# OPTIMAL 25(OH)D SERUM LEVEL IN RELATION TO ASSOCIATION WITH MUSCULOSKELETAL, METABOLIC, NEUROLOGICAL, AUTOIMMUNE AND INFECTIOUS DISEASES

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This article presents an overview of current research on target vitamin D blood levels. It examines the biochemical and metabolic properties of vitamin D, as well as the challenges of standardizing 25(OH)D measurements and the variability of cutoff values across populations. It discusses the ambiguity of the scientific evidence and the need to consider individual factors when interpreting vitamin D levels. This review is unique in its comprehensive approach to analyzing the effects of vitamin D not only on bone health but also on immune and metabolic function, expanding the evolving understanding of the clinical significance of vitamin D. This paper emphasizes the importance of personalized recommendations for vitamin D prescription and dosing based on current clinical evidence and scientific standards. This analysis highlights the need for a personalized approach to vitamin D prescription to achieve and maintain blood levels of 30 to 60 ng/mL, noting that higher levels may be required for individuals with genetic or acquired resistance to the nutrient. The data obtained support the development of evidence-based, personalized clinical strategies for the prevention and treatment of diseases associated with vitamin D deficiency. The synthesized data are important for the development of research and clinical practice in the fields of endocrinology, obstetrics, dermatology, neurology, and immunology.

KEYWORDS: vitamin D; vitamin D deficiency; 25-hydroxyvitamin D; vitamin D metabolism; cholecalciferol; ergocalciferol; endocrinology.

## OPTIMAL SERUM 25(OH)D LEVELS IN RELATION TO MUSCULOSKELETAL, METABOLIC, NEUROLOGICAL, AUTOIMMUNE AND INFECTIOUS DISEASES

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This article presents an overview of current research on determining target blood levels of vitamin D. It examines the bio-chemical and metabolic properties of vitamin D, as well as the challenges of standardizing 25(OH)D measurements and the variability of threshold values across populations. It discusses ambiguities in scientific data and the need to consider individual-ual factors when interpreting vitamin D levels. This review is unique in its comprehensive approach to analyzing the effects of vitamin D not only on bone health but also on immune and metabolic functions, which broadens ever evolving under-standing of the clinical significance of vitamin D. This work emphasizes the importance of personalized recommendations for vitamin D dosing and prescription based on current clinical data and scientific standards. Performed analysis highlights the need for personalized vitamin D supplementation to reach and maintain blood levels between 30 and 60 ng/mL, noting that higher levels might be necessary for people with genetic or resistance acquired. These insights substantiate the devel-opment of evidence-based, personalized clinical strategies for the prevention and treatment of vitamin D deficiency-related disorders. The synthesized data offer significant implications for advanced research and clinical practice in endocrinology, obstetrics, dermatology, neurology and immunology.

KEYWORDS: vitamin D; vitamin D Deficiency; 25-Hydroxyvitamin D; vitamin D metabolism; cholecalciferol; ergocalciferol; endocrinology.

## INTRODUCTION

Vitamin D deficiency is one of the most common nutrient deficiencies worldwide, affecting approximately 1 billion people according to epidemiological studies [1]. Vitamin D's primary biological role in the human body is known to be the regulation of calcium and phosphorus metabolism. Vitamin D has a positive effect on intestinal calcium absorption, increases renal calcium reabsorption, and supports bone mineralization by regulating chondrocyte and osteoblast differentiation [2].

The results of the studies have demonstrated a link between low vitamin D status and an increased risk of developing various socially significant diseases, including musculoskeletal, metabolic, cardiovascular, malignant and infectious diseases. The contribution of vitamin D deficiency to the pathogenesis of neurological, autoimmune and endocrine diseases has also been established [3]. Given the high prevalence of vitamin D deficiency, studies demonstrating the pleiotropic and multimodal effects of vitamin D depending on the level of 25(OH)D in the blood are still extremely few. This is probably due to the fact that any other

effects of vitamin D not associated with phosphorus-calcium metabolism have become the focus of researchers relatively recently, and most studies are focused on the skeletal effects of vitamin D. Given the high prevalence of vitamin D deficiency, the availability of experimental studies devoted to the pleiotropic and multimodal effects of vitamin D, hypotheses on the use of this

The use of vitamin D as a prohormone for the prevention of a number of socially significant diseases is being actively discussed worldwide. This expert council analyzed and summarized existing experimental and clinical data regarding the effects of vitamin D on various organs and systems [4, 5] and proposed possible ways to realize the classical and pleiotropic effects of vitamin D on health.

population.

