Supplements in Primary Care

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NATURAL PRODUCTS

- 2007 National Health Interview Survey
- U.S. public spent approximately $33.9 billion out-of-pocket on CAM
- Visits to CAM practitioners and CAM products, classes, materials
- $14.8 billion spent on nonvitamin, nonmineral, natural products
- Equivalent to 1/3 of out-of-pocket spending on prescription drugs

HERBAL MEDICINE

- About 80% of the earth’s populations use plant medicine as primary source of healing
- Herbs some of the first medicines
- Chemistry of plants more complex than that of pharmaceutical agents
- Different parts of the same plant can have different qualities

BOTANICALS

- Important part of integrative medicine
- Patients may prefer more natural approach to care
- Prescription medications often with intolerable side effects
- In general, effects of herbs tend to be milder and slower in onset
- Herbs with milder adverse effects compared to pharmaceuticals

HERBAL MEDICINE

- Vast majority of evidence originated from direct experience or observation
- Increasing number of randomized controlled trials
  - Study single standardized herb or phytopharmaceutical
  - May not truly reflect practice of herbal medicine (individualized treatments)

BOTANICALS

- Not FDA regulated
- Dietary Supplement Health and Education Act of 1994
  - Ingredients in dietary supplements not subject to premarket safety evals required of food ingredients
  - Must meet other safety provisions
- What is needed to improve botanical quality?
  - Program for certification of botanical activity
  - Validated method to detect contaminants or adulterants
HERBS AND PATIENTS

- Ask - patients often do not disclose use
- Use only products that have passed quality testing on consumerlabs.com (independent testing group)
- Watch for adverse effects
- Watch for drug interactions
- Use standardized products
- Probably should avoid during pregnancy

HERBAL PREPARATIONS

- Whole herb, fresh or dried
  - Flower, stem, or root
  - Can have tea, infusion (hot), decoction (boiled)
- Extracts and tinctures
  - Alcohol or water solvent
  - Solid extracts made by evaporating tincture, residue dried, made into capsules
- Essential oils for aromatherapy, topical

BOTANICAL LABELS

- Serving size is a suggestion
- No established % daily value
- Servings per container
- Common name and botanical name
- Plant part
- Quantity of starting material and of extract
- Extract ratio – provides strength of product
- Standardization – indicates active compound
- Other ingredients

HERBAL PREPARATIONS

- Herbal supplement with multiple ingredients:
  - Amounts of each herb listed unless a proprietary blend
  - Manufacturer
  - Packer
  - Distributor
  - Lot #
  - Expiration date

Courtesy of http://www.anthonyroberts.info
SAFETY

• Interactions with prescription medications - i.e. affect cytochrome P450 enzymes?
• Metabolism and clearance of botanical compounds in children not same as in adults
• Contamination
  - Intentional and unintentional
  - Bacteria, heavy metals, pesticides, herbicides, medications, other supplements

SAFETY CONCERNS

• Any herb used incorrectly can be dangerous
• Hepatic, renal, electrolyte abnormalities with chronic use:
  • Comfrey, chaparral, licorice
• Potential life threatening adverse effects:
  • Mistletoe, digitalis, ephedra, pennyroyal essential oil
  • Watch herbs containing pyrrolizidine alkaloids
• Accidental ingestion of essential oils (pediatrics)

FINDING QUALITY PRODUCTS

• Look for product seals
• Confirm identity and quantity of ingredients on label
• Confirm product free of contaminants and undeclared ingredients
• Demonstrate conformance to industry GMPs
• GMP released June 2007

HERBS AND ADVERSE CARDIOVASCULAR EFFECTS

• Garlic - ↑ bleeding tendency
• Ginkgo - ↑ bleeding tendency & platelet dysfunction
• Ginger - platelet dysfunction
• Ginseng - HTN
• Kava - platelet dysfunction
• Dong quai - ↑ bleeding tendency
• Yohimbine - HTN, arrhythmia
CARDIOVASCULAR DRUG INTERACTIONS

• Warfarin
  - Dong quai, Garlic - case reports of increased INR*
  - Gingko - case report of CNS hemorrhage
  - Ginseng - case report of decreased INR
  - St. John’s wort - CYP3A4 induction (decrease effect)

