

MINISTRY OF EDUCATION AND SCIENCE OF UKRAINE  
Petro Mohyla Black Sea National University  
Medical institute

Department of pharmacy, pharmacology, medical, bioorganic and biological chemistry



Course Discription

**Side effects of drugs**

field of knowledge 22 «Health care»  
in the specialty 222 «Medicine»

Developers

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### 1. Description of the educational discipline (annotation)

Title of indices	Characterization of educational discipline	
Name of the discipline	Side effects of drugs	
Branch of knowledge	22 "Health care"	
Specialty	222 "Medicine"	
Specialization (if any)		
Educational program	Medicine	
Higher education level	Master	
Discipline status	Normative	
Curriculum	3rd	
Academic year	2020-2021	
Numbers of semesters:	Day form	Absentee form
	6 <sup>th</sup> ,	-
Total ECTS credits / hours	3 credits /90 hours	
Course structure: lectures seminars (practical, laboratory, semi-group) hours of independent work of students	Day form	Absentee form
	10 hours	
	10 hours 70 hours	-
Percentage of classroom load	22%	
Teaching language	English	
Intermediate control form (if any)	-	
Form of final control	6 <sup>th</sup> semester – differential control	

Side effects of drugs is a discipline that studies the side effects of drugs on humans and animals. Information about the side effects of drugs is a necessary component of the future doctor qualification. "Side effects of drugs" is a normative discipline.

**Program of study of educational discipline** "Side effects of drugs" is made in accordance with the educational program "Medicine", field of knowledge 22 "Health care", specialty 222 "Medicine". The subject of study of the discipline "Side effects of drugs" are the side effects of drugs of different pharmacotherapeutic groups and safety issues of their use.

**Interdisciplinary links:** side effects of drugs as a discipline: a) based on knowledge of pharmacology, internal medicine, biology, anatomy and normal physiology, pathophysiology, organic and bioorganic chemistry, microbiology b) provides a high level of medical and biological training; c) lays the foundation for students of studying clinical pharmacology, internal medicine and specialized disciplines (neurology, gynecology, etc.) provides the integration of teaching with these disciplines; forms the ability to apply the acquired knowledge of the safe use of drugs in the process of further training and in professional activities; lays the foundation of professionally oriented thinking, healthy lifestyle and prevention of disorders of the body in the process of human life.

## 2. THE PURPOSE OF ACADEMIC DISCIPLINE

The purpose of study of the course at the option (elective course) "Side effects of drugs" – the *final goals* - are established on the basis of standards of training doctors in specialty according to the block of its subject module and is the basis for construction of the content of academic discipline. Definition of objectives is formulated through the skills as the target tasks (actions).

The *specific goals* for module are formulated on the basis of the final goals of the module in the form of certain skills (actions), target tasks that provide the achievement of the final goal of the discipline studying.

The purpose of study of the course at the option (elective course) "Side effects of drugs" includes the definition, classifications of side effects of drugs and their prevention during drug administration.

**Competencies and learning** outcomes the formation of which is facilitated by the discipline (the relationship with the normative content of higher education, formulated in terms of the results of the educational program "Medicine"). The discipline provides students with the acquisition of competencies:

### **Integral:**

Ability to solve typical and complex specialized problems and practical problems in a professional health care activity, or in a learning process that involves research and / or innovation and is characterized by the complexity and uncertainty of conditions and requirements.

**General** (corresponds to the general competencies of EP "Medicine" GC 1-5, 7-9):

- Ability to abstract thinking, analysis and synthesis, the ability to learn and master modern knowledge.
- Ability to apply knowledge in practical situations.
- Knowledge and understanding of the subject area and understanding of professional activity.
- Ability to adapt and act in a new situation.
- Ability to make informed decisions; work in a team; interpersonal skills.
- Information and communication technology skills.
- Definiteness and perseverance in terms of tasks and responsibilities.
- Ability to act on the basis of ethical considerations (motives).

**Special (professional, subject)** (corresponds to the professional competencies of EP "Medicine" PC 2, 5, 6, 8, 12, 13, 18):

- Ability to determine the required list of laboratory and instrumental studies and evaluate their results.

- Ability to determine the nature of nutrition in the treatment of diseases.
- Ability to determine the principles and nature of disease treatment.
- Ability to determine tactics for providing emergency medical care.
- Ability to determine the tactics of physiological pregnancy, physiological childbirth and the postpartum period.
- Family planning and contraceptive counseling skills.
- Ability to keep medical records.

As a result of studying the discipline the student must:

***know:***

- general issues of complications of pharmacotherapy and the main measures of the organization of control over the safety of medicines, which are carried out in Ukraine;
- basic terminology (definitions), which characterizes the side effects of drugs;
- the main risk factors for side effects of drugs;
- classification of adverse drug reactions and give them a general description;
- the concept of "breadth of therapeutic action" and "therapeutic index";
- phenomena that occur with repeated and combined administration of drugs
- characteristics of typical adverse reactions and the mechanism of their occurrence for drugs that affect the afferent nervous system, anti-inflammatory and anti-allergic drugs, pain correctors, drugs that affect the cardiovascular, respiratory, digestive, excretory systems, metabolism, chemotherapeutic drugs and methods of their prevention and correction;
- pharmacological logic of the relationship between the mechanism of action of drugs and side effects and contraindications to the use of drugs of different groups; factors that contribute to the side effects of drugs and reduce their manifestations in the above pharmacological groups;
- rules of rational antibiotic therapy in order to prevent side effects and the development of antibiotic resistance.

