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PHYSICIANS'  
DESK  
REFERENCE  
FOR NONPRESCRIPTION  
DRUGS AND  
DIETARY SUPPLEMENTS™

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Gail Verbano, CSR, CRR, RDR

# PHYSICIANS' DESK REFERENCE FOR NONPRESCRIPTION DRUGS AND DIETARY SUPPLEMENTS™

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**CANCER, NUTRIENTS DEFICIENCY SECONDARY TO**

Cancer may be treated with chemotherapeutic agents. The following products may be recommended for relief of nutrients deficiency:

|   |     |
|---|-----|
| Bugs Bunny Children's Chewable Multivitamin Plus Iron Supplement.....                           | 823 |
| Bugs Bunny Complete Children's Chewable Multivitamin/ Multimineral Supplement (Sugar Free)..... | 823 |
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| Sunkist Children's Chewable Multivitamins - Plus Extra C.....                       | 843 |
| Theragran-M Caplets.....  | 830 |

**CANDIDIASIS, VAGINAL**

May be treated with antifungal agents. The following products may be recommended for relief of symptoms:

|  |     |
|--|-----|
| Massengill Baby Powder Scent Soft Cloth Towelette..... | 756 |
| Massengill Disposable Douches.....                     | 756 |
| Massengill Feminine Cleansing Wash.....                | 756 |
| Massengill Medicated Disposable Douche.....            | 757 |

**CONGESTIVE HEART FAILURE, NUTRIENTS DEFICIENCY SECONDARY TO**

Congestive heart failure may be treated with ACE inhibitors, cardiac glycosides or diuretics. The following products may be recommended for relief of nutrients deficiency:

|  |     |
|--|-----|
| Centrum Tablets.....                             | 834 |
| Centrum Silver Tablets.....                      | 835 |
| One-A-Day Essential Multivitamin Supplement..... | 826 |
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**CONSTIPATION**

May result from the use of ACE inhibitors, HMG-CoA reductase inhibitors, anticholinergics, anticonvulsants, antidepressants, beta blockers, bile acid sequestrants, butyrophenones, calcium and aluminum-containing antacids, calcium channel blockers, ganglionic blockers, hematinics, monoamine oxidase inhibitors, narcotic analgesics, nonsteroidal anti-inflammatory drugs or phenothiazines. The following products may be recommended:

|                                   |     |
|-----------------------------------|-----|
| Ceo-Two Evacuant Suppository..... | 618 |
| Citrucel Orange Flavor.....       | 748 |

|  |     |
|--|-----|
| Citrucel Sugar Free Orange Flavor.....                           | 748 |
| Colace.....  | 736 |
| Correctol Laxative Tablets and Caplets.....                      | 743 |
| Correctol Stool Softener Laxative Soft Gel Tablets.....          | 743 |
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**CYSTIC FIBROSIS, NUTRIENTS DEFICIENCY SECONDARY TO**

Cystic fibrosis may be treated with dornase alfa. The following products may be recommended for relief of nutrients deficiency:

## EMSE® Vitamins, Antioxidants

**Description:** 100% natural-source vitamin E (d-alpha tocopheryl acetate) soft gel capsules. Available in 8 strengths: 30IU, 100IU, 200IU, 400IU, 600IU, 800IU, 1000IU, 1200IU.

**How Supplied:** Supplied in a variety of bottle sizes. Also in creams, ointments, gels, and more.

## Tri-B

**Description:** Tri-B is an nutritional supplement designed to help maintain normal blood levels of Homocysteine. Based upon research in popular medical journals, plasma Homocysteine levels may be involved in the hardening and narrowing of the arteries. Tri-B contains three prominent B Vitamins, B-12, B-6 and Folic Acid.

**One Small Tablet contains:**

|                                      |        |
|--------------------------------------|--------|
| Vitamin B-12 (Cobalamin Concentrate) | 400mcg |
| Vitamin B-6 (Pyridoxine HCL)         | 25mg   |
| Tablet (Folic Acid)                  | 800mcg |

**How Supplied:** Supplied in bottles of 120 and 360

## EDUCATIONAL MATERIAL

"Don't be fooled" is a free 5 page consumer brochure on the difference between natural and synthetic vitamin E. "Help your body fight free radicals" is a free 4 page consumer brochure explaining antioxidants.