  *inconsistent information regarding warfarin and garlic interaction found

Review by Valli in 2002
Journal of the American College of Cardiology

• Anti-platelet drugs
  - Dong quai, Kava, Ginger, Gingko - in vitro antiplatelet activity
  - Garlic - case reports of increased bleeding time
  - Gingko - case reports of hemorrhage

• Digoxin
  - Herbal laxatives (buckthorn, senna) – potassium loss leading to digoxin toxicity
  - St. John’s wort - reduces digoxin serum levels
  - Ginseng (Siberian): possible interference

10 POPULAR BOTANICALS

1. Echinacea
2. St. John’s Wort
3. Black Cohosh
4. Ginger
5. Cinnamon
6. Turmeric
7. Saw Palmetto
8. Valerian
9. Lemon Balm
10. Peppermint oil

ECHINACEA
E. augustifolia, E. purpurea

PRIMARY USE: supportive therapy for colds and infections of respiratory and urinary tracts, enhancing immune response

Some studies show use shortens durations of URIs
Cochrane review 2000

PROPOSED ACTION: immune-modulating, anti-inflammatory

DOSE: dried powdered herb cap: 1 gram tid
**ECHINACEA**  
*E. augustifolia, E. purpurea*

**CONTRAINDICATIONS:** German Commission E contraindicates in progressive systemic diseases like TB, leukocytosis, collagenosis, MS, HIV/AIDS, autoimmune disease (theoretical risk)

**ADVERSE EFFECTS:** allergy is rare but can occur, particularly atopic individuals

**DRUG INTERACTIONS:** probable CYP3A4 inducer, caution when co-administered with drugs dependent on CYP3A4 or CYP1A2

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**ST. JOHN’S WORT**  
*Hypericum perforatum*

**CONTRAINDICATIONS:** not for severe depression

**ADVERSE EFFECTS:** may cause increased sensitivity to sunlight, anxiety, dry mouth, dizziness, gastrointestinal symptoms, fatigue, headache, sexual dysfunction

**DRUG INTERACTIONS:** Numerous, induces cytochrome P450 CYP3A4, P-glycoprotein  
Anticoagulants, cyclosporine, digoxin, OCP, protease inhibitors, statins, SSRIs, irinotecan

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**ST. JOHN’S WORT**  
*Hypericum perforatum*

**PRIMARY USE:** mild to moderate depression, anxiety, OCD, PMS, herpes  
NOT severe depression –not appropriate  
NIH RCT 2002 - JAMA

**PROPOSED ACTION:** antidepressant, antiviral and antimicrobial when used topically

**DOSE:** dose used in clinical trials: 500-1800 mg/d  
Standardized to 0.3% hypercin, 2-5% hyperforin, or both

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**BLACK COHOSH**  
*Actaea racemosa*

**PRIMARY USE:** menopausal symptoms, PMS, dysmenorrhea  
Studies are mixed – long-term data not yet available

**PROPOSED ACTION:** estrogen modulating, antirheumatic, spasmyloytic

**DOSE:** standardized to 26-deoxyactein (1 mg in each 20mg dose of extract)  
Clinical trials use Remifemin 20-80mg bid
**BLACK COHOSH**  
*Actaea racemosa*

**CONTRAINDICATIONS:** pregnancy/lactation, controversy over safety in persons with history of estrogen dependent tumors

**ADVERSE EFFECTS:** low incidence of headaches, GI complaints, heaviness in legs, weight problems. Some reports of possible hepatotoxicity (no conclusive link per NIH). One case report of seizures.