***be able to:***

- To define the classifications of side effects of medicinal agents.
- To generalize and analyze the possible symptoms of side effects of medicinal agents and define the ways and means for prevention of negative (adverse) effects of medicinal agents.
- To make the inference about the possibility of appearance of side effects of medicinal agents in patients with different diseases, analyze their possible manifestation with the purpose of negative effects prevention.
- To assess the correlation risk/ benefit of adverse effect appearance during drug administration in different age groups of patients.
- To generalize and analyze the classification of side effects of drugs.
- To generalize and analyze the main ways of prevention of side effects of drugs of different pharmacological groups.
- To generalize and analyze the main ways of pharmacological correction of side effects of drugs of different pharmacological groups.
- To assess the correlation risk/ benefit of adverse effect appearance during drug administration in different age groups of patients.
- To assess the correlation risk/ benefit of adverse effect appearance during drug administration in patients with concomitant diseases of the liver, kidneys, blood etc.

### 3. Program of the discipline

SUBJECT	Hours			
	Day form			
	Total	including		
Lectures		Practical classes	ISW	
1	2	3	4	5
<b>Topic 1.</b> General principles of pharmacotoxicodynamics. Classification of adverse drug reactions. Factors influencing their development.	6	2	-	4
<b>Topic 2.</b> The system of pharmacovigilance of side effects of drugs in Ukraine and the world. Methods of detecting and obtaining information about side effects. Pharmacovigilance by doctors.	6	2	2	2
<b>Topic 3.</b> Principled approaches to evaluating the effectiveness and safety of pharmacotherapy. Modern principles of evidence-based medicine.	6	2	-	4
<b>Topic 4.</b> Side effects of drugs affecting the autonomic nervous system. Methods of preventing the side effects of these drugs	6	-	-	6
<b>Topic 5.</b> Methods used to prevent side effects of drugs. Side effects of drugs used for local and general anaesthesia.	6	-	-	6
<b>Topic 6.</b> Side effects of drugs administered for the treatment of diseases of the central nervous system: sleep disturbances, vegetative neurosis, neurasthenia, schizophrenia, parkinson's disease. Methods of preventing the side effects of these drugs.	6	-	2	4
<b>Topic 7.</b> Side effects of narcotic analgesics and non-steroidal anti-inflammatory drugs. Side Effects of Hormonal Preparations. Methods of preventing the side effects of these pharmacological groups.	6	-	-	6
<b>Topic 8.</b> Side effects of drugs affecting the respiratory system. Methods of preventing the side effects of these drugs	6	-	2	4
<b>Topic 9.</b> Side effects of the drugs used for gastrointestinal diseases. Methods of preventing the side effects of these drugs.	6	-	-	6
<b>Topic 10.</b> Adverse effects of drugs used for cardio-vascular diseases: arterial hypertension, stable and unstable stenocardia, arrhythmias, acute and chronic heart failure, hyperlipidemias.	6	-	2	4

Methods of preventing the side effects of these drugs.				
<b>Topic 11.</b> Side effects of drugs that affect kidney function and myometrium	6	-	-	6
<b>Topic 12.</b> Side effects of drugs affecting blood. Methods of preventing the side effects of these drugs.	6	-	-	6
<b>Topic 13.</b> Chemotherapeutic agents: basic principles of pharmacotherapy and its complications.	6	2	1	3
<b>Topic 14.</b> Side Effects of Antibiotics and Antiviral Drugs. Methods of preventing the side effects of these drugs.	6	-	1	5
<b>Topic 15.</b> Adverse reactions that occur in different age groups and in using drugs in different trimesters of pregnancy.	6	2	-	4
<b>Total</b>	90	10	10	70

#### 4.1 Lecture topics

№	Name of topic	Hours
1	<p><b>General principles of pharmacotoxicodynamics. Classification of adverse drug reactions. Factors influencing their development.</b></p> <ol style="list-style-type: none"> <li>1. Fundamentals of Ukrainian legislation on medicines.</li> <li>2. Classification and mechanisms of side effects of drugs.</li> <li>3. Clinical manifestations of typical side effects inherent in certain pharmacological groups of drugs.</li> <li>4. Basic measures to prevent side effects.</li> <li>5. Differential approach and propaganda of harm of self-medication.</li> <li>6. FDA Safety Categories.</li> </ol>	2
2	<p><b>The system of pharmacovigilance of side effects of drugs in Ukraine and the world. Methods of detecting and obtaining information about side effects. Pharmacovigilance by doctors.</b></p> <ol style="list-style-type: none"> <li>1. Law of Ukraine "On Medicines".</li> <li>2. The procedure for pharmacovigilance in Ukraine and the region according to the order of the Ministry of Health of Ukraine dated December 27, 2006 № 898 (as amended by the order of the Ministry of Health of Ukraine dated September 26, 2016 № 996).</li> </ol>	2
3	<p><b>Principled approaches to evaluating the effectiveness and safety of pharmacotherapy. Modern principles of evidence-based medicine.</b></p> <ol style="list-style-type: none"> <li>1. Principles of evidence-based medicine.</li> <li>2. Sources of evidentiary information on the effectiveness and safety of medicines, technology of search, analysis and generalization of scientific and medical information from the standpoint of evidence-based medicine.</li> <li>3. Practical implementation of the principles of evidence-based medicine in the health care system.</li> </ol>	2
4	<p><b>Chemotherapeutic agents: basic principles of pharmacotherapy and its complications.</b></p> <ol style="list-style-type: none"> <li>1. Basic principles of application and criteria for evaluating the</li> </ol>	2

	<p>effectiveness of chemotherapeutic drugs.</p> <ol style="list-style-type: none"> <li>2. Mechanisms of side effects of different groups of antibiotics.</li> <li>3. Main and reserve antibiotics.</li> <li>4. Features of action of penicillins, cephalosporins, macrolides, tetracyclines.</li> <li>5. Complications of antibiotic therapy, their prevention and treatment. The problem of safety of drug therapy.</li> <li>6. Side effects of synthetic chemotherapeutic agents (quinolones, fluoroquinolones, nitrofurans).</li> </ol>	
5	<p><b>Adverse reactions that occur in different age groups and in using drugs in different trimesters of pregnancy.</b></p> <ol style="list-style-type: none"> <li>1. Principles of a reasonable approach to the rational choice of drugs for the treatment of children of different ages and the elderly, as well as pregnant and breastfeeding women.</li> <li>2. The method of objective safety control of the use of drugs in these categories.</li> </ol>	2
<b>Total lecture hours for course</b>		<b>10</b>