## Cooke Pharma

1404 OLD COUNTRY ROAD  
BELMONT, CA 94002

**Direct Inquiries to:**  
Customer Service Dept.  
(888) 808-6838

## HEARTBAR™

L-arginine-enriched  
Medical Food

**Description:** The HeartBar™ is a formulation of nutrients and vitamins for the dietary management of vascular disease. These ingredients are placed in a convenient and pleasant-tasting nutrition bar. The major active ingredient in the HeartBar is L-arginine, which is an amino acid required for the production of nitric oxide (NO). Each 50g bar contains L-arginine (3.3 g) and other amino acids, folate (200 µg) and other B-complex vitamins, antioxidant vitamins E (200 IU) and C (250 mg), niacin (25 mg) and phytoestrogens. These nutrients are combined in a fruit, fiber, and soy protein-based nutrition bar. One HeartBar contains 13 g of protein, 27 g of carbohydrate (20 g of sugars, 3 g of fiber), 3 g of fat (1 g saturated fat, 0 mg of cholesterol), and is 190 calories.

**Composition (original flavor):** High fructose corn syrup, soy protein isolate, fructose, toasted soy pieces, raisins, vanilla cookie pieces, L-arginine HCl, natural and artificial flavors, oat fiber, DL-alpha-tocopherol acetate, sodium ascorbate, dipotassium phosphate, niacinamide, cyanocobalamin, pyridoxine hydrochloride, folic acid.

**Clinical Background:** The major active ingredient of the HeartBar, L-arginine, is a semi-essential amino acid, and is the precursor for endothelium-derived nitric oxide (NO). NO is a potent vasodilator, and a major regulator of vasomotion and blood pressure. In addition, NO inhibits platelet aggregation, vascular smooth muscle proliferation and adherence of leukocytes to the vessel wall, key processes in atherosclerosis and restenosis.

Endothelium-derived NO activity is reduced in patients with cardiovascular disease; this abnormality contributes to insufficient blood flow, elevated blood pressure, as well as progression of disease. L-arginine has been shown to enhance the synthesis of NO. In humans, L-arginine improves vasodilation, enhances coronary and peripheral blood flow, and inhibits platelet aggregation.

The usual dietary intake of L-arginine is about 5 g/day, which in some cardiovascular conditions, may not be sufficient intake to maintain healthy NO levels. Two HeartBar/day provides an additional 6.6 g of L-arginine. The other active ingredients of the HeartBar contribute to the production of, or help prevent the breakdown of NO further augmenting the activity of NO.

The HeartBar has been tested clinically in several patient populations and shown to be effective in improving blood flow. In individuals with total cholesterol over 230 mg/dl (n=39), two HeartBars per day restored flow-mediated vasodilation to normal within two weeks. In patients with peripheral arterial disease secondary to atherosclerosis (n=39), 2 HeartBars/day improved pain-free walking distance by 66% (compared to placebo of 18%). In addition to this improvement in physical function, these patients experienced an improvement in quality of life scores as measured by the SF-36 Medical Outcomes Survey.

**Pharmacokinetics:** Following the administration of 1 HeartBar (3.0 g L-arginine), plasma arginine levels rise from 18 µg/ml to a peak of 28 µg/ml within one hour of ingestion. Arginine levels are maintained above those of individuals on an arginine-free diet for at least 8 hours after ingestion. A similar pattern of arginine levels is observed following the ingestion of a single HeartBar after a week of b.i.d. use. These arginine levels compare favorably with L-arginine administration by capsular form.

## Precautions:

### Diabetics

The HeartBar contains 190 calories, 27g of carbohydrate (20g of sugars) and 3 g of

fructose corn syrup, soy protein isolate, fructose, toasted soy pieces, raisins, vanilla cookie pieces, L-arginine HCl, natural and artificial flavors, oat fiber, DL-alpha-tocopherol acetate, sodium ascorbate, dipotassium phosphate, niacinamide, cyanocobalamin, pyridoxine hydrochloride, folic acid.

## Renal Failure Patients

The HeartBar contains 13 g of protein. This amount of protein should be considered when determining total daily protein load.