**DRUG INTERACTIONS:** monitor on BP meds, anti-platelet agents (trace amount of salicylic acid in herb)

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**GINGER**  
*Zingiber officinale*

**CONTRAINDICATIONS:** active gallstone disease  
German Commission E contraindicates use in pregnancy, although studies have shown short-term use is safe

**ADVERSE EFFECTS:** bloating, gas, heartburn, nausea, potentially ulcerogenic, may cause contact dermatitis

**DRUG INTERACTIONS:** anticoagulants/antiplatelet agents

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**GINGER**  
*Zingiber officinale*

**PRIMARY USE:** nausea and vomiting (motion sickness, pregnancy, post-operative), dyspepsia, osteoarthritis

**PROPOSED ACTION:** antiemetic, anti-inflammatory, antiplatelet, digestive stimulant

**DOSE:** dried ginger 2-4 grams/day  
Clinical trials for n/v in pregnancy used 1 gm/d

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**CINNAMON**  
*Cinnamomum cassia*

**PRIMARY USE:** Diabetes mellitus type 2, hypercholesterolemia, GI upset  
NIH studies currently – DM, PCOS

**PROPOSED ACTION:** attenuates insulin resistance, lipid-lowering effects, antioxidant, antimicrobial

**DOSE:** 1-4 grams/day of cinnamon bark extract
| **CINNAMON**  
<table>
<thead>
<tr>
<th><em>Cinnamomum cassia</em></th>
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<tr>
<td><strong>CONTRAINDICATIONS:</strong> ulcers, pregnancy, essential oil should not be ingested</td>
</tr>
<tr>
<td><strong>ADVERSE EFFECTS:</strong> GI irritation</td>
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<td><strong>DRUG INTERACTIONS:</strong> caution with diabetes medications</td>
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<th><em>Curcuma longa</em></th>
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<td><strong>CONTRAINDICATIONS:</strong> gallstone disease, avoid in pregnancy</td>
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<td><strong>ADVERSE EFFECTS:</strong> indigestion, nausea, diarrhea</td>
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<th><em>Curcuma longa</em></th>
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| **PRIMARY USE:** inflammatory diseases or conditions, arthritis, dyspepsia  
Much recent attention – studies to come |
| **PROPOSED ACTION:** curcuminoids with anti-inflammatory, anticancer, antioxidant properties. Inhibits TNF alpha |
| **DOSE:** standardized extracts 95% curcuminoids, 1-2 grams daily  
Piperine (found in black pepper) enhances absorption |

| **SAW PALMETTO**  
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<td><strong>DOSE:</strong> if using capsules, liposterolic extract 160-320 mg/day</td>
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### SAW PALMETTO
*Serenoa repens*

**CONTRAINdications:** none

**ADVERSE EFFECTS:** generally mild, may cause GI upset

**DRUG INTERACTIONS:** none

Note: does not affect PSA levels

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### VALERIAN
*Valeriana officinalis*

**CONTRAINdications:** none aside from use in children under age 3

**ADVERSE EFFECTS:** mild. Headaches, GI upset, some people experience restlessness and stimulation. No evidence of potentiation with alcohol ingestion.

**DRUG INTERACTIONS:** may potentiate effects of other CNS depressants

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### VAlerIAN
*Valeriana officinalis*

**CONTRAINdications:** none

**ADVERSE EFFECTS:** generally mild, may cause GI upset

**DRUG INTERACTIONS:** none

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### LEMON BALM
*Melissa officinalis*

**PRIMARY USE:** insomnia, anxiety, cold sores, dyspepsia, Alzheimer’s disease

Most studies – in combination with other herbs

**PROPOSED ACTION:** anxiolytic, sedative, antibacterial, antiviral, enhance mental functioning

**DOSE:** herbal teas, essential oil, topical creams, extract 300-500 mg 3x daily or PRN
| **LEMON BALM**  
*Melissa officinalis* | **PEPPERMINT OIL**  
*Mentha x piperita* |
<table>
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<tr>
<td><strong>CONTRAINDICATIONS:</strong> none</td>
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<tr>
<td><strong>ADVERSE EFFECTS:</strong> mild GI effects</td>
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<td><strong>DRUG INTERACTIONS:</strong> thyroid medications, caution with CNS depressants</td>
<td><strong>DRUG INTERACTIONS:</strong> cytochrome P450 inhibitor, cyclosporine, antacids, H2 blockers, PPI</td>
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<tr>
<td>Commonly used with valerian, hops, chamomile</td>
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**PEPPERMINT OIL**  
*Mentha x piperita*

| **PRIMARY USE:** nausea, indigestion, IBS, URI symptoms  
Studies for IBS mixed – some evidence it may be modestly effective | **HERBS** |
|---|---|
| **PROPOSED ACTION:** anti-spasmodic, antiseptic | **• Natural products most common CAM therapy used by US adults and children**  
**• Increasing research being conducted**  
**• Potential adverse effects**  
**• Quality concerns – educate yourself and your patients**  
**• Many potential benefits**  
**• More treatment options for your patients** |
| **DOSE:** enteric coated capsules between meals | |
Supplements in Primary Care

