September 20, 2021
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Emery Pharma's Citizen Petition

To Whom It May Concern:

The undersigned, on behalf of Najafi Pharma, Inc. dba Emery Pharma (collectively, "Emery Pharma" or "Petitioner"), submits this Citizen Petition ("Petition") pursuant to Sections 301(21 U.S.C. § 331), 502 (21 U.S.C. § 352), 505 (21 U.S.C. § 355), 702 (21 U.S.C. § 372), 704 (21 U.S.C. § 374), and 705 (21 U.S.C. § 375) of the Federal Food, Drug and Cosmetic Act (the "FDCA"), in accordance with 21 C.F.R. 10.20 and 10.30, to request the Commissioner of Food and Drugs ("Commissioner") to issue a regulation, revise industry guidance, and request a recall and suspend sales of Vitamin B6 from the US market and take such other actions set forth below.

A. Action Requested

Vitamin B6, also known as pyridoxine, is a water-soluble vitamin, extensively promoted as food supplement for health maintenance and wellness.[1] An established recommended dietary allowance (RDA) for Vitamin B6 is between 1.3-1.7 mg per day for most adults. It is well established that when taken in excess, Vitamin B6 can cause symptoms of peripheral neuropathy and neurotoxicity.[1,2] "Mega doses" (50-500 mg) of Vitamin B6 are widely available over the counter (OTC) at pharmacies such as Walgreens, CVS, Costco, Vitamin Shoppe, and on e-commerce sites such as Amazon. According to the NIH Office of Dietary Supplements, 28-36% of the US population reported use of supplements that contained Vitamin B6.[1,2]

The United Kingdom (UK), the European Food Safety Authority, and Australian regulatory agencies have established an upper daily limit of 10 mg, 25 mg, and 50 mg per day, respectively. Due to the adverse effect profile and considerable evidence in case reports and animal studies, we conclude that doses greater than 10 mg/day should be available by prescription only. For OTC products, it is crucial to allow a safety margin between doses that are readily available without a prescription, and doses where neurotoxicity occurs, in accordance with the UK's assessment.

Emery Pharma is petitioning the agency that once all evidence is considered and thoroughly reviewed, they will find Vitamin B6 is misbranded. Emery Pharma urges the Food and Drug Administration to implement safe guidelines for the use of this widely abused vitamin, including the below:

1) Ask manufacturers of Vitamin B6 or B-Complexes to include labeling regarding the potential toxicity of Vitamin B6. Labeling should include a warning to consumers to discontinue B6 supplementation if they experience signs or symptoms of toxicity.
    a. Suggested labeling: "***Warning***: *This medication may be dangerous when used in large amounts or for a long time. Stop taking this medication if you experience tingling, burning, or numbness and see your healthcare practitioner as soon as possible.*

2) Reclassify doses greater than 10 mg as "behind the counter", and available by prescription only, under the supervision of a physician with proper monitoring.

B. Background Information

Introduction:
Vitamin B6, also known as pyridoxine, is a water-soluble vitamin, extensively promoted as a food supplement for health maintenance and wellness.[1] It is naturally present in many foods, fruits, and vegetables. In the United States and other western countries, adults obtain most of their dietary vitamin B6 from fortified cereals, beef, poultry, starchy vegetables, and some non-citrus fruits (see Appendix A).[1] It can be purchased as a stand-alone supplement, included in B Complex vitamins, or present in multivitamins.

Vitamin B6 is a micronutrient required by the body. It plays a role in numerous enzymatic reactions, including neurotransmitter production, amino acid metabolism, glucose metabolism, lipid metabolism, hemoglobin synthesis and function, and gene expression. Additionally, during the COVID-19 pandemic, there have been numerous reports of Vitamin B6 reducing COVID-19 severity, without proper clinical data to substantiate these claims.[42] Pyridoxal-5'-phosphate (PLP) and pyridoxamine-5'-phosphate (PMP) are the active coenzyme forms of Vitamin B6. PLP is used to measure plasma concentrations of Vitamin B6 in a clinical setting.[1]

