

**Ministry of health of the Republic of Belarus  
Educational institution  
«Gomel State Medical University»**

Department of general and clinical pharmacology

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**METHODOLOGICAL RECOMMENDATIONS**

for a practical lesson on the discipline "Clinical pharmacology"  
with six-year students of the Faculty of Foreign Students,  
studying at the specialty 1-79 01 01 "General medicine"

**TOPIC 1: «GENERAL QUESTIONS OF CLINICAL PHARMACOLOGY. INTRODUCTION TO THE DISCIPLINE OF “CLINICAL PHARMACOLOGY”. NOMENCLATURE OF MEDICINES. ORIGINAL AND GENERIC MEDICINAL PRODUCTS. CLINICAL TRIALS AND STATE REGISTRATION OF MEDICINES. TYPES OF EQUIVALENCE OF MEDICINES. BASICS OF EVIDENCE BASED MEDICINE. MEDICAL PRESCRIPTION PROCEDURES. CLINICAL PHARMACOKINETICS AND PHARMACODYNAMICS OF MEDICINES. DRUG INTERACTIONS. ADVERSE DRUG REACTIONS. PRINCIPLES OF USE OF MEDICINES IN WOMEN DURING PREGNANCY AND LACTATION, ELDERLY PATIENTS, PATIENTS WITH LIVER AND KIDNEY DISEASES».**

Time: 6 hours

Approved at the meeting of the department of general and clinical pharmacology  
the protocol № 18 of 30.06.2022

## **LEARNING AND EDUCATIONAL GOALS, OBJECTIVES, MOTIVATION FOR LEARNING THE TOPIC**

The current twenty-first century has been marked by an explosion of pharmacology and pharmaceuticals. This is due to the dramatic increase in the number of new medicinal products or original combinations of already known medicinal products (drugs) entering the pharmacy. The arsenal of ready-to-use medicines includes a large number of highly effective drugs, which, however, have not only therapeutic, but often also undesirable (so-called side-effects) effects. The number of people who do not tolerate one or more drugs is steadily increasing. The leading cause of this phenomenon is the frequent irrational and unreasonable use of medicines. It has been found that in only 13-14% of cases is the use of medication considered justified. Moreover, the increasing prevalence of self-medication is contributing to an increase in drug-related complications. The incidence of side effects is up to 29% in the use of medicines, of which only 4-6% of patients seek medical advice. Hospitalisation is required in 0.3-2.4% of cases, some of which require acute care in an intensive care unit. Almost 85% of adverse drug reactions result in a temporary incapacity for work. Drug therapy complications result in around 80 million additional prescriptions being issued for remedial therapy. Regardless of the specialty, every qualified doctor must therefore possess knowledge not only about the etiopathogenesis of diseases, diagnostic and differential-diagnostic search, algorithm of medical aid, but also about clinical pharmacology of medicines. The knowledge received on this topic will allow students in future to take into account various factors, such as genetic features of a patient, age, sex, concomitant diseases, pregnancy and lactation, to learn to use medicines correctly and consciously.

### **Learning objective:**

– formation of scientific knowledge about the main pharmacological effects, providing therapeutic and preventive effect of drugs on the topic of the class, indications and contraindications for their use, the interaction of drugs, their combined use for use in medical and preventive activities.

### **Educational purpose:**

– to develop their value-personal, spiritual potential, to form the qualities of a patriot and citizen, ready for active participation in the economic, industrial, socio-cultural and public life of the country; to realize the social significance of their future professional activities, to learn to follow academic and work discipline, standards of medical ethics and deontology.

### **Tasks:**

As a result of the study lesson, the student should

#### **know:**

- basic concepts of clinical pharmacology;
- basics of clinical pharmacokinetics and pharmacodynamics of drugs;
- phenomena occurring during the combined administration of drugs;
- principles of choosing the most effective and safe drugs for individual treatment of diseases in patients, optimal dosing regimens of drugs;

- clinically justified combinations of drugs that can be used in specific clinical situations;
- the specifics of prescribing medicines for children and the elderly, for women during pregnancy and lactation, patients with liver and kidney diseases;
- basic concepts of clinical formulation, orders of the Ministry of Health and prescription rules;

- types of clinical trials and rules for their conduct;

**be able to:**

- collect pharmacological and allergological anamnesis and make an adequate choice of medicines, taking into account the peculiarities of their pharmacokinetics and pharmacodynamics for the treatment of a particular patient;
- inform patients about the nature of the action of the medicines prescribed to them, the rules of admission and possible manifestations of side effects;
- to correct the dosage regimen in case of pathological changes in the functions of organs and systems responsible for biotransformation and elimination of medicinal products, as well as in the combined use of medicines;
- evaluate scientific information on the effectiveness of medicines and other means, work with reference and other literature on medicines;

**possess:**

- the ability and willingness to analyze the features of absorption, distribution, biotransformation and excretion of drugs;
- the ability and willingness to rationally dose the drug, including the choice of dosage form, routes of administration and dosage regimen;
- skills in the use of medicines in the treatment, rehabilitation and prevention of various diseases and pathological conditions, taking into account the basic pharmacodynamic parameters;
- skills of searching, analyzing and summarizing information about the use and effect of various medicines.

