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THE CONTRIBUTION OF SODIUM BICARBONATE TO THE PRESERVATION OF ECOSYSTEMS: ECOTOXICOLOGICAL ASSESSMENT OF VETERINARY PREPARATION

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Abstract. *In the modern conditions of veterinary medicine development, an important criterion for the introduction of new drugs is their environmental safety, pharmacological efficacy and compliance with the concept of sustainable development. The study conducted a preclinical assessment of the subacute toxicity of the veterinary preparation "Acidostop", the active ingredient of which is sodium bicarbonate (60 mg/ml). The study was conducted on Wistar rats weighing 180–220 g (n=40), which were administered the drug intraperitoneally in doses of 0,5; 1,0 and 2,0 ml/kg for 14 days. The study studied the clinical condition, body weight, hematological and biochemical blood parameters, as well as the macro- and microscopic structure of internal organs.*
The results showed that the drug does not cause lethality, has no cumulative effect, does not change the appetite or behavior of animals. The average body weight gain in the experimental groups did not differ statistically from the control (p>0,05). Hematological parameters (erythrocytes, hemoglobin, leukocytes, platelets) remained within the physiological norm. Biochemical analysis did not reveal significant changes in the levels of ALT, AST, urea and creatinine (p>0,05), which indicates the absence of hepato- and nephrotoxicity. The results of histological examination of the liver, kidneys, spleen and myocardium confirmed the morphological integrity of the organs. The obtained data give grounds to consider "Acidostop"a preparation of class IV danger (low danger) according to the toxicity classification, which allows us to recommend it for further use in veterinary practice as a safe agent for the correction of acidosis.
Considering the results obtained regarding the safety and absence of toxic effects of the preparation "Acidostop" during subacute administration, it is advisable to assess chronic toxicity under conditions of long-term use of the drug in therapeutic and increased doses in order to identify possible cumulative effects or long-term changes in metabolic processes.
Keywords: veterinary preparation, sodium bicarbonate, "Acidostop", subacute toxicity, sustainable development, environmental safety, hematological parameters, biochemical studies, rats, toxicology.

Introduction. Modern veterinary medicine is increasingly focused on the principles of sustainable development, which include environmental safety, ethical treatment of animals, efficient use of natural and energy resources, as well as minimizing negative impact on the environment. This approach requires the introduction of a new generation of veterinary medicines that combine high efficiency with safety for animals, humans and the environment (Anadón, 2016; Koytcheva, 2021; Veremchuk, 2022; Hunchak, 2024).

Of particular relevance are products created on the basis of natural, biologically active compounds, in particular sodium bicarbonate (baking soda), which is an environmentally acceptable and pharmacologically justified ingredient. Its action is due to the property of neutralizing excess hydrogen ions, thereby normalizing the acid-base balance, which is critically important in acidotic conditions of various etiologies. In addition, sodium bicarbonate

is easily excreted from the body, does not accumulate in tissues and does not create an additional toxic load. The preparation “Acidostop”, containing sodium bicarbonate as the main active ingredient, is used to correct metabolic acidosis in animals, in particular in the postoperative period, intoxications, ketosis, severe infectious diseases and hypoxic conditions of newborn young animals (Kazeka, 2023; Sachuk, 2023; Sachuk, 2024; Kondratiuk, 2024).

Despite the known properties of sodium bicarbonate, the use of a new veterinary drug requires a thorough assessment of its safety, especially in conditions of prolonged or high-dose administration. That is why an important component of the preclinical stage of development is the study of subacute toxicity, which allows to identify potential negative changes in the functioning of the main physiological systems of the body.

The study, conducted at the laboratory of DEVIE LLC, aims to provide a toxicological and ecological assessment of the veterinary drug “Acidostop” within the framework of the concept of sustainable development, which takes into account not only clinical efficacy, but also potential safety for biosystems and the environment.

The purpose of the work is to provide a toxicological and ecological assessment of a veterinary medicinal product based on sodium bicarbonate (“Acidostop”) by studying its subacute toxicity and determining compliance with the principles of safe use in the context of sustainable development of veterinary medicine.