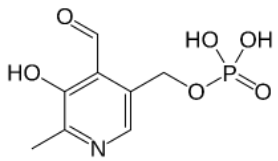
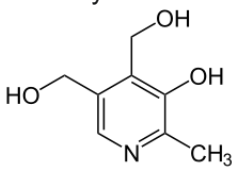
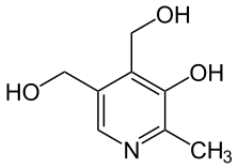
Recommended Intake:
According to the NIH Office of Dietary Supplements, an established recommended dietary allowance (RDA) for vitamin B6 is between 1.3-1.7 mg per day for most adults (See Appendix A).[1] According to an analysis of data from the 2003–2004 National Health and Nutrition Examination Survey (NHANES), most Americans consume adequate amounts of Vitamin B6 in their diets.[2] The average vitamin B6 intake is about 1.5 mg/day in women and 2 mg/day in men.[1,2] According to the NIH Office of Dietary Supplements, 28-36% of the US population reported use of supplements that contained Vitamin B6.[1,2]

Vitamin B6 Deficiency:
Vitamin B6 deficiency is commonly seen in conjunction with deficiency of other B complex vitamins. Isolated Vitamin B6 deficiency is uncommon in the United States and may be asymptomatic for months to years. Deficiency is associated with microcytic anemia, electroencephalographic abnormalities, dermatitis with cheilosis, glossitis, depression and confusion, and weakened immune function.[1,2] Clinically, serum Pyridoxal-5'-phosphate (PLP) is used to measure Vitamin B6 levels in patients. Lower than normal PLP values are often seen in individuals with renal insufficiency, alcohol dependence, obesity, pregnancy, and those with malabsorption syndromes such as celiac disease, Crohn's disease, and ulcerative colitis.[3]

Clinical Applications of B6 Supplementation:
Vitamin B6 supplementation has been discussed in the literature for various indications such as reducing cardiovascular disease risk, reducing the risk of colorectal cancer, improving cognitive function, depression, autism, Parkinson's Disease, reducing symptoms of premenstrual syndrome, and treating morning sickness in pregnant women. However, there is a lack of clinical evidence to support many of these claims in the literature. [4-20, 33] Furthermore, there is a significant lack of data to justify supplementation in individuals with adequate B6 levels, entirely.

Pharmacokinetic and Pharmacodynamic Profile:
Vitamin B6 is water-soluble and has a half-life of about 25-33 days in the body. It is absorbed by the mucosal cells of the small intestine and stored in the muscle, plasma, liver, red blood cells, and is protein-bound.[21, 22] Vitamin B6 primarily excreted renally as 4-pyridoxic acid, and in very high doses, excreted unchanged in the urine.
A majority of vitamin B6 sold in the United States is available in the following forms: A. Pyridoxyl-5'-Phosphate (aka: P-5-P), B. Pyridoxine or C. Pyridoxine hydrochloride (HCl), displayed in Figure 1.[1, 21]

Figure 1. Chemical Structure of Vitamin B6

A. Pyridoxyl-5'-Phosphate	B. Pyridoxine	C. Pyridoxine hydrochloride (HCl)
 *a more metabolically active form of B6*		 *a more soluble form of B6*

Safety, Toxicity, and Adverse Effect Profile:
Toxicity does not typically occur from dietary intake of B6. According to the NIH Office of Dietary Supplements, ingestion of 1–6 g oral pyridoxine per day for 12–40 months can

cause severe and progressive sensory neuropathy characterized by ataxia (loss of control of bodily movements).[1,2] The severity of symptoms appears to be dose-dependent, and depending on the dose and duration of therapy, may or may not be reversible. Because of the severity of adverse events, there have been limited studies to define the dose-response relationship in humans. Evidence for neuropathy in doses between 100-500 mg is largely present in case reports or observations in groups of patients, that were not subject to a proper double-blind, placebo-controlled evaluation. Case reports and animal studies provide significant evidence that prolonged over the counter supplementation without physician oversight may pose harm to individuals (see Appendix A).[24-30, 34-38] Notably, symptoms of Vitamin B6 toxicity mimic symptoms of B6 deficiency.

