

CARDIOTEK-RX- bioperine, folic acid, l-arginine hcl, vitamin b-12, vitamin b6 tablet, coated
SJ PHARMACEUTICALS, LLC

CARDIOTEK-RX

DESCRIPTION:

Cardiotek®-RX is a multi-B arginine supplement containing essential cofactors in reducing elevated homocysteine levels.

DESCRIPTION:

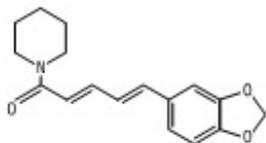
Each orange, football-shaped coated tablet contains:

Bioperine® (Black Pepper Extract) 5 mg
Folic Acid 2 mg
L-Arginine HCl 500 mg
Cyanocobalamin (Vitamin B12) 500 mcg
Pyridoxine (Vitamin B6) 50 mg

Also contains the following inactive ingredients:

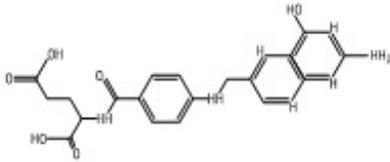
croscarmellose sodium, dicalcium phosphate, FD&C yellow no. 6 aluminum lake, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, stearic acid, titanium dioxide, triacetin. Cardiotek®-RX tablets are free of sugar, lactose and gluten.

Bioperine® increases bioavailability of folic acid, Vitamin B6, and Vitamin B12, and has the following chemical structure:

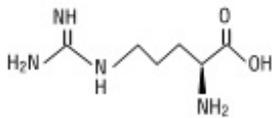


Folic Acid is yellowish-orange crystal. The chemical name is N-[4[[(2-Amino-1, 4-dihydro-4-oxo-6-pteridiny)methyl] amino]benzoyl]-L-glutamic acid. Its empirical formula is C₁₉H₁₉N₇O₆.

The use of supplemental folic acid may be indicated in patients with increased requirements for this vitamin. Folic acid administration may reduce the risk of neural tube defects in the developing fetus. Folate as 5-methyltetrahydrofolate and Vitamin B12 as methylcobalamin participate in the remethylation reaction of homocysteine to methionine.



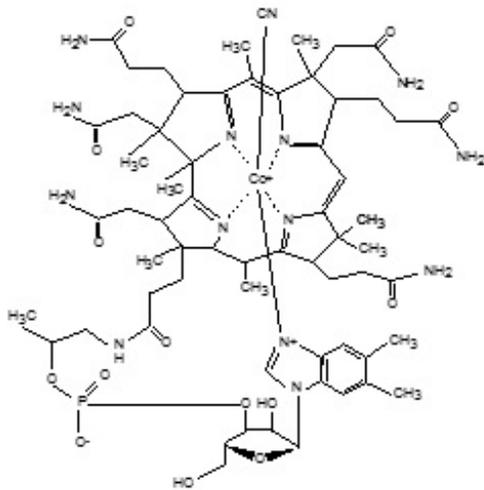
L-Arginine is a basic amino acid with the molecular formula $C_6H_{14}N_4O_2$ and with a molecular weight of 174.20. It has 3 pKs: $pK_1=2.18$, $pK_2=9.09$ and $pK_3=13.2$. Therefore, it carries a positive charge at physiological pH. The stereoisomer of L-arginine, D-arginine, does not have any biological activity, as far as we know. L-Arginine is also known as 2-amino-5- guanidinovaleric acid and (S)-2-amino-5- [(aminoiminomethyl) amino] pentanoic acid. Its one-letter abbreviation is R. It is also abbreviated as Arg. The terms L-arginine and arginine are frequently used interchangeably. The structural formula of L-arginine is as follows:



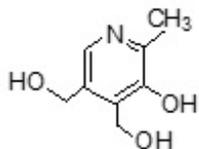
L-Arginine shows promise as a nutritional adjunct in patients undergoing treatment for cardiovascular disease (including atherosclerosis, hypertension, hyperlipidemia and angina pectoris), some forms of male infertility and some kidney disorders and for wound healing in some circumstances. There is preliminary evidence that it could be helpful as a nutritional adjunct in some men undergoing treatment for erectile dysfunction and in some others being treated for migraine, liver disease and primary ciliary dyskinesia. There is conflicting but mostly negative evidence related to claims that it can improve exercise performance and promote lean muscle mass.

Cyanocobalamin (Vitamin B12)

appears as dark red crystals or crystalline red powder. The chemical name is 5,6-dimethylbenzimidazolyl cyanocobamide. Its empirical formula is $C_{63}H_{88}CoN_{14}O_{14}P$. The structural formula of Cyanocobalamin is as follows:



Pyridoxine (Vitamin B6) is a colorless or white crystal or a white crystalline powder. It is stable in air and is slowly affected by sunlight. The chemical name is 2-methyl-3-hydroxy-4,5-bis(hydroxymethyl)pyridine. Pyridoxine's empirical formula is $C_8H_{11}NO_3$. A pyridine derivative, $C_{18}H_{11}NO_3$, occurring especially in cereals, yeast, liver, and fish and serving as a coenzyme in amino acid synthesis.



PRECAUTIONS:

Folic acid in doses above 1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. An oral dose of 100-250 mcg/day will maintain adequate serum Vitamin B12 levels in most patients with pernicious anemia, although some patients may require as much as 1,000 mcg/day. Those

with renal or hepatic failure should exercise caution in the use of supplemental L-arginine. Proteins of the herpes simplex virus are rich in L-arginine, and there are a few reports (mainly anecdotal) of those taking supplemental L-arginine who have had recurrences of oral herpes lesions. Although it is unlikely that those with a history of herpes simplex virus infection will have recurrences if they use L-arginine supplements, they should nevertheless be aware of this possibility.

