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A Librarian's Guide to Dietary Supplements

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A Librarian's Guide to Dietary Supplements

Annette M. Healy
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October 20, 2008

What is a Dietary Supplement?

- Defined in Dietary Supplement Health and Education Act (DSHEA) of 1994
- Product that supplements the diet and contains
 - Vitamin
 - Mineral
 - Herb
 - Amino Acid
- Taken as a tablet, capsule, powder or liquid

Dietary Supplements in the U.S.

- \$21 billion in sales in 2006
- 29,000 products in 1999
- Used by 20 to 60% of adults in US



Current Dietary Supplement Regulation:

- Supplements do not require FDA approval*
- Manufacturer responsible for ensuring that supplement is safe
- FDA must prove a supplement is unsafe before it can be removed from market

* Except for new dietary ingredients

Dietary Supplement Labels

- Must provide
 - List of ingredients
 - Serving size
 - Active ingredients
- Do not have to provide information on:
 - Safety
 - Effectiveness
 - Possible side effects

Supplements may not claim to:

- Diagnose, prevent, treat or cure a specific disease
- These claims allowed only for substances classified as drugs
- Drugs must be approved by FDA before being marketed



Allowable dietary supplement claims

- **Health Claims** – relationship between nutrient and disease or condition
 - Calcium reduces the risk for osteoporosis
 - Requires FDA approval
- **Structure/Function Claims** – nutrient affects normal structure or function
 - Calcium builds strong bones.
 - FDA approval not required

Manufacturer is responsible for ensuring the safety of supplements

- Problems that have been reported:
 - Supplement did not contain dosage on the label
 - Wrong herb/plant used to make the supplement
 - Supplement contained contaminants from chemicals, insects or rodents

New regulations for the manufacture of dietary supplements

- DSHEA of 1994 gave FDA authority to establish Good Manufacturing Practices (GMPs)
 - Ensure identity, purity and strength
 - No contamination
- GMPs approved in 2007
- Three year phase-in (2008-2010)

What does an informed consumer need to know?

- Manufactured correctly
 - Contains correct supplement
 - Contains dose on label
 - Free of contaminants
- Efficacy
- Safety and proper dosing
- Side effects
- Interactions with drugs or supplements
- How to report problems

Online Resources

- Independent testing organizations
 - Manufactured correctly
- Natural Standard (subscription)
 - Efficacy, safety, side effects, interactions
- Dietary Supplements Labels Database
 - Efficacy, safety, side effects, interactions
 - Manufactured correctly (if available)
 - FDA recalls

Independent Testing Organizations

- Verify the identity and quantity of dietary ingredients
- Ensure that the product does not contain contaminants
- Do not test efficacy
 - United States Pharmacopeia (USP)
 - NSF International
 - ConsumerLab.com

- United States Pharmacopeia (USP)

- USP Verified supplements listed online

- <http://www.usp.org/USPVerified/dietarySupplements/>



- NSF International

- NSF Certified supplements listed online

- http://www.nsf.org/consumer/dietary_supplements/index.asp



- ConsumerLab.com

- Summary online for non-subscribers
- Website difficult to navigate

- <http://www.consumerlab.com/>



Natural Standard

- Requires subscription
- Collect and synthesize data on complementary and alternative therapies
- Rate scientific evidence
 - **A** (Strong Scientific Evidence)
 - **B** (Good Scientific Evidence)
 - **C** (Unclear or conflicting scientific evidence)
 - **D** (Fair Negative Scientific Evidence)
 - **F** (Strong Negative Scientific Evidence)

Natural Standard

- Dietary supplement information
 - Rate evidence for each use
 - Professional and consumer versions
 - Dosing
 - Safety
 - Side effects
 - Interactions with drugs or supplements
 - References

Chromium

PROFESSIONAL MONOGRAPH

*A comprehensive evidence-based systematic review of scientific literature, peer reviewed by **Natural Standard** editorial contributors. Provides in-depth coverage of efficacy, adverse effects, interactions, pregnancy/lactation, pharmacology/toxicology, dosing/standardization, and products tested by third-party laboratories. Includes evidence table and discussion(s), statistical analysis, and quality rating of available clinical trials. Cross referenced to other monographs by health condition.*

[Click Here](#)

BOTTOM LINE MONOGRAPH

*A concise evidence-based review, designed for use by patients or professionals. Based on systematic aggregation and analysis of scientific literature, historic/folkloric precedent, and expert consultation. Edited and peer-reviewed blindly by **Natural Standard** editorial contributors. Includes information on effectiveness, side effects, interactions, dosing, pregnancy and breastfeeding.*

[English](#) | [Spanish](#)