Parry and Bredesen (1985) reported a case series of 16 patients with sensory central-peripheral distal axonopathy, who had taken from 200 to 500 mg/day for prolonged periods. Bender (1989) reviewed the risks and benefits of B6 therapy and concluded that doses of "50 mg/day" and above must be considered potentially hazardous. The European Commission, Scientific Committee on Food evaluation (1993) concluded that "intakes greater than 500 mg/day are associated with neurological damage and intakes of more than 50 mg/day are potentially harmful in adults". Rats administered doses of 200 mg/kg for 12 weeks were observed to have axonopathy to the distal portion of sensory nerves.[39]

Guidance from International Regulatory Committees:
Several international regulatory agencies have set fourth guidance regarding B6 dosing, outlined in Figure 2, below. The safety profile of vitamin B6 has been evaluated by United Kingdom (UK) committee on toxicity of chemicals in food, consumer products and the environment, establishing an upper limit of 10 mg per day for B6 supplementation.[32] The recommendation was based on the data from studies in dogs, divided by a safety factor, and supported by the data from the study of Dalton and Dalton (1987), as well as other available human data. In 2000, the European Food Safety Authority set a tolerable upper intake level of 25 mg/day.[40] In 2008, the Australian Complementary Medicines Evaluation Committee recommended warning statements appear on products containing daily doses of 50 mg or more vitamin B6 to avoid potential adverse effects.[31]

"Mega doses" of Vitamin B6, ranging from 50-500 mg, are widely available over the counter in the United States (see Appendix A). Thereby resulting in an urgent need to establish safe guidelines and proper labeling for the use of this widely abused vitamin and reclassify doses >10 mg to be available by prescription only.

Figure 2: International Regulatory Agencies Vitamin B6 Dosing Guidelines

Regulatory Agency	Upper Limit (UL)*	Warning included on the label (Yes/No)
United Kingdom (UK) committee on toxicity of chemicals in food, consumer products and the environment	10 mg	No
European Food Safety Authority (EFSA)	25 mg	No
Australian Complementary Medicines Evaluation Committee	50 mg	Yes
Norwegian Scientific Committee for Food Safety (VKM)	25 mg	No
United States Food and Nutrition Board (FNB) of the Institute of Medicine	100 mg	No

***Upper Limit (UL):** reflects the maximum daily intake levels at which no risk of adverse health effects is expected for almost all individuals in the general population — including sensitive individuals—when the nutrient is consumed over long periods of time.*

C. Case Report

**The following case study was reported to Emery Pharma by local San Francisco based doctors:*

Case Study 1: Patient MN

Chief Complaint:
An otherwise healthy 63-year-old male presented with acute severe sensory peripheral neuropathy. Symptoms included intense heat sensitivity, burning dysesthesias, paresthesia (tingling in the hands and feet), and severe numbness of hands. The patient complained of extreme thirst, frequent urination, with mild facial flushing.

Past Medical History:
The patient had no significant past medical history. The patient had reported recently initiating daily multivitamins, including Vitamin B6 supplements (100 mg per day) 10 months prior. The subject's symptoms began as a "mild burning sensation" of hands and feet in mid-May 2021 and with progressively worsening by mid-June 2021.

Current Medications:
Atorvastatin 40 mg daily- started in 2017
Lisinopril 10 mg daily- started in 2019
Vitamin-B6 100 mg daily- started July 2020

Differential Diagnosis Included:
Diabetic Neuropathy, a pinched nerve, vitamin deficiencies, Guillain-Barré syndrome (GBS), Raynaud's Syndrome, Carpal tunnel syndrome, Multiple Sclerosis

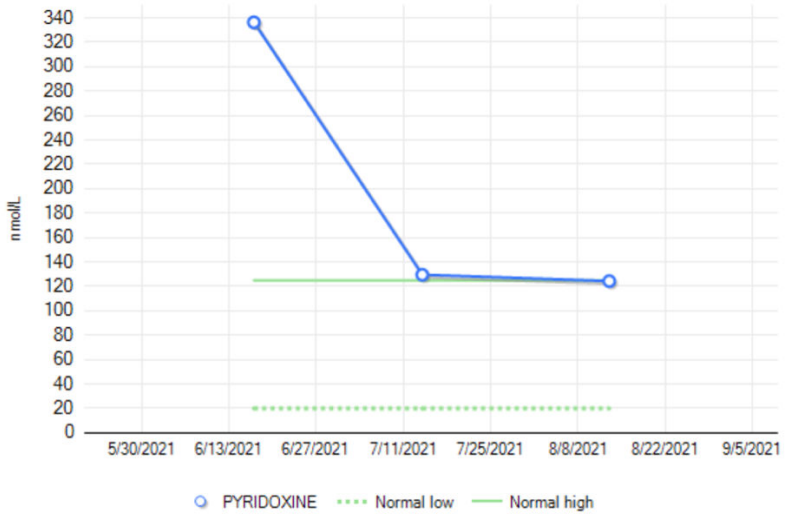
The following laboratory tests were performed (June 17, 2021):

