firm "Darnytsya" in Ukraine, and consists of two packages: package No. 1 contains 17.5 g of glucose monohydrate, and package No. 2 contains 7 g of glycine and 3.5 g of sodium formate. The drug Medikhronal-Darnytsya is available in the form of granules, with different packaging options – 7 or 21 packages of each type in one pack. The drug Medikhronal-Darnytsya also has an unlimited registration certificate from 12.06.2017.

Regarding the geography of production, 50% of drugs with ATC code N07BB10 are manufactured in Lithuania, and the other 50% – in Ukraine. Both drugs have unlimited registration terms, which indicates their stable presence on the market and proven effectiveness in the treatment of alcohol dependence.

Thus, Table 3 demonstrates a wide range of drugs with ATC code N07BB10 with different forms of release (tablets and granules), which allows you to choose the optimal option of pharmacotherapy, depending on the needs of patients.

To determine the availability of drugs of the clinical and pharmacological group of ATC code N07BB for patients, the formula was used:

A = CPG + CLG + NLG where,

A – availability for patients;

CPG – clinical and pharmacological group;

CLG – classification and legal group;

NLG – nomenclature and legal group.

NLG was determined in accordance with the Order of the Ministry of Health of Ukraine dated May 05, 2023 No. 848 “On approval of the List of medicinal products permitted for use in Ukraine, which are dispensed without prescriptions from pharmacies and their structural units” [34].

The results of the study of availability for patients are given in Table 4.

Table 4. Availability for patients of drugs of the N07BB group for pharmacotherapy of alcohol addiction.

No.	INN	Trade name	Pharmaceutical form	Availability		
				CPG	CLG	NLG
1.	Disulfiram	Teturam	tablets of 150 mg, 10 tablets in a blister; 1 or 5 blisters in a cardboard pack	N07BB01	Means used for alcohol addiction. Disulfiram	Dispensed with a doctor's prescription
2.	Disulfiram	Esperal	tablets of 500 mg; No. 20: 20 tablets in a bottle, 1 bottle in a cardboard box	N07BB01	Means used for alcohol addiction. Disulfiram	Dispensed with a doctor's prescription
3.	Disulfiram	Disulfiram	powder (substance) in double polyethylene bags for pharmaceutical use	N07BB01	Means used for alcohol addiction. Disulfiram	Dispensed with a doctor's prescription
4.	Naltrexone	Naltrexone hydrochloride	powder (substance) in a polyethylene	N07BB04	Means used for alcohol	Dispensed with a

			bag for pharmaceutical use		addiction. Naltrexone	doctor's prescription
5.	Naltrexone	Naltrexone hydrochloride	powder (substance) in polyethylene double bags for pharmaceutical use	N07BB04	Means used for alcohol addiction. Naltrexone	Dispensed with a doctor's prescription
6.	Comb drug	Medichronal-Darnytsia	Gran. computer (package 1 + package 2) N. 1, N. 7, N 21	N07B B10	Means used for alcohol addiction. Other means	Without a prescription
7.	Comb drug	Proproten-100	Tablet. homeopathic N.20, N. 40	N07B B10	Means used for alcohol addiction. Other means	Without a prescription

Table 4 contains information on the availability of drugs of group N07BB for patients used in the pharmacotherapy of alcohol addiction. Table 4 provides extended information on seven drugs. The drugs are presented in various dosage forms, including tablets, granules, and powders for pharmaceutical use. Their availability and control regime depend on the specifics of use and form of release:

Disulfiram (Teturam, Esperal, Disulfiram):

The drugs are presented in the form of tablets and powder.

All drugs belong to group N07BB01. Available by prescription, which requires a doctor's consultation before use.

Naltrexone:

Two naltrexone-based drugs in the form of powders for pharmaceutical use.

They belong to group N07BB04. Available only by doctor's prescription.

Combined drugs (Comb drug):

Medikhronal-Darnitsa:

Dosage form - granules (packages 1 and 2).

Available in packaging sizes N. 1, N. 7, N. 21.

Is dispensed without a prescription, which facilitates access to treatment.

Proproten-100:

Homeopathic tablets (N. 20, N. 40).

Also available to patients without a prescription, convenient for self-administration by patients.

The expansion of the list of N07BB drugs demonstrates the growing number of available options for pharmacotherapy depending on the needs of patients. Prescription drugs (Disulfiram and Naltrexone) allow for controlled use under the supervision of a specialist, while over-the-counter drugs (Medikhronal-Darnitsa, Proproten-100) are aimed at convenience and accessibility for a wide range of patients.

Conclusions. Marketing analysis was conducted and the availability of drugs for the pharmacotherapy of alcohol addiction by ATC code N07BB was assessed. Found that the drugs are divided into three main clinical and pharmacological groups: Disulfiram (N07BB01), Naltrexone (N07BB04) and other drugs (N07BB10). Disulfiram and Naltrexone drugs are available only by prescription, which ensures controlled use. Combined drugs (Medichronal-Darnytsia, Proproten-100) are available without a prescription, which increases accessibility for patients. Analysis of dosage forms (tablets, granules, powders) showed the possibility of individualizing therapy depending on the

needs of patients. The results obtained emphasize the importance of developing pharmaceutical support for effective treatment of alcohol addiction, considering social and medical needs.

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