**Motivation for mastering the topic:**

The specifics of the training of doctors in this specialty determines the need for students to purposefully study knowledge about the content of clinical pharmacology, the basics of clinical pharmacokinetics and pharmacodynamics, the basic concepts of clinical formulation and documents regulating the rules of prescribing.

## **MATERIAL EQUIPMENT**

Reference and informational literature, charts, tables, presentations, drug collections.

## **CONTROL QUESTIONS FROM RELATED DISCIPLINES**

- **from biochemistry and physiology:** physical properties and structure of cell membranes, transport of substances through biological membranes in norm and pathology;
- **from general and bioorganic chemistry:** fundamentals of chemical kinetics and catalysis, buffer solutions and systems, pH calculation;

- **from biochemistry:** kinetics of enzymatic reactions, the Michaelis-Menten kinetics equation, the concept of enzyme inhibitors, types of enzyme inhibitors;
- **from the Latin language:** the basic rules for the coordination of parts of speech and registration of prescription prescriptions when prescribing medicines;
- **from pharmacology:** general issues of pharmacology, pharmacokinetics and pharmacodynamics of drugs, general formulation and rules for prescribing drugs;
- **from immunology:** organs, cells, molecules of the immune system, allergy, hypersensitivity, features of the immune system in patients of different age categories;
- **from pediatrics:** physiological features of childhood, especially pathological conditions and diseases in children;
- **from obstetrics and gynecology:** physiology and pathology of pregnancy and lactation period.

## CONTROL QUESTIONS ON THE TOPIC OF THE CLASS

1. Goals and objectives of the academic discipline "Clinical pharmacology", the main stages of the development of clinical pharmacology, the relationship with other natural science and special academic disciplines. Clinical pharmacology as the basis of rational pharmacotherapy. Basic principles of evidence-based medicine.
2. The nomenclature of medicines (international nonproprietary and trade names). Principles of drug development. Original and generic medicines.
3. The purpose, objectives and methods of clinical trials of medicines. Medical, methodological and ethical aspects of clinical trials. Ethics Committee, its role and tasks. Types and phases of clinical trials.
4. Biological and therapeutic equivalence of medicines. Principles of bioequivalence research of generic medicines. State registration of medicines. The main provisions of evidence-based medicine.
5. Prescription and over-the-counter medicines. The procedure for issuing a doctor's prescription for medicines sold in a pharmacy at full cost, for narcotic and psychotropic substances, for medicines on preferential terms, including free of charge.
6. Clinical pharmacokinetics. Ways of administration of medicines, their characteristics. Distribution of medicines in the human body. The metabolism of drugs. The main pharmacokinetic parameters. Bioavailability of medicines. Factors affecting the pharmacokinetics of drugs. Features of pharmacokinetics of drugs with prolonged use. Clinical pharmacodynamics and evaluation of its main parameters. The dose-effect relationship. The relationship between pharmacokinetics and pharmacodynamics.
7. Combined use of medicines. Types of medicinal interactions. Polypragmasy.
8. Features of pharmacokinetics and pharmacodynamics of drugs in elderly patients, women during pregnancy and lactation, patients with liver and kidney diseases.
9. Adverse adverse reactions to medications. Classification of side effects of medicines. Local manifestations of undesirable effects of drugs in systemic use. Undesirable systemic effects of drugs with local administration.
10. Identification, registration and prevention of undesirable (side) reactions. Notification of a suspected adverse reaction to a drug. Informing patients about possible manifestations of undesirable (side) reactions to medicines.

## PROCESS OF THE STUDY

### **Theoretical part**

Answers to theoretical questions on the topic of the lesson are presented on pages 7-45 of the following training manual:

Курс лекций по клинической фармакологии: пособие для студентов 6 курса лечеб. фак. / М. Р. Конорев [и др.]; М-во здравоохранения Республики Беларусь, УО "Витебский гос. ордена Дружбы народов мед. ун-т", Каф. общ. и клин. фармакологии с курсом ФПК и ПК; под ред. М. Р. Конорева. - Витебск: ВГМУ, 2020. - 381 с. – Режим доступа: <https://elib.vsmu.by/handle/123/22910> – Дата доступа: 03.05.2021.