- Complete blood count (CBC)
- Protein electrophoresis interpretation serum
- Serum protein electrophoresis
- Hemoglobin A1C
- Fasting blood glucose
- Fasting Lipid Panel
- C-Reactive protein
- Vitamin B1 (Thiamine)
- **Vitamin B6 (pyridoxine)***
  - Normal: 20-125 nmol/L
  - Result: **336.5 nmol/L**
- Vitamin B12 (cobalamin)
- Vitamin D (25-OH)
- thyroid-stimulating hormone (TSH)
- Prostate Specific Antigen (PSA)

All laboratory values were within normal limits, with the exception of vitamin B6, which was ~ 5x the median normal range.

The patient discontinued Vitamin B6 and continued to experience symptoms for the first 30 days. The subject was advised to avoid any multivitamins and foods with a high Vitamin B6 content. At this time, there is not enough data to determine whether or not the patient's neuropathic symptoms will be reversible. Upon filing of this Citizen Petition, the subject's B6 level is ~ 124 nmol/L and 80% of the neuropathy have subsided, and heat sensitivity symptoms persist.

Figure 3: Patient MN's Vitamin B6 Levels Over Time



Serum Pyridoxine Results (nmol/L)
Normal Range: 20-125
June 17, 2021: 336.5
July 14, 2021: 129.6
August 13, 2021: 124.4

D. Conclusion

Without question, when taken in excess, Vitamin B6 can cause peripheral neuropathy and neurotoxicity. The lowest dose reported to cause adverse effects, by Dalton and Dalton, is 50 mg.[30] Although this study lacks proper methodology and comparative placebo-controlled data, when presented alongside various case reports and animal studies, the evidence presented cannot be ignored. Especially with regard to safety of vitamins, as they are widely available over the counter. The possibility that many cases of Vitamin B6 neurotoxicity have gone undetected or have been misdiagnosed as "idiopathic neuropathy" cannot be excluded. Emery Pharma is petitioning the FDA to require proper labeling of vitamin B6 and B complexes (outlined in Section A). Additionally, it is prudent for the agency to request all manufacturers to voluntarily recall B6 supplements to include warning labels for consumers. Doses greater than 10 mg should be sold "behind the counter", with a prescription and under the supervision of a physician. When considering the consequences of inaction and the health of the public, we hope that the FDA will follow these recommendations.

E. Statement of Grounds

Due to the COVID-19 pandemic, Americans are turning to vitamins and supplements to boost immune function. The percentage of supplement users in the United States has increased from 47% to 76%.[43] Prior to the pandemic, 28-36% percent of the US population reported use of supplements that contained vitamin B6.[1,2] More than half of Americans believe that Vitamins and Supplements available OTC have been evaluated by the FDA. Nearly one-third believe that if a supplement has a potential for toxicity, it would not be sold in the US.[43]

High doses of Vitamin B6, ranging from 50-500 mg are widely available over the counter (OTC) at pharmacies such as Walgreens, CVS, Costco, Vitamin Shoppe. To prevent neurotoxicity and potential harm to the general population, Emery Pharma strongly advises imposing an upper intake level of 10 mg per day, in accordance with the United Kingdom's regulatory agencies. Given the lack of data to support supplementation in patients without B6 deficiency, and the potential for harm, it is necessary for the FDA to take action.

There is existing precedence for this recommendation, in the case of Vitamin D supplementation. Vitamin D3 is available in 400 IU, 800 IU, 1000 IU, 2000 IU, 5000 IU, 10,000 IU, over the counter. Due to the adverse effect profile and risk of hypercalcemia, patients prescribed 50,000 IU require a prescription and lab monitoring under the supervision of a physician.[41] This principal should be applied in the case of Vitamin B6. Amidst the COVID-19 pandemic, the US healthcare system is overburdened, and Americans have turned to vitamins and dietary supplements more than ever. At Emery Pharma, our goal is to utilize our bioanalytical and pharmacological expertise to help protect the health and wellness of Americans.