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Department of Family Medicine
Ohio State University Medical Center

Essential Fatty Acids

Linoleic/Alpha-linoleic ratio in Western diets is 20:1 to 40:1 – ideal thought to be 4:1 to 1:1

Metabolic Pathway of Essential Fatty Acids

- Delta 6 desaturase (D6D)
  - Rate limiting enzyme
  - Both LA (omega-6) and ALA (omega-3 – soy, flax) depend on D6D
  - Limited quantity
**Delta 6 desaturase (D6D)**
- Function impaired by
  - Excess cholesterol, sugar and alcohol consumption
  - Trans-fats
  - Stress hormones
  - Smoking
  - Gender
  - Aging
  - Cofactor deficiency – Mg, Zn, biotin, Vit B3, B6 and C
  - Diabetes
- Only 0.2-8% of ALA is converted to EPA and only about 0.5% to DHA (in studies on humans)

**Omega 3 fatty acid (Alpha-linoleic)**
- EPA (eicosapentaenoic acid)
- DHA (docosahexaenoic acid)

  **Effects:**
  - Antiarrhythmic – electrically stabilize the heart muscle cells
  - Anti-inflammatory – convert into anti-inflammatory eicosanoids (prostaglandins and leukotriens) – may stabilize arterial plaque. EPA inhibits D5D enzyme which converts DGLA to arachidonic acid
  - Antithrombotic – decrease stickiness of platelets, reduce risk of forming a blood clot. Decrease fibrinogen and blood viscosity

**OMEGA 3 FATTY ACIDS**
- Anti-atherosclerotic – may make arteries more elastic, reduce the risk of high blood pressure triggering plaque rapture
- Improve endothelial function
- Increase vasodilatation
- Reduce triglycerides level, raise HDL, decrease Lp (a), and increase particle size of LDL
- Decrease free radical production

- Anti-arrhythmic – electrically stabilize the heart muscle cells

- Anti-inflammatory – convert into anti-inflammatory eicosanoids (prostaglandins and leukotriens) – may stabilize arterial plaque. EPA inhibits D5D enzyme which converts DGLA to arachidonic acid

- Antithrombotic – decrease stickiness of platelets, reduce risk of forming a blood clot. Decrease fibrinogen and blood viscosity

- DHA – reduces insulin resistance in overweight patients (improves cell membrane receptor function and signal transduction)
Omega 3 Fish Oil

- Low omega-3 levels in plasma and red blood cells are associated with depression. Epidemiological research suggests eating fish lowers the risk of depression and suicide.
- Higher fish and fish oil intake has been linked to decreased risk of developing Alzheimer’s disease in population studies.
- Might slow cognitive decline in patients with very mild cognitive dysfunction.

- Other uses:
  - Abdominal, menstrual cramping, dysmenorrhea, menorrhagia, joints, cognitive impairment, skin
- Dose:
  - 2000-3000 mg po bid-tid (use triple strength only – EPA/DHA should be > 50% of serving size)
  - SFx: Gen well tolerated; fishy burp (keep in freezer), doses > 3 g/day may have anti-platelet activity

Safety of fatty acid supplementation

- ALA (flax, soy)
  - Nine cohort and case control studies show association between either ALA intake or ALA blood content and prostate cancer with mechanism not understood
  - In vitro data shows that ALA promotes prostate cancer

- Fish oil
  - Concerns about increased bleeding time in the scientific literature, but there are no published reports
  - May increase LDL by approximately 5% in those with elevated triglycerides, but the additional LDL is large particles – less pathogenic
Purchasing considerations

- Liquid Fish oil - more concentrated, more economical
- Capsules
  - Concentration on EPA/DHA should be >50% of the capsule
  - Majority of capsules offer 20-30%, some 50-60% and only a few offer >70%
  - Lovaza (Omacor) – 1gm caps – 840mg of EPA+DHA