DOSAGE AND ADMINISTRATION:

Adult dosage 1 to 2 tablets daily, or as prescribed by a physician or practitioner.
Not recommended for use in pediatrics.

WARNING:

Keep this and all medicine out of the reach of children.
is a registered trademark of Sabinsa Corporation. Patent Numbers: 6,849,645/5,972,382/5,744,161/5,536,506/6,054,585

Rx only

Distributed by:
SJ Pharmaceuticals, LLC
1212 Collier Road NW
Atlanta, GA 30318
Rev. 10/17 7102

NDC 24839-333-30

**CARDIOTEK®-RX TABLETS
Multi-B and Arginine Supplement**

Each tablet contains:
Bioperine® (Black Pepper Extract) .. 5 mg
Folic Acid 2 mg
L-Arginine HCl 500 mg
Vitamin B12 500 mcg
Vitamin B6 50 mg

SJ Pharmaceuticals, LLC

Rx only CONTENTS: 30 Tablets

DOSAGE AND ADMINISTRATION:

Adult dosage 1 to 2 tablets daily, or as prescribed by a physician or practitioner.
Not recommended for use in pediatrics.

**KEEP THIS AND ALL MEDICINE
OUT OF THE REACH OF CHILDREN.**

Pharmacist: Dispense in a tight, lightresistant container as defined in the USP/NF with a child resistant closure. Store at room temperature 15°C to 30°C (59°F-86°F). **BIOPERINE®** is a registered trademark of Sabinsa Corporation.

Patent Numbers: 6,849,645/5,972,382/

5,744,161/5,536,506/6,054,585

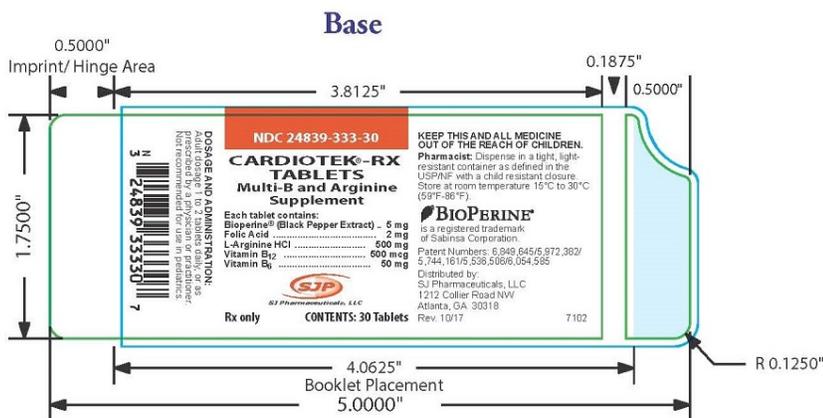
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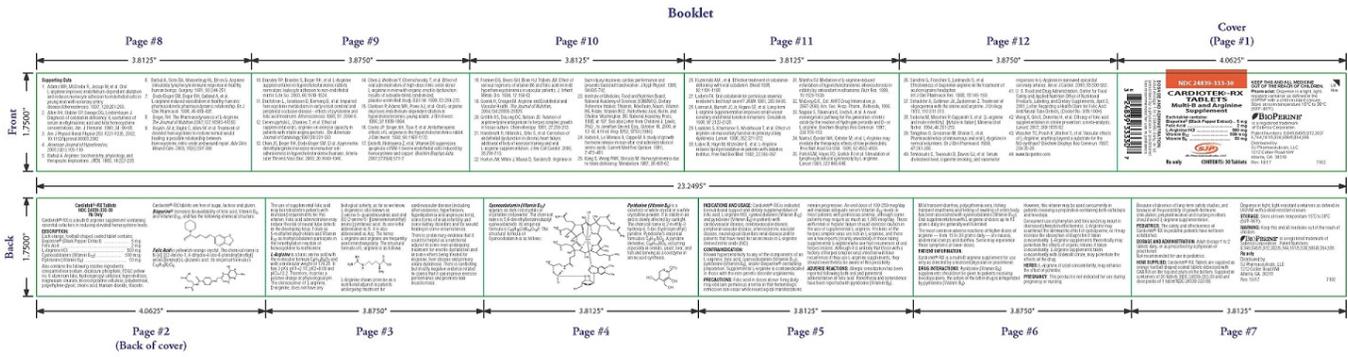
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Atlanta, GA 30318

Rev. 10/17





CARDIOTEK-RX

bioperine, folic acid, l-arginine hcl, vitamin b-12, vitamin b6 tablet, coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:24839-333
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BLACK PEPPER (UNII: KM66971LVF) (BLACK PEPPER - UNII:KM66971LVF)	BLACK PEPPER	5 mg in 58 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	2 mg in 58 mg
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	.5 mg in 58 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	.5 mg in 58 mg
PYRIDOXINE (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	50 mg in 58 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24839-333-30	1740 mg in 1 BOTTLE		
2	NHRIC:24839-333-99	58 mg in 1 DOSE PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		05/01/2008	

Supplement Facts

Serving Size : **Serving per Container :**

Amount Per Serving **% Daily Value**

color

shape	
imprint	
scoring	1
size (solid drugs)	8 mm

Labeler - SJ PHARMACEUTICALS, LLC (845662720)

Registrant - NEXGEN PHARMA (040488621)

Establishment

Name	Address	ID/FEI	Business Operations
NEXGEN PHARMA		040488621	manufacture(24839-333)

Revised: 4/2018

SJ PHARMACEUTICALS, LLC