### Definition and Epidemiology

Vitamin D deficiency is a condition characterized by a decrease in serum 25(OH)D concentrations below optimal values, which can potentially lead to decreased intestinal calcium absorption, the development of secondary hyperparathyroidism and an increased risk of fractures, especially in the elderly [2].

Vitamin D deficiency and insufficiency are defined as serum 25(OH)D levels less than 20 ng/ml and 20 to 30 ng/ml, respectively [2]. An analysis of 14 population-based studies assessing the prevalence of vitamin D deficiency in European countries showed that among 55,844 European residents of various ages, blood 25(OH)D levels below 12 ng/ml were observed in 13% of those examined, with significant seasonal differences (the proportion of 25(OH)D levels below 12 ng/ml was 18% in the period from October to March and 8% from April to November). Levels below 20 ng/ml were detected in 40% of those examined [6, 7].

The results obtained in the study of the prevalence of vitamin D deficiency and insufficiency in the Russian Federation are consistent with global data regarding seasonal fluctuations, but significantly exceed the scale of the values

The prevalence of vitamin D deficiency and insufficiency in other countries is largely due to the geographic location of the Russian Federation, as well as the lack of centralized fortification of foods with this nutrient. Thus, blood 25(OH)D levels of less than 30 ng/ml were diagnosed in 70–95% of examined adults [8–14].

It should be noted that the first multicenter registry study conducted in the Russian Federation demonstrated the presence of blood 25(OH)D levels below 20 ng/ml in 56% of the examined individuals in the spring (March-May) and in 26% in the autumn (October-November) observation period, and levels below 30 ng/ml in 84% and 62%, respectively [15]. These data are consistent with the results of a prospective cohort study assessing 25(OH)D levels in pregnant women, which demonstrated the presence of low vitamin D levels in the first trimester of pregnancy in 84.3% of cases, regardless of the time of year the examination was conducted [16]. Similar data on the prevalence of deficiency of this nutrient in the Russian Federation were presented at the beginning of the COVID-19 pandemic [17].

## VITAMIN D METABOLISM

It is known that vitamin D enters the body in two ways: through the synthesis of cholecalciferol (D3 ) from the precursor 7-dehydrocholesterol in the skin under the influence of ultraviolet (UV) radiation of type B, as well as with food in the form of vitamin D of animal origin - cholecalciferol (D3 , INN of the drug - cholecalciferol) and of plant origin - ergocalciferol (D2 ).

The metabolic steps for both forms of vitamin D (D2 and D3 ) are common and include the first step of hydroxylation by the enzymes CYP2R1 and CYP27A1 in the liver to form calcidiol (25(OH)D) and the second step by the enzyme CYP27B1, mainly in the kidneys, to the active metabolite of calcitriol, 1,25(OH)2D. The main function of 1,25(OH)2D is to maintain calcium and phosphorus homeostasis. However, by binding to intracellular specific vitamin D receptors (VDRs) in tissues, 1,25(OH)2D initiates many extraosseous metabolic processes. Unlike renal CYP27B1, extrarenal forms of the enzyme, which mediate numerous pleiotropic effects, are regulated not by signaling from parathyroid hormone (PTH), fibroblast growth factor (FGF-23), calcium, or phosphate, but by regulatory factors that depend on a specific function. It should also be noted that the regulation of extrarenal CYP27B1 is dependent on the concentration of circulating 25(OH)D in the blood [3, 18, 19].

## PLEIOTROPIC EFFECTS OF VITAMIN D

Previous studies have shown that vitamin D regulates the cell cycle and thus has a significant impact on the functioning of human organs and systems. By binding to VDR receptors on cells of the immune, nervous, digestive, reproductive, and cardiovascular systems, vascular system, vitamin D has regulatory, anti-inflammatory, antiproliferative, and antifibrotic effects [20].

There is limited information in the literature on the optimal threshold values of 25(OH)D concentration in blood serum for the implementation of pleiotropic effects, which vary from 25 ng/ml to 60 ng/ml [21–23]. These 25(OH)D concentrations are consistent with the recommendations of the Russian Association of Endocrinologists, where target levels are prescribed as 30–60 ng/ml [2].

