

## The Significant Gap in Iran's Pharmaceutical Market: Multivitamin/Mineral Supplements for Pediatric Patients with Chronic Kidney Disease

Z. Nazari Taloki (PhD)<sup>\*1</sup> 

1. Non-Communicable Pediatric Diseases Research Center, Health Research Institute, Babol University of Medical Sciences, Babol, I.R. Iran.

**\*Corresponding Author: Z. Nazari Taloki (PhD)**

**Address:** Non-Communicable Pediatric Diseases Research Center, Health Research Institute, Babol University of Medical Sciences, Babol, I.R. Iran.

**Tel:** +98 (11) 32199592. **E-mail:** zahra\_nazari\_taloki@yahoo.com

### Article Type

Letter to the Editor

**Received:** Jul 6<sup>th</sup> 2025, **Revised:** Sep 3<sup>rd</sup> 2025, **Accepted:** Oct 4<sup>th</sup> 2025

**Keywords:** *Chronic Kidney Disease (CKD), Pediatric, Growth and Development, Zinc, Dietary Supplements, Trace Elements, Micronutrients.*

**Cite this article:** Nazari Taloki Z. The Significant Gap in Iran's Pharmaceutical Market: Multivitamin/Mineral Supplements for Pediatric Patients with Chronic Kidney Disease. Journal of Babol University of Medical Sciences. 2026; 28: e42.

**Dear Editor**

Pediatric chronic kidney disease (CKD) is characterized by a persistent decline in renal function or evidence of kidney damage lasting more than three months, based on age-appropriate diagnostic criteria (1). Unlike adult CKD, pediatric cases frequently result from congenital abnormalities, predominantly congenital anomalies of the kidney and urinary tract (CAKUT). The incidence of CKD stages 2 to 5 among Iranian children has been reported at 3.34 cases per million annually (2). Children with CKD face multiple nutritional challenges, including malabsorption, dietary restrictions, and losses of vitamins during dialysis, resulting in deficiencies of both water-soluble and fat-soluble vitamins as well as trace minerals. These deficiencies adversely impact growth and development (3). The Pediatric CKD Nutrition Taskforce recommends that the nutritional status and growth of children with CKD stages 2 to 5, as well as those undergoing dialysis (stage 5D), be assessed regularly. Guidelines recommend receiving 100% of the Dietary Reference Intake (DRI) for key vitamins and minerals, including B-complex vitamins, vitamins A, C, D, E, and K, folic acid, copper, and zinc. In cases of inadequate dietary intake or confirmed deficiency, supplementation is recommended. In particular, children undergoing dialysis should regularly consume water-soluble vitamins (4). Existing evidence also emphasizes the periodic monitoring of serum vitamin and mineral levels in order to prescribe targeted supplements, optimize clinical outcomes, and reduce complications (5, 6).

With respect to fat-soluble vitamins, intake of vitamins A, K, and E should not exceed established DRIs; supplementation is reserved for documented deficiency or very low dietary intake (3, 4). Vitamin D supplementation is indicated when serum 25-hydroxyvitamin D levels fall below 30 ng/mL, using either ergocalciferol (D2) or cholecalciferol (D3). This approach leverages extra-renal enzymatic conversion to the active form, 1,25-dihydroxyvitamin D. Active vitamin D therapy is guided by factors including proteinuria severity, parathyroid hormone (PTH) levels, and serum calcium and phosphorus concentrations (4, 7, 8).

Anemia caused by iron and erythropoietin deficiencies is common in CKD patients; management depends on hemoglobin levels and involves oral or parenteral iron supplementation and erythropoiesis-stimulating agents (9). Recommended DRIs for copper and zinc should be followed, with routine serum zinc assessments in patients on protein-restricted diets (4, 7). Zinc deficiency can worsen anemia by limiting iron availability and erythroid progenitor function, whereas zinc excess may exacerbate anemia through impaired gastrointestinal iron absorption—either directly or by reducing copper bioavailability—and through induction of erythropoietin resistance (10).

A major concern in the Iranian pharmaceutical market is the absence of pediatric-specific multivitamin-mineral supplements for CKD, resulting in reliance on adult formulations that do not correspond to pediatric dosing requirements by age and sex (Table 1) (4). While this discrepancy may be less critical for water-soluble vitamins, the zinc content mismatch is especially significant. Adult multivitamin formulations typically contain approximately 25 mg of elemental zinc, which far exceeds the pediatric recommended intake of 2–11 mg across different age groups. Continued use may lead to metabolic complications, including impaired absorption of iron and copper and erythropoietin resistance (10). The latest Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines in 2020 advise against routine zinc supplementation without prior serum level monitoring, even in dialysis patients who are more likely to be deficient (7).