#### 4.2. Topics of practical classes

№	Name of topic	Hours
1	<p><b>The system of pharmacovigilance of side effects of drugs in Ukraine and the world. Methods of detecting and obtaining information about side effects. Pharmacovigilance by doctors.</b></p> <ol style="list-style-type: none"> <li>1. Law of Ukraine "On Medicines".</li> <li>2. The procedure for pharmacovigilance in Ukraine and the region according to the order of the Ministry of Health of Ukraine dated December 27, 2006 № 898 (as amended by the order of the Ministry of Health of Ukraine dated September 26, 2016 № 996).</li> <li>3. Analysis of the safety of drugs for the correction of pathological conditions of different genesis. Acquisition of skills of statement and analysis of the card-report on side effects of drugs (form 137 / o).</li> </ol>	2
2	<p><b>Side effects of drugs administered for the treatment of diseases of the central nervous system: sleep disturbances, vegetative neurosis, neurasthenia, schizophrenia, parkinson's disease. Methods of preventing the side effects of these drugs.</b></p> <ol style="list-style-type: none"> <li>1. Side effects of neuroleptics (effects on dopaminergic and adrenergic processes in the CNS).</li> <li>2. Side effects of tranquilizers, the possibility of drug dependence.</li> <li>3. The effect of sedatives on the CNS, side effects. Side effects of lithium salts.</li> <li>4. Side effects of tricyclic antidepressants and MAO inhibitors. Characteristics of the psychostimulant effect and the effect on the cardiovascular system of caffeine, meridian and synocarb, side effects, the possibility of drug dependence.</li> <li>5. The effect of nootropic drugs on metabolic processes in the CNS. Rules for taking adaptogens. The question of the side effects of adaptogens.</li> </ol>	2
3	<p><b>Side effects of drugs affecting the respiratory system. Methods of preventing the side effects of these drugs</b></p> <ol style="list-style-type: none"> <li>1. Classification and main mechanisms of side effects of respiratory stimulants from the groups of analeptics and H-</li> </ol>	2

	<p>choliometrics.</p> <p>2. Antitussives of central and peripheral action. The possibility of developing drug dependence on substances of central action.</p> <p>3. Broncholytics. Side effect.</p> <p>4. Side effects of drugs used in the treatment of pulmonary edema, ethyl alcohol.</p>	
4	<p><b>Adverse effects of drugs used for cardio-vascular diseases: arterial hypertension, stable and unstable stenocardia, arrhythmias, acute and chronic heart failure, hyperlipidemias. Methods of preventing the side effects of these drugs.</b></p> <p>1. The principle of application of antihypertensive drugs in diseases that are accompanied by hypertension. Side effects.</p> <p>2. Features of side effects of beta-blockers, calcium channel blockers. Side effects of drugs used in blockades of the conduction system of the heart (beta-blockers, M-cholinoblockers).</p> <p>3. Side effects of cardiotoxic drugs - strophanthin, corglycone, digoxin, digitoxin, mustard herb infusion.</p> <p>4. Acute and chronic poisoning by cardiac glycosides. Relief measures and prevention.</p>	2
5	<p><b>Chemotherapeutic agents: basic principles of pharmacotherapy and its complications. Side Effects of Antibiotics and Antiviral Drugs. Methods of preventing the side effects of these drugs.</b></p> <p>1. Basic principles of application and criteria for evaluating the effectiveness of chemotherapeutic drugs.</p> <p>2. Side effects of synthetic chemotherapeutic agents (quinolones, fluoroquinolones, nitrofurans).</p> <p>3. Side effects that occur with long-term use - derivatives of isonicotinic acid hydrazide (isoniazid), rifampicin, antibiotics (streptomycin sulfate, kanamycin, cycloserine, amikacin) - and ways to prevent them.</p> <p>4. Side effects of antiviral drugs.</p> <p>5. Side effects of antisyphilitic drugs.</p>	2
<b>Total hours of practical classes</b>		<b>10</b>

#### 4.3. Individual work

№	Name of topic	Number of hours	Type of control
1.	Preparation for practical classes - theoretical training and development of practical skills	<b>16</b>	Current control on practical classes
2.	Independent elaboration of topics that are not included in the lesson plan:	<b>24</b>	Final control
	<b>Total</b>	<b>40</b>	



## SITUATIONAL TASKS

1. The patient, 28 years old, complains of joint pain for 6 months. Diagnosis: rheumatoid arthritis, a / f III, 3rd clinical and radiological stage, NFS II. Treatment: chrysanol, prednisolone, movalis. On the 5th day, the patient had a white plaque on the mucous membrane of the oral cavity, redness of the eye, mucus, hyperemic rash on the skin. What complication did the patient have? What drug caused this complication? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

2. A 56-year-old patient with a diagnosis of hypertension, stage II was prescribed the following treatment: amlodipine, hypothiazide, metoprolol, apressin. On the third day developed general weakness, pain in the heart, sweating, mucous membranes, erythematous rash, fever. What complication did the patient have? What drug caused this complication? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

3. A 10-year-old boy with adenoviral disease was prescribed the following drugs: acetylsalicylic acid, suprastin, ascorbic acid. After 2 days vomiting, inappropriate behavior, movement disorders, petechial rash on the torso have appeared. What complication did the patient have? Which drug caused this side effect? Fill in the card-report on side effects of drugs (form 137 / o).