It should be recognized that, unlike the effect of vitamin D on calcium metabolism, its extraosseous pleiotropic effects are much more difficult to evaluate in clinical practice. Based on cohort studies, it has been hypothesized that higher serum 25(OH)D levels are necessary for the pleiotropic effects to be realized. For example, associations have been found between a lower incidence of cancer, cardiovascular, and autoimmune diseases, the development of diabetes mellitus (DM), falls, fractures, and even mortality with higher serum 25(OH)D values [24, 25]. However, all of these differences were obtained based on the analysis of clinical outcomes in large population cohorts. However, in such studies, it may be difficult to prove a cause-and-effect relationship between one factor, for example, the level of vitamin D status, and a clinical outcome, in particular the development of cancer or other diseases.

To understand the additional benefit associated specifically with vitamin D supplementation, large-scale randomized controlled trials have been conducted assessing the efficacy of achieving 25(OH)D levels of 40 ng/mL and 50 ng/mL, with endpoints of mortality, cancer, type 2 diabetes mellitus (T2DM), falls, fractures, and cardiovascular events. These studies failed to find significant differences in the primary outcomes between the groups of patients taking vitamin D supplements [26–31]. All of these studies fully met the criteria for conducting randomized clinical trials of medicinal products. However, there were a number of limitations: the populations included in most protocols were not limited to patients with baseline vitamin D deficiency; In some of them, prophylactic doses of cholecalciferol (ÿ800 IU per day) were allowed in the placebo groups; some studies did not take into account the individual characteristics of vitamin D metabolism in the included patients [32].

Thus, taking into account the results
Based on the clinical, epidemiological, and cohort studies conducted, we can talk about the potential benefits of taking vitamin D to improve health indicators and quality of life, in particular to reduce the risk of type 2 diabetes, acute respiratory viral infections, impact on reproductive outcomes, etc. It should be emphasized that the required doses of vitamin D and the "optimal level of 25(OH)D" may differ depending on the goals set (Table 1). Further large-scale studies require

**Table 1.** Pleiotropic effects of vitamin D and associated mechanisms and nosologies

| Effects on various body systems | Mechanism of development and clinical effects | Estimated optimal level 25(OH)D (ng/ml) |
|---|---|---|
| Musculoskeletal system [33] | 1,25(OH)2D interacts with the vitamin D nuclear receptor (VDR) in the small intestine, increasing the expression of epithelial calcium channel and calcium binding protein, leading to increased calcium absorption from the diet.<br><br>**Positive clinical effect** - effective absorption of calcium in the intestine, favorable response to bisphosphonate therapy | >30 |
| Cells and tissues of the immune system [22, 33–38] | Effect on the differentiation of active CD4+ T cells; enhancement of the inhibitory function of T cells; differentiation of monocytes into macrophages with increased antibacterial and antiviral activity; suppression of IL-12, ÿ-interferon, Th1 immune responses ; suppression of TGF-ÿ/Smad3.<br><br>**Positive clinical effect** - reduction in the frequency of recurrent infections, respiratory diseases (flu, tuberculosis, COPD), chronic fatigue syndrome, Behcet's disease, inflammatory bowel disease, rheumatoid arthritis | >50 |
| Antiproliferative, antifibrotic action [37, 39–42] | Induction of apoptosis in malignant cells (Bcl2/Bax interaction); influence on neurotrophic factors; inhibition of the TGF-ÿ/EGFR growth cycle, reduction of keratinocyte proliferation.<br><br>**Positive clinical effect** - reduction in the incidence of prostate cancer, breast cancer, colon cancer, myeloproliferative diseases and all-cause mortality | ÿ40 |
| Cardiovascular system [37, 43–45] | Feedback with the renin-angiotensin system, regulation of blood pressure and electrolyte balance; regulation of the process of myocardial cell hypertrophy; suppression of inflammatory cytokines, angiogenesis and vascular calcification.<br><br>**Positive clinical effect** - reduction in the prevalence and severity of arterial hypertension, myocardial infarction, congestive heart failure, atherosclerosis | ÿ40 |
| Nervous system [46–54] | Neurotrophic (effect on nerve growth factor NGF), neuroprotective (influence on synaptic plasticity processes), anti-inflammatory, antioxidant (suppression of oxidative stress in neurons and microglia), antinociceptive action, regulation of dopamine and serotonin transmission; optimal functioning of cortical neurons<br><br>brain.<br><br>**Positive clinical effect** - improved cognitive functioning; reduced risk of developing neurodegenerative, autoimmune neurological diseases, neuropsychological disorders; sleep disorders; reduced frequency and intensity of primary headaches (migraines) | >40 |