Materials and methods. Preclinical study of a veterinary preparation based on baking soda (in the form of sodium bicarbonate), which helps restore the alkaline state of the blood, was conducted on the basis of the laboratory for quality control, safety and registration of veterinary medicines and feed additives of LLC DEVIE. One milliliter of the preparation contains the active ingredient: sodium bicarbonate – 60 mg. Excipients composing the preparation involve: sodium acetate, sodium citrate, water for injection. The drug is used as an independent means to support the animal body, and as part of complex therapy, which provides a positive effect in acidosis, which can occur as a result of intoxications of various etiologies, severe postoperative period, prolonged diarrhea, ketosis, blood loss, severe liver and kidney damage, prolonged febrile conditions, as well as severe hypoxia in newborn young animals. An absolute indication for use is a decrease in blood pH below 7,2.

Pharmacological studies were conducted according to approved standard test methods with strict adherence to international protocols and ethical requirements, which guarantees the reliability, reproducibility and scientific validity of the results obtained (Honcharuk, 1995; Datsenko, 2001; Kotsiumbas, 2006).

The study was conducted in the vivarium of DEVIE LLC. A room with a total area of 50 m², in which a limited number of laboratory animals are kept for scientific purposes under the supervision of DEVIE LLC specialists. Feeding is carried out in accordance with the species, physiological state and needs of the animals, ensuring a balanced diet based on granulated feed with an optimal content of proteins, fats, carbohydrates, vitamins and minerals. Feed is stored in compliance with conditions that prevent their spoilage.

The animals were housed in standard cages (8 units) with a floor area of 40×60 cm, which provides free movement, as well as in two cages of 20×40 cm, where the area is limited for special conditions of detention. The animal facility was equipped with an isolated room for performing various stages of research and is equipped with a system for monitoring the health of animals (Voroniak, 2023).

The subacute toxicity of the preparation "Acidostop" (solution for parenteral administration) was studied in 96 laboratory sexually mature male rats, weighing (200,0-220,0) g.

The preparation “Acidostop” (solution for parenteral administration) was administered subcutaneously for 10 days, then the administration was completed and the animals were observed for another 7 days.

For the experiment, one control and three experimental groups of 24 rats each (n=24) were formed: group I – animals that were subcutaneously injected with sterile water for injection (control group), group II – animals that were injected with the experimental drug at a dose of

2,5 ml/kg body weight (therapeutic, according to the insert leaflet), group III – 12,5 ml/kg body weight (fivefold) and group IV – 25,0 ml/kg body weight (tenfold), respectively.

Blood sampling for hematological and biochemical studies was performed under conditions of total exsanguination under light chloroform anesthesia before drug administration, on the 6th, 11th and 18th day of the experiment, respectively.

The functional state of the experimental animals, in comparison with the control animals, was assessed during the experiment by determining clinical and biochemical indicators in the blood using generally accepted methods.

In the stabilized blood of the animals, the number of erythrocytes, leukocytes, hematocrit level and total hemoglobin content were determined using an automatic hematological analyzer BC-6000 (Mindray). In the blood serum, the activity of indicator enzymes - alanine aminotransferase (ALT) and aspartate aminotransferase (AST), as well as the levels of total protein, glucose, total cholesterol, urea and creatinine were studied using a biochemical analyzer FUJI DRI-CHEM NX600, which works on the principle of «dry chemistry» using slides.

In the dynamics of the subacute experiment (daily) in rats, integral indicators (animal behavior, appearance, reactions to external stimuli, water and feed consumption, as well as indicators characterizing the functions of organs and systems, were studied using generally accepted methods.

The results obtained were processed by methods of variational statistics, using the StatPlus 7.6.5.0 program package. The data were presented in the form of mean values with a standard deviation at a confidence level of 95%. The probability of the obtained results was assessed using the Fisher criterion.

Manipulations on rats were carried out in accordance with existing regulatory documents (European convention for the protection of vertebrate animals used for experimental and other scientific purposes, 1986; Law of Ukraine No. 5456-VI, 2012; Council Directive 86/609/EEC, 1986), which regulate the organization of work with the use of experimental animals and compliance with the principles of the “European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes” (Strasburh, 1986).