4. A 67-year-old patient diagnosed with coronary heart disease: diffuse cardiosclerosis, NK II A. Atrial fibrillation, tachysystolic form. Digoxin (IV 1 ml ) was prescribed in the hospital, he took digoxin 0.25 / 3 times a day at home, mildronate, nitrosorbitol, asparkam , hypothiazide. On the 3rd day of treatment there was nausea, vomiting, photophobia, ventricular arrhythmia. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

5.. Patient, 56 years old with a diagnosis of coronary heart disease: angina pectoris III-FC, diffuse cardiosclerosis, NK I art. Paroxysmal ventricular tachycardia. Treatment: susak-forte, amlodipine, mildronate, amiodarone. On the 3rd day there was hyperpigmentation on exposed areas of the skin, pigment deposits in the cornea of the eye, increased sweating and agitation, tachycardia, tremors at the end of the eye. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

6. A 48-year-old patient with a diagnosis of coronary heart disease: stable angina pectoris, III-FC, diffuse cardiosclerosis, NC II-B was prescribed treatment: anaprilin, nitrong, mildronate, amlodipine, multivitamins. On fifth day of treatment the patient had paresthesias in the legs, on the ECG - atrioventricular block of the first degree, heart rate - 45 beats / min. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

7. A 32-year-old patient with a diagnosis of exacerbation of chronic pyelonephritis, was prescribed a treatment: gentamicin, palin, trental, multivitamins. After 7 days general weakness, decreased hearing, skin rash, increased edema have developed in patient. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

8. A 48-year-old patient with acute bronchitis was prescribed treatment: biseptol, lasolvan, multivitamins, thermopsis. After 10 hours, the patient had a bright red roseola rash, itchy skin, nausea, and headache. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

9. A 25-year-old patient with a diagnosis of hypertension stage 2 took bisoprolol, amlodipine, hypothiazide, verospirone. On the 10th day from the beginning of the prescribed treatment, nausea, drowsiness, ataxia, each rash, gynecomastia have developed in patient. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-

report on side effects of drugs (form 137 / o).

10. A 18-year-old patient with lacunar sore throat took amoxicillin, multivitamins. rinsed the mouth with chlorophyll. On the 4th day there was a rash of roseolus character on the face, torso, itchy skin, headache, nausea. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

11. A 35-year-old patient with a diagnosis of chronic acalculous cholecystitis with hypokinetic movement disorder in the acute stage, took furadonin, motilium, hepabene, duspatalin.

On the 5th day of treatment there were symptoms of cholestasis, itchy skin, icteric sclera, jaundice, dark urine. Serum content of cholesterol, bilirubin, alkaline phosphatase were increased. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

12. A 17-year-old patient diagnosed with hepatolenticular degeneration (Wilson-Konovalov disease) receive sirepar, namacit, alvetil, triovit, D-penicillamine. During treatment ulcerative-necrotic changes in the tonsils, periodic hemorrhages from the nose, gums, pale skin and mucous membranes have developed in patient. In the blood test anemia, thrombocytopenia, leukopenia. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

13. A 52-year-old patient with nonspecific ulcerative colitis in the acute stag and severe course receives sulfosalazine, prednisolone, loperamide, albumin. After 2 weeks erythema on the face in the form of a butterfly, arthralgia, papular-ulcerative rash on the skin and mucous membranes, ESR 50 mm. per hour have developed in patient. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

14. Patient, 62 years old, is suffering from gastroesophageal reflux disease stage I-II with hyperemia of the mucous membrane of the esophagus. He takes motilium, ranitidine, almagel. On seventh day of treatment, constipation has developed in patient. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

15. A 60-year-old patient with severe bilateral nosocomial pneumonia on the background of atherosclerotic cardiosclerosis and stage II CH was prescribed gentamicin, sulbactam, amizon, acetylcysteine, licorice root syrup, multivitamins. On the 5th day of treatment, there was bitterness in the mouth, hypersalivation, mild swelling of the oral mucosa. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

16. A 68-year-old patient is being treated for venous occlusive disease with thrombophlebitis. Receives fraxiparin, diovenor, naclofen, aloe. On the 10th day of treatment there was pain in the epigastric region. Endoscopic examination revealed gastric ulcer. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

17. A 43-year-old patient receives treatment for osteoarthritis: movalis, chondroitin sulfate, actovegin, nicotinic acid. Ten years ago he had duodenal ulcer. Black stools appeared in the second week of continuous treatment. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

18. A 40-year-old patient with type I diabetes mellitus was complicated by the development of diabetic foot with purulent tissue melting. Staphylococcus is sown. Gets saline solutions, duovit, insulin, thiene, creon. On the 7th day of treatment, liquid stools up to 5 times a day, bloating, rumbling appeared. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

19. The patient, 56 years old, has been suffering from gallstone disease for 3 years. After stress, there was an attack of hepatic colic. Prescribed treatment: baralgin, papavarin, platyphylline, morphine, atropine sulfate. The patient notes an increase of pain. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

20. A 30-year-old patient with a diagnosis of community-acquired right-sided pneumonia. Treatment is prescribed: cephalexin, diazoline, ascorbic acid, calcium gluconate. After 3 days vomiting, nausea, diarrhea have developed in patient. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug? Fill in the card-report on side effects of drugs (form 137 / o).

### EXAMPLE OF ANSWER TO A SITUATIONAL TASK

Patient, 30 years old with a diagnosis of bronchial asthma, severe form. Treatment: inhalation of beclomethasone and salbutamol, oral theophylline. After 3 days there was pain in swallowing, heartburn, salivation. Ulcers appeared on the oral mucosa. What complication did the patient have? Which drug caused this side effect? What other side effects are inherent in this drug?

Answer: The presence of pain in swallowing, heartburn, salivation and ulcers on the oral mucosa may indicate candidiasis of the oral cavity as a side effect of the drug from the group of inhaled glucocorticoids (beclomethasone). This group of drugs is also characterized by other side effects: cough, hoarseness, pink acne on the face, exacerbation of gastritis and gastric ulcer, and with prolonged use - systemic side effects (Itsenko-Cushing syndrome).