F. Environmental Impact

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.30, and believes that this Petition qualifies for a categorical exclusion from the requirement to submit an environmental assessment or environmental impact statement.

G. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information will be submitted by the Petitioner only upon request of the Commissioner following review of this Petition.

H. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all the information and views on which the petition relies, and that it

includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

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Appendix A.

Table 1: Recommended Dietary Allowances (RDAs) for Vitamin B6 [1]

Age	Male	Female	Pregnancy	Lactation
Birth to 6 months	0.1 mg*	0.1 mg*		
7–12 months	0.3 mg*	0.3 mg*		
1–3 years	0.5 mg	0.5 mg		
4–8 years	0.6 mg	0.6 mg		
9–13 years	1.0 mg	1.0 mg		
14–18 years	1.3 mg	1.2 mg	1.9 mg	2.0 mg
19–50 years	1.3 mg	1.3 mg	1.9 mg	2.0 mg
51+ years	1.7 mg	1.5 mg		

* Adequate Intake (AI)

Sources of Vitamin B6 in Our Diets

Table 2: Vitamin B6 Content of Selected Foods[1]

Food	Milligrams (mg) per serving	Percent DV*
Chickpeas, canned, 1 cup	1.1	65
Beef liver, pan fried, 3 ounces	0.9	53
Tuna, yellowfin, fresh, cooked, 3 ounces	0.9	53
Salmon, sockeye, cooked, 3 ounces	0.6	35
Chicken breast, roasted, 3 ounces	0.5	29
Breakfast cereals, fortified with 25% of the DV for vitamin B6	0.4	25
Potatoes, boiled, 1 cup	0.4	25
Turkey, meat only, roasted, 3 ounces	0.4	25
Banana, 1 medium	0.4	25
Marinara (spaghetti) sauce, ready to serve, 1 cup	0.4	25
Ground beef, patty, 85% lean, broiled, 3 ounces	0.3	18
Waffles, plain, ready to heat, toasted, 1 waffle	0.3	18
Bulgur, cooked, 1 cup	0.2	12
Cottage cheese, 1% low-fat, 1 cup	0.2	12
Squash, winter, baked, ½ cup	0.2	12
Rice, white, long-grain, enriched, cooked, 1 cup	0.1	6
Nuts, mixed, dry-roasted, 1 ounce	0.1	6
Raisins, seedless, ½ cup	0.1	6
Onions, chopped, ½ cup	0.1	6

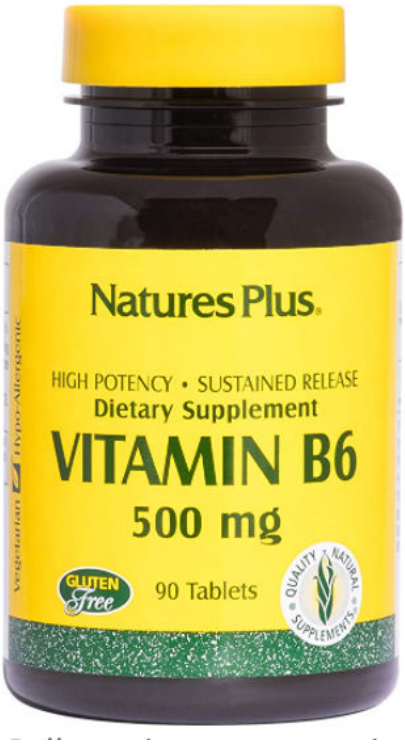
Table 2: Vitamin B6 Content of Selected Foods[1]

Food	Milligrams (mg) per serving	Percent DV*
Spinach, frozen, chopped, boiled, ½ cup	0.1	6
Tofu, raw, firm, prepared with calcium sulfate, ½ cup	0.1	6
Watermelon, raw, 1 cup	0.1	6

**DV = Daily Value*

Table 3: Widely Available Over the Counter (OTC) Vitamin B6 Products in "Mega Doses"