Continuation of Table 1

| Effects on various body systems | Mechanism of development and clinical effects | Estimated optimal level 25(OH)D (ng/ml) |
|---|---|---|
| Reproductive system [55–57] | Regulation of the expression of genes involved in the synthesis and metabolism of estrogen; increased aromatase production; regulation of the release of GnRH, LH, FSH; enhanced function of the corpus luteum and progesterone.<br>**Positive clinical effect** - normalization of the menstrual cycle, reduction in the prevalence and severity of PCOS, gestational diabetes, preeclampsia and premature birth | >40 |
| | Protection and prevention of ÿ-cell destruction, reduction of autoimmune damage by inhibiting proinflammatory cytokines (TNF-ÿ). ÿ-cells of the pancreas [58]<br>**Positive clinical effect** - reduced risk of earlier onset and more severe course of type 1 and type 2 diabetes | >50 |
| Vitamin D resistance [36–38] | Genetic or acquired resistance to vitamin D is a key pathogenic mechanism in autoimmune diseases, including psoriasis. Vitamin D regulates the function of keratinocytes, key cells in the pathogenesis of psoriasis.<br>**Positive clinical effect** - reduction in the prevalence and severity of autoimmune diseases, multiple sclerosis, psoriasis | ÿ80 |

**Note:** COPD — chronic obstructive pulmonary disease; GnRH — gonadotropin-releasing hormone; LH — luteinizing hormone; FSH — follicle-stimulating hormone; PCOS — polycystic ovary syndrome; TNF-ÿ — tumor necrosis factor-alpha.

a personalized approach with an emphasis on assessing the effects of vitamin D therapy in groups with varying degrees of deficiency.

## VITAMIN D STATUS CORRECTION

A 25(OH)D concentration range of 30–40 ng/mL can usually be achieved with vitamin D supplementation at doses of 2000–4000 IU/day. To achieve values above 40 ng/mL, higher doses of cholecalciferol are required in most cases [59]. Research results have shown that whole-body exposure to a single minimal erythematous dose of

simulated sunlight can result in the production of 10,000 to 25,000 IU of vitamin D in the skin [60]. Thus, it is logical to assume that such doses of vitamin D can be considered safe. This fact can be confirmed by the data from published studies that reported the safety of taking high doses of vitamin D. In particular, the results of observation of 3882 participants included in a study in Canada between 2013 and 2015 are publicly available and indicate the effects of taking vitamin D3 at a dose of up to 15,000 IU / day for 6-18 months. The aim of this study was to determine the doses of vitamin D required to achieve a concentration of 25 (OH) D> 40 ng / ml. It was found that to achieve the target concentration of 25 (OH) D, participants with a normal BMI should

Participants with overweight and obesity were advised to take at least 6000 IU of vitamin D per day, while overweight and obese participants were advised to take 7000 IU/day and 8000 IU/day, respectively. It is important to note that, in rare cases, serum 25(OH)D concentrations reaching 120 ng/ml were not associated with either calcium homeostasis disturbances or toxicity [61].

Also of interest are the results of another study in which 777 long-term hospitalized patients took 5,000 to 50,000 IU/day of vitamin D.

During the observation, it was found that the subgroup of patients taking vitamin D at a dose of 5000 IU/day achieved average 25(OH)D concentrations of 65±20 ng/ml after 12 months of therapy, while patients taking 10,000 IU/day achieved 25(OH)D levels of 100±20 ng/ml. It should be noted that none of the patients who achieved 25(OH)D concentrations in the range of 40–155 ng/ml developed hypercalcemia, nephrolithiasis, or any other symptoms characteristic of the clinical manifestations of vitamin D overdose [62]. It is also necessary to dwell on the results of the only open, multicenter, comparative, randomized, phase III clinical trial conducted in the Russian Federation, the purpose of which was to evaluate the efficacy and safety of therapy with

Fortedetrim, in comparison with therapy with Vigantol®, in patients with vitamin D deficiency [63]. The study involved 150 patients.