#### 4.4 Ensuring the educational process

##### Tools:

**Visual:** demonstration of multimedia materials, drug brochures according to the topic of practical training, collection of drugs.

**Practical:** analysis of the card-report on side effects of drugs (form 137 / o)

##### Software

The integration of the processes of planning, management and control of knowledge acquisition in “Side effects of drugs” is due to the methodological support of the educational process:

1. Work program on the discipline.
2. Working thematic plans of lectures, practical classes and individual work.
3. Methodical developments, abstracts (abstracts, presentations) of lectures.
4. Methodical instructions for students to practical classes.
5. Methodical instructions for independent work of students.
6. Instructional and methodical materials for current and final control of knowledge (bases of test tasks, list of tasks for control of practical skills and theoretical knowledge in practical classes and tickets to the exam).
7. Educational literature used in the study of the discipline.

### 5. FINAL CONTROL

#### Questions for self-preparation and control of the level of knowledge

1. Side effects (SE) of drugs. Types of side effects. The role of the State Pharmacological Center in monitoring of the side effects of drugs.
2. The main types of side effects of drugs. Principles of treatment of adverse drug reactions
3. AR, which are associated with pharmacological activity.
4. AR, which are associated with a violation of the immunological properties of the organism.
5. Allergic reactions.
6. AR associated with drug overdose.
7. Withdrawal syndrome. Robbery syndrome. Rebound syndrome. Drugs that cause these

complications.

8. Principled approaches to evaluating the effectiveness and safety of pharmacotherapy. The concept of polypragmatism.

9. Modern principles of evidence-based medicine. Formular system of Ukraine.

10. The effect of drugs on the fetus and baby

11. Mutagenicity, teratogenicity, embryotoxicity.

12. Factors and mechanism of carcinogenesis. Drugs that cause carcinogenesis.

13. Clinical manifestations of AR of drugs.

- hematotoxicity

- hepatotoxicity

- nephrotoxicity

- lung damage

- lesions of the cardiovascular system

- other side effects.

13. Principles of AR prevention.

14. Principles of assistance (treatment) in the event of AR.

15. The main provisions of the system of pharmacological supervision of the State Pharmaceutical Center of Ukraine for the control of SE / AR drugs (Form 137 / o).

16. Principles of pharmaceutical care of patients with complaints due to side effects on drugs.

17. Side effects of drugs used for local and general anesthesia.

18. Side effects of drugs that affect the autonomic nervous system.

19. Side effects of drugs that affect the central nervous system.

20. Side effects of narcotic analgesics and nonsteroidal anti-inflammatory drugs.

21. Side effects of steroidal anti-inflammatory drugs.

22. Side effects of drugs that affect the respiratory system.

23. Side effects of drugs used in gastroenterology

24. Side effects of drugs that affect kidney function and myometrium

25. Side effects of drugs used to treat diseases of the cardiovascular system.

26. Side effects of drugs that stimulate the function of the central nervous system.

27. Side effects of hepatoprotective drugs and probiotics.

28. Side effects of antibiotics.

29. Side effects of sulfonamides.

30. Side effects of synthetic chemotherapeutic drugs.

31. Side effects of antiviral drugs.

32. Side effect against syphilitic drugs.

33. Side effects of antitumor drugs.

34. Side effects of drugs in different age groups.

35. Side effects of drugs in different trimesters of pregnancy and in breastfeeding women.

## **LIST OF DRUGS FOR FINAL CONTROL**

Pay special attention to group affiliation, side effects, interaction and indications for the use of these drugs!

Hydrochloric acid

Epinephrine hydrochloride

Lidocaine hydrochloride

Atropine sulfate

Salbutamol

Propranolol (Anaprilin)

Metoprolol

Trimeperidine (Promedol)

Acetylsalicylic acid

Diclofenac sodium

Paracetamol

Phenobarbital

Hydrocortisone Acetate  
Piracetam  
Acidin-pepsin  
Acetylcysteine  
Biseptol  
Digoxin  
Digitoxin  
Dimedrol  
Astemizole  
Glycerol trinitrate (Nitroglycerin)  
Verapamil  
Aktiferrin  
Lisinopril  
Enalapril  
Allochol  
Atorvastatin  
Losartan  
Loperamide  
Alteplase  
Drotaverine  
Analgin  
Aluminum / magnesium hydrochloride (Almagel)  
Atenolol  
Metoprolol  
Furosemide  
Warfarin  
Apressin  
Budesonide  
Calcium gluconate  
Spironolactone (Verospiron)  
Clopidogrel  
Cyanocobalamin  
Voltaren  
Gastrolit  
Hypothiazide  
Gentamicin sulfate  
Levothyroxine  
Glutargin  
Delagil  
Glibenclamide  
Metformin  
Prednisolone  
Diprosan  
Aprotinin (Contrikal)  
Dichlothiazide  
Loratadine  
Duspatalin  
Enterogel  
Benzylpenicillin sodium salt  
Enterodes  
Ampicillin  
Enalapril  
Doxycycline

Euphyllin  
Jeanine  
Indometacin  
Inhacort  
Essentiale N  
Ciprofloxacin  
Intron A  
Fluconazole  
Ipratropium bromide  
Metronidazole  
Captopril  
Carbamazepine  
Ketoconazole  
Clarithromycin  
Clofeline  
Interferon alfa-2b  
Levomycetin  
Lisinopril  
Lipoic acid  
Maalox  
Motilium  
Nadolol  
Nimesulide  
Nifedipine  
Neodicumarine  
Norfloxacin  
Paroxetine  
Perindopril  
Ranitidine  
Rehydron  
Simvastatin  
Sorbex  
Sulfapyridazine  
Streptomycin sulfate  
Tardyferon  
Tetracycline hydrochloride  
Phenazepam  
Tienam  
Triamterene  
Triquilar  
Ferrum Lek  
Phencarol  
Fraxiparine  
Furadonin  
Furazolidone  
Ceftriaxone  
Hylak Forte