This manuscript highlights the significant gap in pharmaceutical formulations for pediatric CKD, with the clinical pharmacist author serving as an essential intermediary between clinical demands and pharmaceutical industry responses. Research and development departments of pharmaceutical companies must prioritize the design and production of pediatric-appropriate multivitamin/mineral supplements containing essential micronutrients at precisely calibrated dosages. Such interventions will adhere to pediatric nephrology guidelines and improve nutritional management and clinical outcomes for this vulnerable population.

**Table 1. Comparison of Recommended Dietary Allowances (RDAs) and Adequate Intakes (AIs), along with Tolerable Upper Intake Levels (ULs), for children (4), versus Iranian adult CKD multivitamin supplements and pediatric CKD multivitamin supplements available worldwide**

|                  | Infant       |               | Children      |               | Male          |               | Female        |               | CKD<br>Multivitamin<br>Supplement<br>for Adults in<br>Iran | CKD<br>Multivitamin<br>Supplement<br>for pediatrics<br>in the world |
|------------------|--------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|------------------------------------------------------------|---------------------------------------------------------------------|
|                  | 0-6<br>month | 7-12<br>month | 1-3<br>year   | 4-8<br>year   | 9-13<br>year  | 14-18<br>year | 9-13<br>year  | 14-18<br>year |                                                            |                                                                     |
| Vitamin A (µg)   | 400<br>(600) | 500<br>(600)  | 300<br>(600)  | 400<br>(900)  | 600<br>(1700) | 900<br>(2800) | 600<br>(1700) | 700<br>(2800) | 0                                                          | 0                                                                   |
| Vitamin C (mg)   | 40           | 50            | 15<br>(400)   | 25<br>(650)   | 45<br>(1200)  | 75<br>(1800)  | 45<br>(1200)  | 65<br>(1800)  | 60                                                         | 60                                                                  |
| Vitamin E (mg)   | 4            | 5             | 6<br>(200)    | 7<br>(300)    | 11<br>(600)   | 15<br>(800)   | 11<br>(600)   | 15<br>(800)   | 50                                                         | 0                                                                   |
| Vitamin K (µg)   | 2            | 2.5           | 30            | 55            | 60            | 75            | 60            | 75            | 0                                                          | 0                                                                   |
| Vitamin B1 (mg)  | 0.2          | 0.3           | 0.5           | 0.6           | 0.9           | 1.2           | 0.9           | 1             | 1.5                                                        | 1.5                                                                 |
| Vitamin B2 (mg)  | 0.3          | 0.4           | 0.5           | 0.6           | 0.9           | 1.3           | 0.9           | 1             | 1.7                                                        | 1.7                                                                 |
| Vitamin B3 (mg)  | 2            | 4             | 6 (10)        | 8 (15)        | 12<br>(20)    | 16<br>(30)    | 12<br>(20)    | 14<br>(30)    | 20                                                         | 20                                                                  |
| Vitamin B5 (mg)  | 1.7          | 1.8           | 2             | 3             | 4             | 5             | 4             | 5             | 10                                                         | 10                                                                  |
| Vitamin B6 (mg)  | 0.1          | 0.3           | 0.5<br>(30)   | 0.6<br>(40)   | 1<br>(60)     | 1.3<br>(80)   | 1<br>(60)     | 1.2<br>(80)   | 10                                                         | 10                                                                  |
| Vitamin B7 (µg)  | 5            | 6             | 8             | 12            | 20            | 25            | 20            | 25            | 300                                                        | 300                                                                 |
| Vitamin B9 (µg)  | 65           | 80            | 150<br>(300)  | 200<br>(400)  | 300<br>(600)  | 400<br>(800)  | 300<br>(600)  | 400<br>(800)  | 1000                                                       | 1000                                                                |
| Vitamin B12 (µg) | 0.4          | 0.5           | 0.9           | 1.2           | 1.8           | 2.4           | 1.8           | 2.4           | 6                                                          | 6-10                                                                |
| Copper (µg)      | 200          | 220           | 340<br>(1000) | 440<br>(3000) | 700<br>(5000) | 890<br>(8000) | 700<br>(5000) | 890<br>(8000) | 0                                                          | 0                                                                   |
| Selenium (µg)    | 15<br>(45)   | 20<br>(60)    | 20<br>(90)    | 30<br>(150)   | 40<br>(280)   | 55<br>(400)   | 40<br>(280)   | 55<br>(400)   | 0                                                          | 0                                                                   |
| Zinc (mg)        | 2<br>(4)     | 3<br>(5)      | 3<br>(7)      | 5<br>(12)     | 8<br>(23)     | 11<br>(34)    | 8<br>(23)     | 9<br>(34)     | 25                                                         | 0                                                                   |

**Conflict of Interest:** The author declares no conflicts of interest.

### **Acknowledgment**

I would like to express my gratitude and appreciation to the pediatric nephrologists in the Non-Communicable Pediatric Diseases Research Center at Amirkola Children's Hospital for their constant guidance.

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