### **The practical part**

- 1) Take notes of the theoretical material demonstrated by the teacher;
- 2) Master the methodology of solving problems and prescribing prescriptions on the topic of the lesson.

### **Monitoring the assimilation of the topic**

It is carried out in the form of independent written work (solving practical problems and prescribing prescriptions for an individual task).

## **METHODOLOGICAL RECOMMENDATIONS FOR ORGANIZATION AND EXECUTION OF STUDENTS' INDEPENDENT WORK (SIW)**

### **The time given for independent work can be used by students for:**

- preparing for the practical classes;
- completing the tasks on the topic of the class in the workbook;
- preparing thematic reports, essays and presentations;
- taking notes from academic literature.

### **The main methods of organizing independent work:**

- completing tests and practical tasks of the electronic educational-methodical complex (EEMC) for self-monitoring and self-assessment.

### **The list of tasks of the SIW:**

- solving practical problems in the EEMC;
- completing the test tasks of the EEMC;
- writing an educational medical history.

### **Control of the SIW is carried out in the form of:**

- assessment of an oral answer to a question, report, report, or solution of a task in a practical class;
- individual conversation;
- checking the educational history of the disease.

## **METHODOLOGICAL RECOMMENDATIONS FOR ORGANIZATION AND EXECUTION OF CONTROLLED INDEPENDENT WORK OF STUDENTS (CIWS)**

### **Recommended forms of CIWS organization:**

- doing exercises on the topic of the class in the workbook;
- writing an essay on a given topic;

- preparing a report and a multimedia presentation on a given topic.

### **The list of tasks of the CIWS:**

Topics of essays / multimedia presentations:

1. New directions in pharmacology – chronopharmacology, pharmacogenetics, pharmacovaleology.

### **Forms of control of CIWS realization:**

- checking the educational history of the disease;
- review and evaluation of the abstract on a given topic;
- checking and evaluating a multimedia presentation on a given topic.

## **LIST OF REFERENCES**

1. Клиническая фармакология: учебник для студентов учреждений высш. проф. образования, обучающихся по специальностям "Лечеб. дело", "Педиатрия", "Фармация" / под ред. В.Г. Кукеса, Д.А. Сычева. - 6-е изд., испр. и доп. - Москва: ГЭОТАР-Медиа, 2021. - 1017 с.: ил., табл. - Рек. ГБОУ ВПО "Первый Моск. гос. мед. ун-т им. И. М. Сеченова". – Режим доступа:

<http://www.studmedlib.ru/book/ISBN9785970458815.html> – Дата доступа: 03.05.2021.

2. Курс лекций по клинической фармакологии: пособие для студентов 6 курса лечеб. фак. / М. Р. Конорев [и др.]; М-во здравоохранения Республики Беларусь, УО "Витебский гос. ордена Дружбы народов мед. ун-т", Каф. общ. и клин. фармакологии с курсом ФПК и ПК; под ред. М. Р. Конорева. - Витебск: ВГМУ, 2020. - 381 с. – Режим доступа: <https://elib.vsmu.by/handle/123/22910> – Дата доступа: 03.05.2021.

3. Аляутдин, Р. Н. Фармакология. Ultra-light: учебное пособие / Р. Н. Аляутдин. - 2-е изд., испр. и доп. - Москва: ГЭОТАР-Медиа, 2020. - 592 с. – Режим доступа: <http://www.studmedlib.ru/book/ISBN9785970457047.html> – Дата доступа: 03.05.2021.

4. Кукес, В. Г. Клиническая фармакология и фармакотерапия : учебник / под ред. В. Г. Кукеса, А. К. Стародубцева, Е. В. Ших. - 4-е изд. ,перераб. и доп. - Москва : ГЭОТАР-Медиа, 2020. - 880 с. – Режим доступа: <http://www.studmedlib.ru/book/ISBN9785970452790.html> – Дата доступа: 03.05.2021.

5. Инструкция о порядке выписки рецепта врача: постановление Министерства здравоохранения Республики Беларусь от 31.10.2007 №99 с изм. и доп. в постановлении Министерства здравоохранения Республики Беларусь от 27.12.2006 г. № 120; 17.06.2019 г. №60 – Режим доступа:

[https://pravo.by/upload/docs/op/W21934489\\_1566594000.pdf](https://pravo.by/upload/docs/op/W21934489_1566594000.pdf) – Дата доступа: 03.05.2021.

6. Постановление Министерства здравоохранения Республики Беларусь от 17 июня 2019 г. № 60 "Об изменении постановления Министерства здравоохранения Республики Беларусь от 31 октября 2007 г. № 99 – Режим доступа: [https://pravo.by/upload/docs/op/W21934489\\_1566594000.pdf](https://pravo.by/upload/docs/op/W21934489_1566594000.pdf) – Дата доступа: 12.05.2022.