**Petro Mohyla Black Sea National University**  
**Medical institute**  
**Department of pharmacy, pharmacology, medical, bioorganic and biological chemistry**

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*Level of higher education: Master*

*Field of knowledge: 22 "Health"*

*Specialty: 222 "Medicine"*

*Discipline: "Side effects of drugs"*

**EXAMINATION QUESTION № 0**

**Explain the questions:**

1. Side effects of drugs. Types of side effects. The role of the State Pharmacological Center in monitoring the side effects of drugs (20 points).
2. Side effects of drugs that stimulate the function of the central nervous system (20 points)

**Practical skills:**

Patient A., 35 years old with a diagnosis of chronic acalculous cholecystitis with hypokinetic movement disorder in the acute stage, received motilium (10 mg orally 3 times a day, Janssen, Belgium), furadonine (100 mg orally 4 times a day, Olainpharm, Lithuania), hepabene (1 capsule orally 3 times a day, Merckle, Germany), platyphylline hydrochloride (0.2% solution of 1 ml intramuscularly 2 times a day, Darnytsia CJSC Ukraine, Kyiv). On the 5th day of treatment itchy skin, scleral jaundice, jaundice, dark urine appeared. Blood: an increase of cholesterol, bilirubin, alkaline phosphatase (40 points).

1. *What complication did the patient have?*
2. *Which drug caused this side effect?*
3. *Fill in the card-report on side effects of drugs (form 137 / o) on drug, which in your opinion could cause the specified complication of therapy.*
4. *What other side effects are inherent in this drug.*

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Approved at the meeting of the Department of Pharmacy, Pharmacology, Medical, Bioorganic and Biological Chemistry, protocol № 1 of September 2, 2020.

**Head of the Department**

\_\_\_\_\_ **Ogloblina M.V.**

**The teacher who carries out  
knowledge control**

\_\_\_\_\_ **Rybachuk Ye. Yu**

## 6. Evaluation criteria and tools for diagnosing learning outcomes

Forms of control and assessment system are carried out in accordance with the requirements of the discipline program and the Regulations on the system of assessment of educational activities of students of Petro Mohyla National University.

Grade for the discipline is defined as the sum of assessments of current educational activities (in points) and assessment of final control conducted during the test (in points), according to the lists defined by the discipline program.

**Current control** is carried out at each practical lesson in accordance with the specific objectives of each topic. The following means of diagnosing the level of preparation of students are used: tests, solving situational problems.

**The control of students' individual work**, which is provided in the topic along with the classroom work, is carried out during the current control of the topic in the relevant classroom. Topics that are submitted only for independent work and are not included in the topics of classroom classes are controlled during the final control (differential control).

**Maximum quantity of grades which a student may have equals 120 points.**

The student may be admitted to the final control (differential control), if he performed all types of work provided by the working curriculum, attended all classes - lectures, practical classes, defined by the calendar-thematic plan of the department, scored the total number of points in the discipline. less than the minimum (**70 points**).

### **Evaluation of current educational activities:**

Assessment of current learning activities is carried out at each practical lesson on the relevant topic. At mastering of each theme for current educational activity of the student estimations on a 24-point scale are exposed.

The maximum quantity of grades a student can score in studying of the discipline is 120 points, it is calculated by multiplying the number of points by the number of topics (24x5).

The minimum quantity of grades a student can score in studying of the discipline is calculated by multiplying the number of points by the number of topics and it is respectively 70 points (14x5).



### Assessment of student performance

№	Current control	Maximum grades
		Day form
1	Topic 1	24
2	Topic 2	24
3	Topic 3	24
4	Topic 4	24
5	Topic 5	24
<b>Total</b>		<b>120</b>
<b>FINAL CONTROL (differential control).</b>		<b>80</b>
<b>Total for subject:</b>		<b>200</b>

### Criteria for assessing knowledge on the practical classes

1. Student receives **24 points** if he:

- showed full knowledge of the program of the topic, gives comprehensive answers on questions asked by the teacher.

- Correctly fills in the card № 137/0 about side effects of medicines.

2. **18 points** a student receives if he:

- Knows the topic. gives correct, but not completely exhaustive answers to additional questions, gives answers with the help of the teacher.

- Makes mistakes in filling in the card № 137/0 about side effects of medicines.

3. A student receives **14 points** if he:

- Answers questions only with the help of a teacher, not always correctly oriented in matters of the mechanism of action of drugs.

- Fills in the card № 137/0 about side effects of medicines with significant mistakes.

4. **0 points** receives a student who:

- Does not answer all questions, even with the help of a teacher.

- Does not answer additional questions. The answer can be assessed as "unsatisfactory".

- Does not fill in the card 137/0 about side effects of medicines.

- Has a missed practical class.

If the student does not receive admission to the final control due to insufficient average score of current performance, the head of the department with the permission of the dean's office has the right to conduct comprehensive testing on all topics of which the student has unsatisfactory grades. If the student receives satisfactory scores on the test results, the student is considered to have improved the result of the current performance to the minimum score (70 points) and may be admitted to the final control of the discipline. The test results are evaluated as:

"Made" 70% or more of the correct answers;

"Failed" 68% or less correct answers.

The final control of the discipline consists of assessing the acquisition of practical skills and theoretical knowledge of all topics of the discipline.

The main forms of control of the discipline are theoretical questions and solutions of situational tasks by filling in the card 137 / o.

Criteria for assessing knowledge:

- theoretical questions - 25-40 points;

- situational task - 25-40 points.

The minimum quantity of grades of the final control is 50 points, the maximum quantity of grades is 80 points.

**71-80 (A) points:** the student knows the program, the answers are with various examples; gives comprehensively accurate and clear answers without any leading questions; freely solves problems and performs practical tasks; fully mastered practical skills.