## Allergies

The base of the bar is of soy protein, which is generally considered hypoallergenic. However, the original flavor contains vanilla cookie pieces that contain wheat flour. Therefore, individuals with allergies to wheat products should be cautious.

## Sepsis

The hypotension associated with sepsis is, in-part, mediated by excessive NO production. Such patients should not be given HeartBar.

**Adverse Reactions:** No serious adverse reactions have been demonstrated or reported in clinical trials or in the HeartBar Safety-In-Use study.

Minor adverse reactions are infrequent, generally related to gastrointestinal disturbances and appear unrelated to the L-arginine in the bar (Adverse events were just as common in the group given placebo bar). In a two-week study of the HeartBar, 4 of 41 individuals reported increased flatulence that resolved after several days of bar use. One of 41 individuals complained of increased frequency of bowel movements and soft stools. In a 10-week study of the HeartBar, 2 of 41 individuals reported dry mouth. A change in bowel habits was reported by 1 individual in each of the placebo and HeartBar groups.

The bar is not indicated for individuals with diabetic retinopathy, neoplastic disease or inflammatory arthritis.

## Administration:

### Symptomatic or High-Risk Population

One HeartBar twice daily

### At-risk Population

One HeartBar daily

**How Supplied:** Individually wrapped bars, cartons of 16 and cases of 64.

### Original Flavor

Individual Bars NDC 63535-10102

By Carton NDC 63535-10103

### Berry Flavor

Individual Bars NDC 63535-10202

By Carton NDC 63535-10203

**References:** Lucher, TF *et al.* Annu Rev Med, 44: 395-418, 1993.

Moncada, S. *et al.* FASEB J, 13: 1319-1330, 1995.

Cooke, JP and Dzau, VJ, Annu Rev Med, 48: 489-509, 1997.

Maxwell, AJ and Cooke, JP, Curr Opin Nephrol Hypertens, 7: 63-70, 1998.

Shown in Product Identification Guide, page 507

## Niche Pharmaceuticals, Inc.

200 N. OAK  
P.O. BOX 449  
ROANOKE, TX 76262

Direct inquiries to:  
Stephen Brandon  
(817) 491-2770  
Fax (817) 491-3533

### MAG-TAB® SR

[māg-tāb]

(Magnesium L-lactate dihydrate)  
Sustained release Magnesium Supplement

**Description:** Mag-Tab SR is a sustained release oral magnesium supplement. Each pale yellow caplets contain 7mEq (84 Mg) magnesium as magnesium L-lactate dihydrate (835 Mg in a patented, sustained release wax matrix formulation).

**Indications/Uses:** As a dietary supplement, Mag-Tab SR, is indicated for patients with, or at risk for, magnesium deficiency. Hypomagnesemia and/or magnesium deficiency can result from inadequate nutritional intake or absorption, magnesium depleting drugs such as diuretics, or alcoholism.

**Warnings:** Patients with renal disease should not take magnesium supplements without the advice and direct supervision of a physician. Excessive dosage of magnesium can cause loose stools or diarrhea.

**Dosage:** As a dietary supplement, take 1 or 2 caplets b.i.d. or as directed by a physician.

**How Supplied:** Mag-Tab SR is available for oral administration as uncoated yellow caplets, in bottles of 60 and 100.

### UniFiber®

[uni fi 'ber]

(Powdered Cellulose)  
3 grams Fiber per tablespoon

**Description:** UniFiber is an all natural insoluble bulk fiber supplement that promotes normal bowel function by adding needed bulk to the diet. UniFiber contains powdered cellulose 75%, water 5%, corn syrup 19%, and xanthan gum 1%. UniFiber mixes easily with liquids or soft foods, and is tasteless, non-gelling, and pleasant to take. One tablespoon of UniFiber provides 3 grams of concentrated dietary fiber.

**Nutrition Information:** Each 4 gram (1T) serving of UniFiber contains 3 grams of fiber equivalent to the amount of fiber in one large bran muffin, 4 calories, 0% fat, 0% cholesterol, 0% protein, and is free of all electrolytes.

**Indication/Uses:** As a dietary supplement, UniFiber is indicated for patients needing a concentrated source of fiber to help maintain and promote normal bowel function. Because UniFiber is electrolyte free and contains no excitoxins, it is an ideal fiber supplement for patients on a restricted diet, such as the OB patient, kidney patients on dialysis, diabetic patients, and the elderly.