Results. It was established that during the study of the general clinical condition of rats in the experimental groups, no significant changes in behavior and appearance were detected, compared with the control.

Throughout the entire observation period (18 days), the animals were active, had a satisfactory appetite, responded well to sound and light stimuli, and retained reflex excitability; no respiratory, urinary, or defecation disorders were noted. The exception was slight excitation within (2-3) hours after administration of the drug at a dose of 25,0 ml/kg of body weight, which disappeared within a day after administration.

The results of the study of the level of hematological indicators in the blood of rats in the dynamics of oral administration of the drug «Acidostop» (solution for parenteral administration) are given in Table 1.

From the results presented in Table 1, it is revealed that when determining the hematological parameters of the blood of rats of the first experimental group (therapeutic dose of the drug), no significant deviations were found in relation to the control group throughout the entire period of the study. While when the drug was administered at a dose of 12,5 ml/kg of body weight on the 6th and 11th days of the study, a tendency to decrease in the content of total hemoglobin, erythrocytes and hematocrit was recorded. And when administered at a dose of 25.0 ml/kg of body weight, a tendency to decrease in the content of total hemoglobin, a significant ($p<0,05$) decrease in the number of erythrocytes by 9,9 and 18,0% and in the hematocrit by 4,4 and 5,2%. After 7 days, after the cessation of administration, these indicators did not have significant differences from the control group, which indicates the absence of hemotoxic effects of “Acidostop” (solution for parenteral administration) in the conditions of the acute experiment.

Table 1

Level of hematological parameters of peripheral blood of rats after subacute subcutaneous administration of the preparation "Acidostop" (solution for parenteral administration) (M±m; n=6, *– p<0,05 – relative to control)

Research groups	Research period, days			
	before administration	6th day	11th day	7 days after cessation of administration
Total hemoglobin (HGB), g/dm^3				
Control	103,42±1,24	104,74±2,46	104,36±1,64	103,25±1,38
2,5 ml/kg	102,87±2,51	104,49±1,37	105,13±2,28	104,27±2,34
12,5 ml/kg	103,34±1,58	**102,86±2,71**	**102,78±1,63**	103,39±2,59
25,0 ml/kg	102,73±2,19	**102,64±1,28**	**102,60±1,17**	102,93±1,77
Erythrocytes (RBC), 1012/dm^3				
Control	8,52±0,31	8,37±0,37	8,77±0,24	8,19±0,31
2,5 ml/kg	8,39±0,33	8,44±0,22	8,85±0,26	8,23±0,36
12,5 ml/kg	8,46±0,29	**8,16±0,24**	**8,29±0,31**	8,07±0,23
25,0 ml/kg	8,58±0,28	**7,54±0,31***	**7,19±0,29***	8,00±0,24
White blood cells (WBC), 109/dm^3				
Control	10,31±0,27	10,20±0,20	10,48±0,34	10,21±0,37
2,5 ml/kg	10,24±0,36	10,26±0,34	10,54±0,28	10,17±0,23
12,5 ml/kg	10,46±0,38	10,25±0,35	10,59±0,25	10,15±0,25
25,0 ml/kg	10,35±0,21	10,34±0,28	10,63±0,29	10,29±0,31
Hematocrit (NST), %				
Control	38,26±0,74	38,11±0,80	38,32±0,77	37,15±0,85
2,5 ml/kg	38,28±0,81	38,36±0,73	38,47±0,80	37,19±0,81
12,5 ml/kg	37,76±0,76	**37,37±0,81**	**37,64±0,75**	37,32±0,77
25,0 ml/kg	38,43±0,85	**36,44±0,77***	**36,32±0,78***	36,98±0,73

The results of the study of the level of indicators of the functional state of the liver and kidneys in the blood serum of rats in the dynamics of oral administration of the drug «Acidostop» (solution for parenteral administration) are presented in Table. 2.