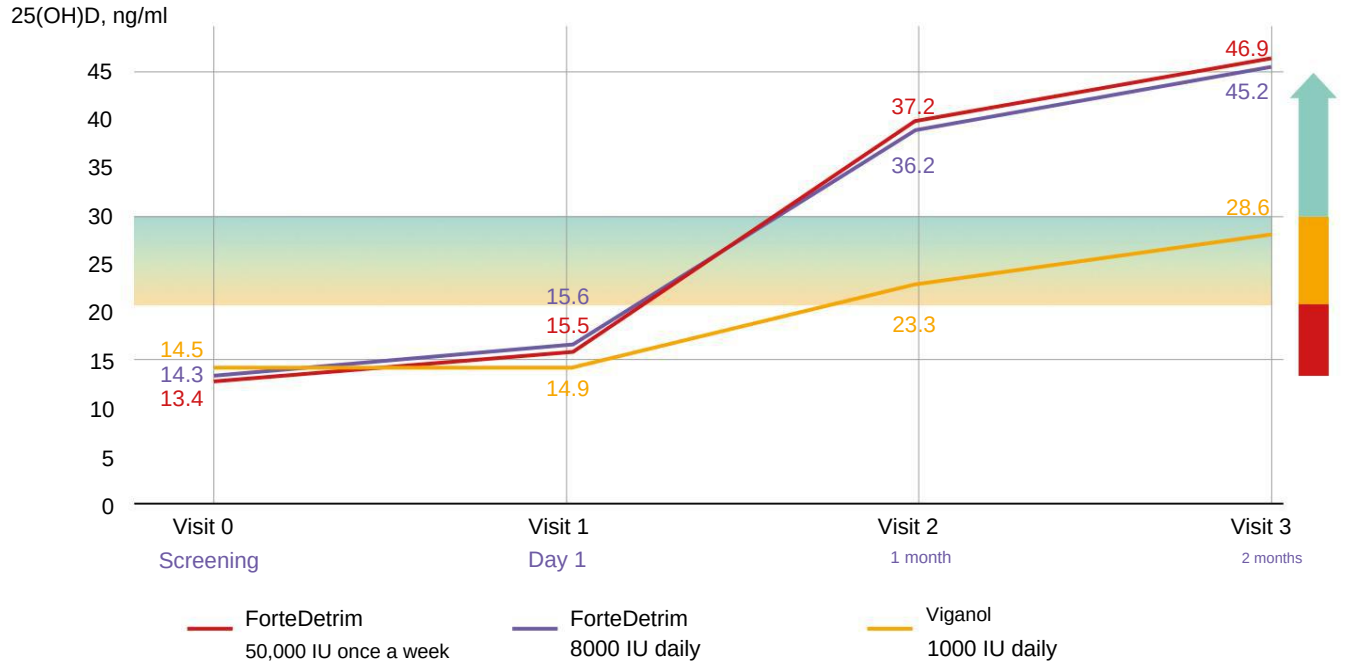


**Figure 1.** Changes in serum 25(OH)D concentration after 2 months of treatment for vitamin D deficiency [63].

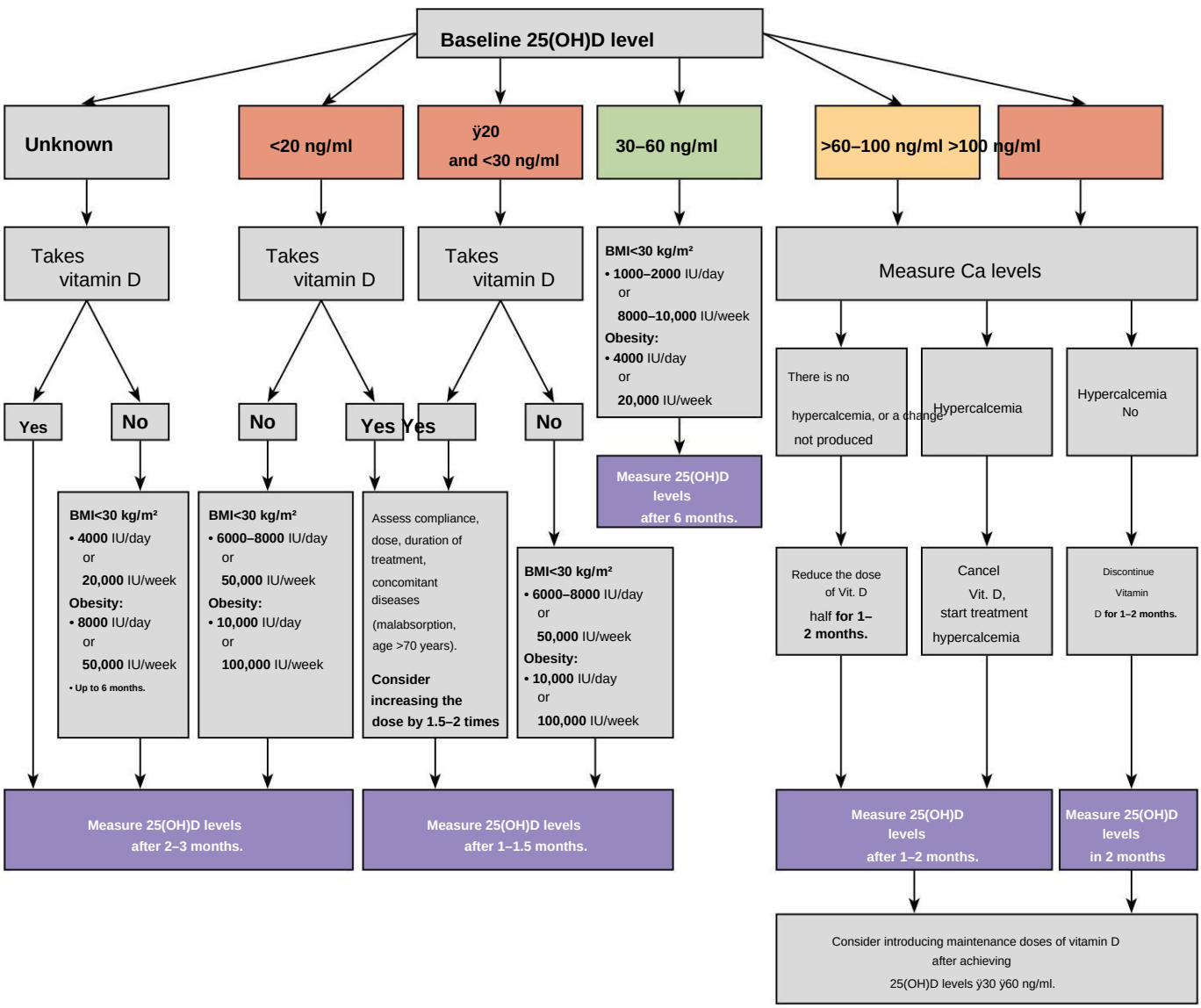


**Figure 2.** Algorithm for prescribing vitamin D preparations to achieve optimal 25(OH)D values in blood serum [2, 64].

subjects randomized into 3 groups (50 people each), in which Fortedetrim capsules were used for loading doses in groups 1(T) and 2(R), respectively, 50,000 IU once a week (5 capsules of 10,000 IU) and 8,000 IU daily (2 capsules of 4,000 IU), and in comparison group 3(X) — Vigantol® 1,000 IU daily (2 drops). Comparative treatment results are clearly demonstrated in the graph (Fig. 1).

As can be seen from the data presented in the graph, therapy with Fortedetrim at doses of 8000 IU daily or 50,000 IU once a week in groups 1 and 2, respectively, compared with the comparison group taking vitamin D at a dose of 1000 IU, not only led to a rapid increase in the level of 25(OH)D in the blood serum after a month of therapy, but was also not associated with a difference in the number and severity of undesirable and side effects [63]. Finally, it should be noted that today the need to eliminate vitamin D deficiency in the population remains relevant for healthcare, with the achievement of a concentration of 25(OH)D in the blood

serum of at least 20 ng/ml. For this, in addition to a healthy lifestyle, including proper nutrition and physical activity, it is necessary to take adequate doses of vitamin D supplements. The algorithm for prescribing vitamin D supplements depending on the initial level of 25(OH)D is presented in Figure 2.

## CONCLUSION

Given the abundant evidence of significant health benefits associated with achieving serum 25(OH)D levels above 30–40 ng/ml and the absence of side effects, it is advisable to take a responsible approach to the use of vitamin D supplements. Establishing individual threshold values

The selection of 25(OH)D levels for the pleiotropic and multimodal effects of vitamin D should take into account the nosology, age, weight, gender, and ethnicity of patients. Optimal serum 25(OH)D values are considered to be a

range from ÿ30 ng/mL to ÿ60 ng/mL; however, individuals with genetic or acquired resistance to vitamin D may need to exceed the upper limit. It is also necessary to consider that patients with certain pathological conditions, such as obesity and diabetes mellitus, as well as those taking medications that affect vitamin D metabolism, may require doses exceeding the general population therapeutic, maintenance, and prophylactic doses.

Thus, determining methods for achieving and maintaining optimal vitamin D levels in the blood should be based on an individualized approach, taking into account a range of factors and clinical data. These findings have important practical implications for endocrinology and related disciplines, contribute to the development of personalized medicine, and ensure improved prevention and treatment of diseases associated with vitamin D deficiency.

## ADDITIONAL INFORMATION

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