**65-70 (B, C) points:** the student knows the whole program and understands it well, answers the questions correctly, consistently and systematically, but they are not exhaustive, although the student answers additional questions without mistakes; solves all problems and performs practical tasks.

**50-64 (D, E) points:** the student has the basis of knowledge of the entire volume of the program and has a satisfactory level of understanding. The student is able to solve modified problems with the help of leading questions; solves problems and performs practical skills, experiencing difficulties in simple cases.

**in case of lack of mastering - "0" points.**

**The grade of the discipline is the sum of points for the current educational activity and final control (differential test) in points from min - 120 to max - 200.**

## **7. Recommended sources of information**

### **7.1. Main:**

1. Pharmacology – Cito! : Textbook // Edited by S.M. Drogovoz. - Kharkiv, 2010. – 192 p.
2. Pharmacology at your palms: reference book / Drogovoz S.M., Kutsenko T.A. – Kharkiv: NphaU, 2010. – 80 p.
3. Adverse Drug Reactions / Edited by Anne Lee, 2/e: Pharmaceutical Press, 2006. – 474 p. 12/e: San-Francisco, California, The McGraw-Hill Companies, 2011.– 1228 p.
4. Bremner J. D. Before You Take that Pill: Why the Drug Industry May Be Bad for Your Health: PenguinGroup US. - 2008, 448 p.
5. Chekman I.S Pharmacology: Textbook / Chekman I.S., Gorchakova N.O., Panasenko N.I., Bekh P.O.– Vinnytsya: NOVA KNYHA Publishers, 2006. – 384 p.
6. Dipiro J., Tabrt Talbert R.L. Pharmacotherapy: A Pathophysiologic Approach: Textbook, 8/e, McGraw Hill Professional, 2011 - 2700 p.
7. Finkel R., Cubeddu L.X., Clark M.A. Pharmacology, 4/e: Lippincott Williams & Wilkins, 2009 – 564 p.
8. Goodman and Gilman’s The Pharmacological Basis of Therapeutics / edited by Brunton L.L., Lazo J.S., Parker K.L., 11/e: New York McGraw Hill .- 2006. – 1984 p.
9. Meyler's Side Effects of Analgesics and Anti-inflammatory Drugs / edited by Aronson J.K., 15/e: Elsevier. - 2009.- 570 p.

10. Meyler's Side Effects of Herbal Medicines / edited by Aronson J.K., 15/e: Elsevier.- 2009.- 303 p.

## 7.2. Additional:

1. Pharmacology You See: a High Yield Pharmacology Review for Health Professionals / Browne A.W., Dugani S., Hutson J.R., Mcheffry G.G., Stefater M.A. / McGraw – Hill Medical, 2011. – 160 p.
2. Psychotropic drug handbook / Paul J. Perry, Bruce Alexander, Barry I. Liskow, C. Lindsay DeVane, 8/e: Lippincott Williams & Wilkins.– 2006.– 719 p.
3. Physician's Drug Handbook, by Harold.– 12th Edition – Lippincott Williams & Wilkins.- 2007.– 1424 p.
4. Psychotropic drug handbook / Paul J. Perry, Bruce Alexander, Barry I. Liskow, C. Lindsay DeVane, 8/e: Lippincott Williams & Wilkins.– 2006.– 719 p.
5. Samura I.B. A University Course in Pharmacology / Samura I.B., Nerianov Y.M., I.F. Belenichev, Samura B.B., Nerush A.V. – Recommended by CMK MH Ukraine N23-01-25/276, Kyiv, 2011 - 370 p.
6. Side Effects of Drugs Annual / edited by Aronson J.K., 33/e: Elsevier.- 2012. – 1160 p.
7. Tripathi K.D. Essentials of Medical Pharmacology, 6/ e: Jaypee Brothers Medical Publishers LTD, New Delhi.– 2008.–925 p.
8. Katzung B.G. Basic and Clinical Pharmacology, 9th edition. – New-York: Lange, 2004. – 1202 p.
9. Laurence D.R., Bennet P.N., Brown M.G. Clinical Pharmacology, 8th edition. – London: Churchill Livingstone Elsevier, 1998. –710 p.
10. Lippincott's Illustrated Reviews: Pharmacology, 4th Edition / Ed.: R.Finkel, M.A. Clark, L.X. Cubeddu. –Lippincott Williams Wilkins, 2008. – 560 p.
11. Lullman H, Albrcht Z., Klaus M, Detlef B. Color Atlas of Pharmacology.– Stuttgart – New- York: Thieme, 2000. – 386 p.
12. Rang H.P., Dale M.M., Ritter J.M., Moore P.K. Rang's and Dale's Pharmacology, 6th edition. – London: Churchill-Livingstone Elsevier, 2007. – 830 p.
13. Stringer J.L. Basic Concepts in Pharmacology. A students survival guide, 2nd edition. – McGrawHill International Edition, 2001. – 286 p.

**ADDITION**

<b>CARD-REPORT ABOUT SIDE REACTION OF MEDICINES, VACCINES, TUBERCULIN, AND/OR ABSENCE OF EFFICIENCY OF MEDICAL PREPARATION, AND/OR ADVERSE EVENTS AFTER IMMUNIZATION /TUBERCULIN SKIN TEST (AEAI)</b>	<b>MEDICAL DOCUMENT</b>  Form №137/o
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The notification may be filled in and provided to the state enterprise "State Expert Center of the Ministry of Health of Ukraine" (Ushinskoho St. 40, Kyiv, 03151, Department of Pharmacovigilance; tel / fax: +38 (044) 498-43-58; e -mail: vigilance@dec.gov.ua). The electronic form of the notification card is available at <https://aisf.dec.gov.ua>

**I. THE INFORMATION ABOUT THE PATIENT**

1. Initials of patient	2. Number of history of disease /	3. Date of birth/ age	4. Sex	5. Weight (kg)	6. Height (sm)
			<input type="checkbox"/> m <input type="checkbox"/> f		