**Contraindications:** Intestinal obstruction or fecal impaction.

### Dosage:

**Adults:** Stir one tablespoon into a glass with 3 or 4 ounces of fruit juice, milk, or water; or mix with soft foods such as applesauce, mashed potatoes, or pudding. Can be taken up to 3 times daily if needed, or as recommended by a doctor. Generally produces effect in 12 - 72 hours.

**Tube Feedings:** Mix one tablespoon in 30 - 60 cc of water.

**Children (6 to 12 years):** ½ dose 2 or 3 times daily.

**How Supplied:** UniFiber is available over the counter in powder containers of 5 oz (36 servings), 9 oz (64 servings), or 16 oz (114 servings)

## Novartis Consumer Health, Inc.

560 MORRIS AVE.  
SUMMIT, NJ 07901-1312

Direct Product Inquiries to:  
Consumer & Professional Affairs  
(800) 452-0051  
Fax: (800) 635-2801

Or write to above address.

### SLOW FE®

Slow Release Iron Tablets

**Description:** SLOW FE supplies ferrous sulfate for the treatment of iron deficiency and iron deficiency anemia with a significant reduction in the incidence of the common side effects of oral iron preparations. The wax matrix delivery system of SLOW FE is designed to maximize the release of ferrous sulfate in the duodenum and the jejunum where it is best tolerated and absorbed. SLOW FE has been clinically shown to be associated with a lower incidence of constipation, diarrhea and abdominal discomfort when compared to an immediate release iron tablet<sup>1</sup> and a leading sustained release iron capsule.<sup>2</sup>

**Formula:** Each tablet contains 160 mg. dried ferrous sulfate USP, equivalent to 50 mg. elemental iron. Also contains cetostearyl alcohol, FD&C Blue No. 2 aluminum lake, hydroxypropyl methylcellulose, lactose, magnesium stearate, polysorbate 80, talc, titanium dioxide, yellow iron oxide.

**Dosage:** ADULTS—one or two tablets daily or as recommended by a physician. A maximum of four tablets daily may be taken. CHILDREN—one tablet daily. Tablets must be swallowed whole.

**Warning:** Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

**Warning:** The treatment of any anemic condition should be under the advice and supervision of a physician. As oral iron products interfere with absorption of oral tetracycline antibiotics, these products should not be taken within two hours of each other. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

Blister packaged for your protection. Do not use if individual seals are broken.

**How Supplied:** Child-resistant blister packages of 30, 60, and 90.

Do Not Store Above 30°C (86°F). Protect From Moisture.

Tablets made in Great Britain  
Novartis Consumer Health, Inc.  
Summit, NJ 07901-1312

### References

1. Brock C et al. Adverse effects of iron supplementation: A comparative trial of a wax-matrix iron preparation and conventional ferrous sulfate tablets. *Clin Ther.* 1985; 7:568-573.
2. Brock C, Curry H. Comparative incidence of side effects of a wax-matrix and a sustained-release iron preparation. *Clin Ther.* 1985; 7:492-496.

Shown in *Product Identification Guide*, page 514

### SLOW FE® WITH FOLIC ACID (Slow Release Iron, Folic Acid)

**Description:** Slow Fe + Folic Acid delivers 50 mg. elemental iron (160 mg. dried ferrous sulfate) plus 400 mcg. folic acid using the unique wax matrix delivery system described above (for SLOW FE® Slow Release Iron Tablets).

Provides women of childbearing potential with the daily target level of folic acid to reduce the risk of neural tube birth defects. These birth defects are rare, but serious, and occur within 25 days of conception, often before a woman knows she's pregnant.

**Formula:** Each tablet contains: Active Ingredients: 160 mg. dried ferrous sulfate, USP (equivalent to 50 mg. elemental iron) and 400 mcg. folic acid. Inactive Ingredients: cetostearyl alcohol, hydroxypropyl methylcellulose, lactose, magnesium stearate, polysorbate 80, talc, titanium dioxide, yellow iron oxide.

**Dosage:** ADULTS—One or two tablets once a day or as recommended by a physician.

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