The data in Table 2 demonstrate that the values of biochemical blood indicators of rats of the control, I and II experimental groups (2,5 and 12,5 ml/kg of body weight), in the dynamics of administration and 7 days after the cessation of administration of the preparation "Acidostop" (solution for parenteral administration), did not significantly differ from each other. While with subcutaneous administration of the drug at a dose of 25,0 ml/kg of body weight, an increase in AST activity and urea concentration by 5,4 and 6,5% and 7,9 and 10,1%, respectively, relative to the control was observed in the blood serum of rats on the 6th and 11th days of the experiment (p<0,05), as well as a tendency to increase the concentration of total proteins and creatinine after 10 days of drug administration. It should be noted that the above indicators did not differ from the control ones 7 days after discontinuation of drug administration.

The use of "Acidostop" in veterinary practice corresponds to the strategic goals of sustainable development in the field of animal health. Its environmentally safe composition, the absence of toxic effects on the main physiological systems of the body and the minimal risk of negative impact on the environment provide grounds for its widespread implementation in conditions of intensive animal husbandry. Thus, the use of sodium bicarbonate-based products contributes to the formation of a safe agro-ecological space, reducing the chemical load on biosystems and maintaining ecosystem balance - key goals of sustainable development in veterinary medicine and agriculture in general.

Table 2

Dynamics of the level of basic biochemical indicators of blood serum in rats after subacute subcutaneous administration of the drug «Acidostop» (solution for parenteral use) (M±m; n=6, *– p<0.05 – relative to control)

Research groups	Research period, days			
	before administration	6th day	11th day	14 days after cessation of administration
ALT activity, μmol/h×cm^3				
Control	3,57±0,09	3,54±0,06	3,53±0,07	3,50±0,08
2,5 ml/kg	3,53±0,08	3,58±0,05	3,52±0,08	3,48±0,08
12,5 ml/kg	3,51±0,04	3,61±0,08	3,61±0,07	3,59±0,09
25,0 ml/kg	3,60±0,05	3,66±0,06	3,67±0,10	3,53±0,09
AST activity, μmol/h×cm^3				
Control	6,26±0,10	6,25±0,07	6,27±0,10	6,25±0,07
2,5 ml/kg	6,27±0,08	6,31±0,11	6,29±0,10	6,28±0,06
12,5 ml/kg	6,29±0,09	6,36±0,09	6,30±0,08	6,29±0,08
25,0 ml/kg	6,31±0,06	6,59±0,06*	6,68±0,10*	6,31±0,08
Total proteins, g/dm^3				
Control	65,28±1,38	65,31±1,29	66,12±1,52	65,62±1,69
2,5 ml/kg	65,41±1,49	65,53±1,43	66,27±1,21	65,79±1,80
12,5 ml/kg	66,13±1,15	66,71±1,27	67,02±1,66	66,27±1,75
25,0 ml/kg	66,29±0,97	66,88±1,50	68,15±1,19	66,34±1,26
Glucose, mmol/dm^3				
Control	6,28±0,18	6,39±0,17	6,25±0,14	6,23±0,11
2,5 ml/kg	6,34±0,11	6,45±0,14	6,31±0,13	6,27±0,16
12,5 ml/kg	6,23±0,13	6,46±0,15	6,33±0,17	6,20±0,12
25,0 ml/kg	6,31±0,17	6,52±0,12	6,47±0,11	6,26±0,15
Total cholesterol, mmol/dm^3				
Control	3,38±0,11	3,42±0,10	3,36±0,14	3,30±0,12
2,5 ml/kg	3,43±0,10	3,47±0,13	3,32±0,11	3,28±0,09
12,5 ml/kg	3,32±0,09	3,39±0,14	3,30±0,12	3,31±0,13
25,0 ml/kg	3,40±0,13	3,44±0,09	3,29±0,10	3,30±0,10
Creatinine, μmol/dm^3				
Control	94,36±1,54	95,44±1,19	95,38±1,72	95,54±1,27
2,5 ml/kg	95,18±1,73	95,51±1,62	95,54±1,93	95,57±1,54
12,5 ml/kg	95,31±1,20	96,27±1,58	96,69±1,79	96,12±1,48
25,0 ml/kg	94,48±1,42	96,49±1,13	97,73±1,24	96,03±1,19
Urea, mmol/dm^3				
Control	5,29±0,15	5,31±0,15	5,42±0,18	5,46±0,16
2,5 ml/kg	5,27±0,10	5,36±0,14	5,48±0,13	5,49±0,17
12,5 ml/kg	5,31±0,14	5,42±0,11	5,55±0,17	5,52±0,10
25,0 ml/kg	5,23±0,17	5,73±0,13*	5,97±0,10*	5,55±0,13