Product Name	Retailer	Strength (mg)	Daily Value for 1 serving (%)
Nature Made	Walgreens Rite Aid Target Costco CVS	100 mg	5882%
The Vitamin Shoppe	The Vitamin Shoppe	100 mg	5882%
Nature's Bounty	Walmart Amazon.com Walgreens	100 mg	5882%
Natures Plus	Amazon.com	500 mg	25,000%
Source Natural	Amazon.com Evitamins.com	500 mg	29,412%
Best Naturals	Amazon.com	200 mg	11,764%
Solgar	Vitamin Shoppe Amazon.com	250 mg	14,706%



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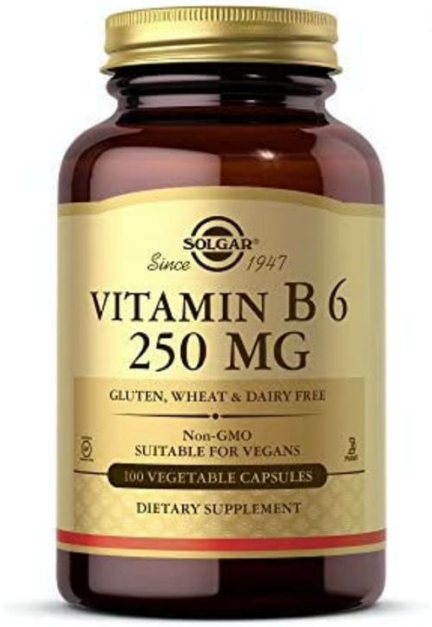
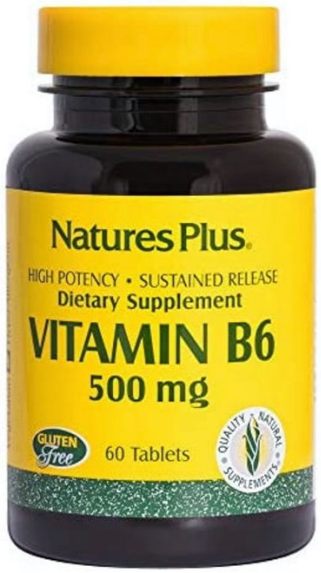
SOURCE NATURALS®
DIETARY SUPPLEMENT
B-6
500 MG • 100 TABLETS
Suggested Use: 1 tablet daily. Do not exceed suggested use.
NOTE: If you are pregnant, may become pregnant, or breastfeeding, consult your health care professional before using this product.
Do not use if either tamper-evident seal is broken or missing. Keep out of the reach of children.
Suitable for vegetarians. Contains no yeast, dairy, egg, gluten, corn, soy or wheat. Contains no sugar, starch, preservatives, or artificial color, flavor or fragrance.
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.
SN0416 REV A201
Supplement Facts
Serving Size 1 Tablet
Amount Per Serving %DV
Vitamin B-6 (as pyridoxine HCl) 500 mg 29,412%
Other ingredients: dibasic calcium phosphate, stearic acid, modified cellulose gum, silica, and magnesium stearate.
Vitamin B-6 is an essential nutrient required for the metabolism of lipids, carbohydrates, and proteins. It facilitates the conversion of amino acids from one to another as needed, and is necessary for normal synthesis of hemoglobin, as well as for the normal function and growth of red blood cells. It is also needed for the synthesis of neurotransmitters and for converting essential fatty acids into prostaglandins (chemical messengers).*


SOLGAR
Since 1947
VITAMIN B 6
250 MG
GLUTEN, WHEAT & DAIRY FREE
Non-GMO
SUITABLE FOR VEGANS
100 VEGETABLE CAPSULES
DIETARY SUPPLEMENT


SUGGESTED USE: As a dietary supplement for adults, take one (1) vegetable capsule daily, preferably with a meal or as directed by a healthcare practitioner.
Supplement Facts
Serving Size: 1 Vegetable Capsule
Amount Per Serving %DV
Vitamin B6 250 mg 14,706%
(as pyridoxine HCl)
DV = Daily Value
Other Ingredients: Vegetable Cellulose, Microcrystalline Cellulose, Vegetable Magnesium Stearate.
GMO
Non-GMO
Vegan
GF
Gluten Free
Dairy Free
Kosher
Halal



Supplement Facts

Serving size: 1 tablet
Servings per container: 120

	Amount per serving	%Daily Value
Vitamin B-6 (as pyridoxine hydrochloride)	200 mg	11764%

Other Ingredients: Dicalcium phosphate, cellulose, silica, vegetable magnesium stearate, stearic acid, croscarmellose sodium.