Purchasing considerations

- Choose a company independently certified for quality manufacturing by NSF, NPA, USP or TGA
- Choose brand that passed independent analysis by www.consumerlab.com
- Not Consumer Reports testing – they do not specify methodology in their report

Purchasing considerations

- Quality control
- Choose brand that has testing from www.ifosprogram.com
- Watch for
  - Mercury less than 10 ppb
  - Dioxins (total) less than 1 ppt
  - Oxidation (total) less than 13meq/L
  - PCB’s (total) less than 45 ppb

SAMe

- Indications:
  - Depression, OA
- Dose:
  - Depression 400-800 mg po bid
  - OA 200 mg po bid
- Comments:
  - Produced endogenously by ATP activation of methionine; SAMe synthesis is closely linked to B12 and folate metabolism
**SAMe**

- Mech: associated with increased serotonin turnover and elevated dopamine and norepinephrine levels; beneficial in OA due to analgesic and anti-inflammatory effects.
- SFx: Associated with higher doses: flatulence, nausea, vomiting, diarrhea, constipation, dry mouth, headache, mild sleep disturbance, loss of appetite, sweating

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**Melatonin**

- **Indications:**
  - circadian rhythm disorders, sleep-wake cycle disturbance, improved sleep latency, but not efficiency
  - Light inhibits melatonin secretion, and darkness stimulates secretion.
  - Hot water feet soaks stimulate production of melatonin
- **Dose:** 0.3 – 5 mg po qhs (immediate and sustained forms available)
- **Comments:**
  - Endogenously produced in pineal gland from tryptophan.
  - Light inhibits melatonin secretion, and darkness stimulates secretion.
  - Hot water feet soaks stimulate production of melatonin
- **SFx:**
  - Gen well tolerated; daytime drowsiness (20%), headache (7.8%), and dizziness (4%).
  - In perimenopausal women, melatonin has caused a resumption of spotting or menstrual flow.

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**Calcium**

**Facts:**

- We start losing our bone density at age 30 y/o
- Calcium supplementation is associated with 12% reduction in fractures
- Dietary sources give the greatest benefit
- Calcium taken with food, and in divided doses improves absorption
NIH guidelines on Ca+

• Women < 65 using HRT: 1,000 mgs
• Menopausal women not on HRT: 1,500 mgs
• All women over 65: 1,500 mgs

Calcium

• Can uncover magnesium deficiency – constipation while taking
• May need magnesium replacement at the same time

Magnesium

• Indications:
  – Osteoporosis
  – PMS
  – Migraines
  – Muscle aches/cramps
  – Anxiety
  – Constipation
• Dose: magnesium Oxide 250 mg po bid-tid
• SFx: diarrhea if taken in high doses (topical magnesium can be considered)

Magnesium

• RBC magnesium level more accurate reflection
• Keep serum level at 2.5
• Best tolerated 30 min after meal or at bedtime (also assists with sleep) (try to avoid Ca+Mg forms)

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Adrenal support

- Check cortisol and DHEA serum levels
- Short term DHEA replacement often will normalize cortisol levels
- Long term high doses associated with
  - BP elevation
  - prostate, testicular ca
  - overandrogenization in women due to conversion to testosterone

5-HTP (5-hydroxytryptophan)

- Indications:
  - insomnia, depression, anxiety
- Dose:
  - 300-400 mg at HS
- Mechanism:
  - increases serotonin levels
  - caution in conjunction with SSRIs and St. John’s Wort
- Dietary sources:
  - meat, fish, beans and eggs

Adrenal support

- Dosing
  - 10-25 mg PO daily for women
  - 25-50 mg PO daily for men
- Maintain serum levels
  - 200-400 mcg/dl women
  - 400-600 mcg/dl men
- Once feel better - wean and start Rhodiola (Rhodiola rosea) – can be taken long term
Vitamin D

- Vitamin D deficiency is now associated with increased risk for breast cancer, ovarian cancer, celiac disease, kidney disease, immunological problems, and inflammation response.
- Ethnicities having darker complexions are at highest risk, with African Americans at the greatest risk.