FLASHCARD

*Quick look-up or patient handout. Easy reading level for consumers. Adapted from a **Natural Standard** comprehensive professional evidence-based systematic review. Concise information includes brief summary, uses, safety, side effects, interactions and dosing.*

[Click Here](#)

Dietary Supplements Labels Database

- <http://dietarysupplements.nlm.nih.gov/dietary/>
- Launched October 2007 by NLM
- > 800 Active Ingredients
- > 2000 Brands
- > 150 Manufacturers
- FDA Warnings and Recalls

Dietary Supplements Labels Database

- Active Ingredients
 - Description
 - Related Names
 - Brands that contain the ingredient
 - Fact Sheets (for consumers)
 - PubMed searches
 - Uses in humans
 - Adverse effects
 - Mechanism of Action



Browse & Search

▼ Brands

▲ Active Ingredients

▶ Alphabetical List

▶ Vitamins

▶ Minerals

▶ Herbs/Plants

▶ Amino Acids

▶ Enzymes

▶ Specialty

▶ Search

▼ Manufacturers



Cassia bicolorata

Active Ingredient:

information from selected non-manufacturer sources

Name	Thiamin (Vitamin B-1)
Description	3-((4-Amino-2-methyl-5-pyrimidinyl)methyl)-5-(2-hydroxyethyl)-4-methylthiazolium chloride. [MeSH]
Related Names/Sources	B1; Thiamin; Thiamin (Vitamin (B-1)); Thiamin HCl; Thiamin Hydrochloride; Thiamin Mononitrate; Vitamin B-1; Vitamin B1 (Thiamin); Vitamin B1 Hydrochloride (Thiamine Hydrochloride); Vitamin B1 Mononitrate (Thiamine Mononitrate)
Related Brands	Brands that contain this ingredient
Reference Links	General Information
	Thiamin (Vitamin B-1) [MedlinePlus]
	Uses (in humans)
	Thiamin (Vitamin B-1) [ClinicalTrials.gov]
	Clinical Trial Literature [PubMed]
	Effectiveness Literature [PubMed]
	Administration Literature [PubMed]
	Adverse Effects (in humans)
	Adverse Effects Literature [PubMed]
	Poisoning Literature [PubMed]
	Mechanism of Action
	Actions [PubMed]
	Kinetics [PubMed]

Dietary Supplements Labels Database

- Brands
 - Search by Product Name
 - Label information
 - Independent testing results (if available)
 - Limit search results by ingredients
 - No sugar
 - No wheat
 - Kosher

Caltrate 600 Calcium Supplement Tablets

The label claims have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. Consult your healthcare professionals before taking any dietary supplements.

Product Information

Ingredient Information

Manufacturer Information

Unit

Tablet

Supplement Facts

Supplement Facts

Serving Size 1 Tablet

Ingredients Amount/Serving %DV

Calcium 600 mg 60%

% Daily Value

Other Ingredients

Calcium Carbonate, Starch. Contains less than 2% of the following: Croscarmellose Sodium, Magnesium Stearate, Titanium Dioxide. May contain less than 2% of the following: Glycerin, Methylcellulose, Polydextrose.

Does not contain

No Sugar, No Lactose, No Salt, No Preservatives.

Manufacturers Suggested Use

SUGGESTED USE: Take one tablet twice daily with food or as directed by your physician. Not formulated for use in children. As with any supplement, if you are pregnant or nursing a baby, contact your healthcare professional. Store at room temperature. Keep bottle tightly closed.

Label Warning

Warnings: Keep out of reach of children.

Bottle sealed with printed foil under cap. Do not use if foil is torn. Store at room temperature.

Claims by Manufacturer

(None)

Fact Sheets by NIH and Other Research Centers

NIH and other research centers have developed Fact Sheets for the following ingredients in this brand:

- [Calcium](#) [ODS-Fact Sheet]

More information about the uses, adverse effects, and mechanism of action of each active ingredient in this brand can be found by clicking that active ingredient on the "[Ingredient Information](#)" page.

Other Label Information

Made in U.S.A.

Marketed by: Wyeth Consumer Healthcare Madison, NJ 07940

Information Line

800-282-8805

Date Entered

2005-06-22

Third-Party Test Result



Passed tests performed by [ConsumerLab.com](#). (2/28/06).

ConsumerLab.com is a provider of independent test results for dietary supplement products. Tests are used to determine the amount of ingredient claimed on the container label; the existence of unwanted contaminants, such as lead, in the product, and the ability of the product to dissolve and be absorbed in the body.

ConsumerLab.com does not test the efficacy of products.

How do I report problems with dietary supplements?

- MedWatch – Report adverse events to the FDA
 - <http://www.fda.gov/medwatch/>
 - Health professionals
 - Consumers



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