CAUTION: For adults only, if you are pregnant, nursing, taking any medications or have any medical condition, consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur.

No Artificial Color, Flavor or Sweetener, No Preservatives, No Sugar, No Starch, No Corn, No Soy, No Egg, No Lactose, No Gluten, No Wheat, No Yeast, No Fish.

Manufactured for Best Naturals,
PO Box 394, Kenilworth NJ 07033 USA
www.shopbestnaturals.com
For additional information call 1-877-659-6004
Lot# Exp#

Table 4. EFSA's Case Reports of Neuropathy in Patients Taking High Doses of Vitamin B6 [39]

Dose (g/day)	Duration (months)	Reference
0.1-0.2	36	Parry and Bredersen (1985)
0.1-2.5	9	Parry and Bredersen (1985)
0.1-4.0	72	Parry and Bredersen (1985)
0.2-0.5	24	Berger and Schaumburg (1984)
0.5	8	Parry and Bredersen (1985)
0.5	24	Parry and Bredersen (1985)
0.5-2.0	3	Parry and Bredersen (1985)
1.0	12	Waterson and Gilligan (1987)
1.0-2.0	36	Parry and Bredersen (1985)
1.5-2.0	24	Parry and Bredersen (1985)
1.5-2.5	>12	Parry and Bredersen (1985)
2.0	24	Friedman *et al* (1986)
2.0	12	Parry and Bredersen (1985)
2.0	12	Parry and Bredersen (1985)
2.0	4	Schaumburg *et al* (1983)
2.0	34	Schaumburg *et al* (1983)
2.0	40	Schaumburg *et al* (1983)
2.0-3.5	10	Parry and Bredersen (1985)
2.0-4.5	>12	Parry and Bredersen (1985)
2.0-5.0	2	Parry and Bredersen (1985)
2.0-5.0	4	Parry and Bredersen (1985)
3.0	4	Schaumburg *et al* (1983)
3.5	1	Parry and Bredersen (1985)
4.0	10	Schaumburg *et al* (1983)
5.0	2	Schaumburg *et al* (1983)
6.0	3	Schaumburg *et al* (1983)

Appendix B
Independent Testimonial from Ilkcan Cokgor, MD, Neurologist.

ILKCAN COKGOR, MD
NEUROLOGY CLINIC OF MARIN
50 RED HILL AVENUE, SAN ANSELMO, CA 94960

08/30/2021

To whom it may concern,

I have been practicing general neurology for the last 30 years. I am located right now in Marin County, California, where many residents are health conscientious. They take many vitamins for various reasons like anti-aging, heart and brain health, and arthritis. I see patients with peripheral neuropathy which means numbness and tingling of feet with or without weakness. This is a common condition in people older than 60 years of age. It has many reversible causes but it could be purely idiopathic or age-related. I order blood work to check different vitamin levels, diabetes, thyroid disease, cancer, and autoimmune disorders in everyone I diagnose with peripheral neuropathy. Lately, I have been seeing more and more young and middle-aged people with painful numb feet and sometimes hands. These patients have no prior history of any chronic or acute illnesses, they are healthy young people. Yet, they suddenly develop numb feet or bodies associated with burning pain and abnormal sensations. When I work them up, I notice that their labs show very high vitamin B6 levels with no other illnesses or other lab abnormalities.

Vitamin B6 toxicity is a well-known cause of peripheral neuropathy to neurologists. It causes very painful numbness of the feet and hands. It can cause balance and gait problems as well. However, public doesn't know it. Unfortunately, many people regardless of their ages, weights, and medical conditions, take different vitamins like multivitamins or B complex which contain very high doses of B6. Many of these vitamin complexes include larger than approved or required doses of B6. These vitamins are not regulated by FDA and they may contain ingredients that may conflict with pharmaceutical medications or medical conditions. I believe the public is getting harmed by overdosing themselves with unnecessarily high doses of vitamin B6. I have many patients I see with neuropathy symptoms who get better after they stop taking their vitamins. I strongly recommend that vitamin B6-containing supplements should be monitored or should have warning signs about possible B6 toxicity.

Sincerely,

Ilkcan Cokgor, MD

References

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