Vitamin D

- Oral D 3 700-800 IU daily with or without Ca seems to reduce fracture risk in elderly people. NNT=27 to prevent one nonvertebral fracture, and NNT=45 to prevent one hip fracture (tx 2-5 yrs).
- Women with serum levels of about 52 ng/ml had a 50% lower risk of developing breast cancer compared to women with serum levels of less than 13 ng/ml, corresponding to about 4000 IU/day.

Vitamin D

- 60-90% of individuals have serum vitamin D levels < 32. This includes those taking supplementation.
- Low levels of vitamin D reduce Ca+ absorption to 10% of ingested dose.
- Dose:
  - Current guidelines from the National Osteoporosis Foundation are 1,000 IU daily for adults at age 50 and older
  - 2000-4000 IU/day D3 maintenance
  - 50K IU D2 1-2x/wk x 12 wks for deficiency
- Vitamin D3 is absorbed best, and is available in liquid form.

Vitamin D

- Healthy menopausal women who take supplemental calcium 1400-1500 mg/day plus vitamin D3 1100 IU/day have a 60% lower relative risk for developing cancer of any type; NNT=25.

- Vitamin D: what is an adequate vitamin D level and how much supplementation is necessary?
  Bischoff-Ferrari H Centre on Aging and Mobility, University of Zurich, Department of Rheumatology and Institute of Physical Medicine, Zurich, Switzerland.

Strontium ranelate

- Indications: bone health
- Dose: 2 grams po daily, providing 680 mg elemental stronium
- Comments: Stimulates bone formation and reduce bone resorption. Reduced the risk of vertebral fractures by 40% in postmenopausal women with osteoporosis and a history of vertebral fracture. Increased BMD by 14% at the lumbar spine and 8% at the femoral neck.
- SFx: mild and transient nausea, diarrhea, headache, dermatitis, and eczema.


Energy production

- Aspartate and Malic acid 1 gm BID x 12wks
  - improve levels of thiamine pyrophosphate (TPP) (low in mitochondrial dysfunction syndrome causes high levels of lactic acid, and muscle pain
- Carnitine
  - only acetyl-L form is effective
  - D-L form can worsen symptoms
- CoQ-10 100 mg BID
  - improves exercise tolerance
  - is depleted by statin drugs

B-complex and Folic Acid

- Indications:
  - Menopause transition, helps with mood symptoms, bloating, energy level, concentration
  - Integrative Breast Care in women with dense breasts, family history of breast cancer, personal history of breast biopsy

- Dose B-100, or B-50 Time release 1-2 a day before meals, last dose should not be after 4-5 PM
- SFx: nausea


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- Demonstrate conformance to industry GMPs
- On-going monitoring

USP Verified Mark
• USP Dietary Supplement Verified Mark
  Allowed for finished products that:
  – Pass GMP inspection
  – Pass documentation review
  – Pass testing for strength, quality, purity
  – Pass post verification surveillance testing
  – Independent 3rd party certification

Reputable Web Recourses
• Canada’s Natural Health Products
  Compendium of Monographs
  www.hc-sc.gc.ca
• Consumer Labs
  www.consumerlab.com/
• Natural Medicine Comprehensive
  Database
  www.naturaldatabase.com/

Reading the Label
• Statement of identity
• Net quantity
• Name and place of business
• Nutrition labeling
• Ingredient list

Reputable Web Recourses
• Consumer Reports Rating
  http://www.consumerreports.org/health/home.htm
• Natural Standard
  http://www.naturalstandard.com
• Office of Dietary Supplements (ODS) Fact
  sheets
  www.ods.od.nih.gov
Final points

- Ask patients about all the supplements and vitamins they are taking
- Most of the time they will not volunteer information
- Show interest in their preferences

OSU CENTER FOR INTEGRATIVE MEDICINE

- Opened in 2005
- MDs
- Nutrition/Supplements
- Chiropractic
- Massage therapy
- Acupuncture
- Ayurveda
- Community classes (yoga, nutrition, etc)

Final points

- Ask them to bring bottles with them
- Check for repeated ingredients, especially fat soluble vitamins (risk of overdose)
- If questions refer to CIM