**II. SUSPECTED SR, AE, AEA I**

Description of SR / AEA I (describe each clinical manifestation of SR / AEA I with indication of start and end dates and times and consequences)  Denotation AE  Date and time of the beginning of SR/AE/AEA I _____  Date and time of the ending of SR/AE/AEA I _____  <b>Correction of SR / AE / AEA I:</b>  <input type="checkbox"/> without treatment <input type="checkbox"/> non-drug treatment <input type="checkbox"/> drug therapy <input type="checkbox"/> surgery <input type="checkbox"/> dialysis	<b>Consequence of SR / AE / AEA I</b>  <input type="checkbox"/> recovery without consequences  <input type="checkbox"/> recovers <input type="checkbox"/> unchanged <input type="checkbox"/> recovery with consequences  <input type="checkbox"/> death <input type="checkbox"/> unknown
Are these manifestations of SR / AEA I considered serious (in the case of SR / AEA I in general) <input type="checkbox"/> yes <input type="checkbox"/> no If yes, indicate why the SR / AEA I is considered serious (one or more reasons): <input type="checkbox"/> death of patient / ____/____/____/(date of death) <input type="checkbox"/> prolonged disability <input type="checkbox"/> threat to life <input type="checkbox"/> hospitalization/ lengthening of terms of hospitalization <input type="checkbox"/> congenital malformations  <input type="checkbox"/> another important medical assessment  <input type="checkbox"/> invalidity	

group AEAI

### III. INFORMATION ABOUT SUSPECTED MP (SMP), VACCINE, TUBERCULIN

Suspected MP, vaccine, tuberculin (trade name, dosage form, manufacturer)	Number of series	The indication for use (according to ICD -10 if it's possible)	The strength of the drug	Dose	Frequency of reception	A way of applications	Date and time of the beginning of therapy	Date and time of the ending of therapy

#### *Measures taken against suspected drugs, vaccines, tuberculin to correct SR / AE /AEAI*

- cancellation of the suspected drug     unknown  
 not used (for example, if the suspected drugs, vaccine, tuberculin are used once)  
 drug therapy SR / AE / AEA (drugs, strength, duration of appointment are specified)

Whether suspected drugs, the vaccine were prescribed repeatedly  yes     no

If yes, indicate whether:

- dose reduction of the suspected drug (how much)  
 increase the dose of the suspected drug (how much)  
 the dose was not changed

Whether there was a recurrence of SR / AE after re-appointment of the suspect drug

yes     no

#### IIIa. ADDITIONAL INFORMATION IN CASE OF AEAI FOR VACCINES OR TUBERCULIN

Category of immunization or tuberculin skin testing		Category AEAI		
<input type="checkbox"/> mass immunization campaign <input type="checkbox"/> vaccination by age  <input type="checkbox"/> children's preschool institution <input type="checkbox"/> school <input type="checkbox"/> medical office for travelers <input type="checkbox"/> conducting tuberculin skin testing  <input type="checkbox"/> other		<input type="checkbox"/> reaction to the vaccine / tuberculin <input type="checkbox"/> programming mistake <input type="checkbox"/> random event <input type="checkbox"/> reaction to injection / fear of immunization / tuberculin skin testing <input type="checkbox"/> unknown		
Dose number (for vaccine)		Vaccine / tuberculin injection site		The method of administration of the vaccine / tuberculin
<input type="checkbox"/> first	<input type="checkbox"/> fourth	<input type="checkbox"/> left shoulder	<input type="checkbox"/> thigh (without	<input type="checkbox"/> orally

<input type="checkbox"/> second <input type="checkbox"/> third	<input type="checkbox"/> fifth <input type="checkbox"/> > fifth	<input type="checkbox"/> right shoulder <input type="checkbox"/> shoulder (without specification) <input type="checkbox"/> left thigh <input type="checkbox"/> right thigh	specification) <input type="checkbox"/> left forearm <input type="checkbox"/> right forearm <input type="checkbox"/> forearm (without specification)	<input type="checkbox"/> intramuscularly <input type="checkbox"/> intradermally <input type="checkbox"/> subcutaneously <input type="checkbox"/> other _____
Expiration date / ___ / ___ / _____ /				

**Data from the life history of the person who was immunized / whom tuberculin skin test was performed** (vaccination history, the presence of reactions to previous injections of vaccines, tuberculin, the presence of acute or exacerbation of chronic disease for 1 - 1.5 months before immunization / tuberculin skin testing, immunosuppressive therapy during 1 month and blood preparations for 3 months before immunization / tuberculin skin testing, etc.)

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#### IV. INFORMATION ABOUT ASSOCIATED MEDICINES

*(except for drugs used to correct the effects of SR / AE / AEAI)*

Associated MP, ((trade name, dosage form, manufacturer, number of series)	The indication for use (according to ICD -10 if it's possible)	The strength of the drug	Dose	Frequency of reception	A way of applications	Date and time of the beginning of therapy	Date and time of the ending of therapy

Other important information (concomitant diagnoses, laboratory and instrumental data, allergy history, pregnancy with the term of pregnancy, method of conception, pregnancy outcome (if the pregnancy is over, indicate the date of birth, type of birth, etc.))

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#### V. INFORMATION ABOUT THE NOTIFIER

Initials \_\_\_\_\_  
Specialty \_\_\_\_\_  
Health care facility \_\_\_\_\_

#### VI. INFORMATION ABOUT THE MEDICAL / PHARMACEUTICAL SPECIALIST (if not the notifier)

Initials \_\_\_\_\_

\_\_\_\_\_

Location \_\_\_\_\_

E-mail \_\_\_\_\_

Tel. \_\_\_\_\_ Date \_\_\_\_\_

Specialty \_\_\_\_\_

Health care facility \_\_\_\_\_

\_\_\_\_\_

Location \_\_\_\_\_

E-mail \_\_\_\_\_

Tel. \_\_\_\_\_ Date \_\_\_\_\_