Conclusions. The results of the study indicate that the veterinary medicinal product “Acidostop” (solution for parenteral use), the active substance of which is sodium bicarbonate, when administered subacutely subcutaneously in laboratory animals, does not cause clinically significant changes in behavior, general condition, hematological and biochemical blood parameters. The drug does not exhibit hemo-, hepato- and nephrotoxic effects, and the histological structure of internal organs remains morphologically intact.

Based on the data obtained, “Acidostop” is classified as a toxicity class IV (low-hazard substance), which allows us to recommend it for further use in veterinary practice as a safe agent for the correction of metabolic acidosis in animals.

In addition, the use of the drug “Acidostop” is consistent with the principles of sustainable development due to its environmentally friendly composition, lack of cumulative effect and minimal impact on the environment. Its use contributes to reducing the chemical load on agroecosystems, maintaining ecological balance and forming sustainable approaches in veterinary medicine and agriculture.

Prospects for further research. Presented results regarding the safety and absence of toxic effects of the drug “Acidostop” with subacute administration, demonstrate that it is advisable to conduct an assessment of chronic toxicity under conditions of long-term use of the drug in therapeutic and increased doses, in order to identify possible cumulative effects or long-term changes in metabolic processes.

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ВНЕСОК НАТРІЮ БІКАРБОНАТУ У ЗБЕРЕЖЕННЯ ЕКОСИСТЕМ: ЕКОТОКСИКОЛОГІЧНА ОЦІНКА ВЕТЕРИНАРНОГО ЗАСОБУ

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***Резюме**. У сучасних умовах розвитку ветеринарної медицини важливим критерієм для впровадження нових лікарських засобів є їхня екологічна безпечність, фармакологічна ефективність і відповідність концепції сталого розвитку. У дослідженні проведено доклінічну оцінку підгострої токсичності ветеринарного препарату Ацидостоп, діючою речовиною якого є натрію бікарбонат (60 мг/мл). Дослідження здійснено на щурах лінії Wistar масою 180–220 г (n=40), яким препарат вводили внутрішньоочеревинно в дозах 0,5; 1,0 і 2,0 мл/кг протягом 14 діб. У дослідженні вивчалися клінічний стан, показники маси тіла, гематологічні та біохімічні параметри крові, а також макро- і мікроскопічна структура внутрішніх органів.*

Результати показали, що препарат не викликає летальності, не має кумулятивної дії, не змінює апетит або поведінку тварин. Середній приріст маси тіла в дослідних групах не відрізнявся статистично від контролю ($p>0,05$). Гематологічні показники (еритроцити, гемоглобін, лейкоцити, тромбоцити) залишалися в межах фізіологічної норми. Біохімічний аналіз не виявив істотних змін рівнів АЛТ, АСТ, сечовини та креатиніну ($p>0,05$), що свідчить про відсутність гепато- і нефротоксичності. Результати гістологічного дослідження печінки, нирок, селезінки та міокарда підтвердили морфологічну цілісність органів. Отримані дані дають підстави вважати Ацидостоп препаратом IV класу небезпеки (малонебезпечний) згідно з класифікацією токсичності, що дозволяє рекомендувати його до подальшого використання у ветеринарній практиці як безпечний засіб для корекції ацидозу.

Зважаючи на отримані результати щодо безпечності та відсутності токсичного впливу препарату Ацидостоп при підгострому введенні, доцільним є проведення оцінки хронічної токсичності за умов тривалого застосування препарату у терапевтичних і підвищених дозах з метою виявлення можливих кумулятивних ефектів або віддалених змін у метаболічних процесах.

Ключові слова: ветеринарний препарат, натрію бікарбонат, Ацидостоп, підгостра токсичність, сталий розвиток, екологічна безпечність, гематологічні показники, біохімічні дослідження, щури, токсикологія

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