Folic Acid
http://www.drugs.com/sfx/folic-acid-side-effects.html
http://www.drugs.com/folic_acid.html

Before taking this medicine

You should not use this medication if you have ever had an allergic reaction to folic acid.

If you have any of these other conditions, you may need a dose adjustment or special tests to safely use folic acid:

- kidney disease (or if you are on dialysis);
- hemolytic anemia;
- pernicious anemia;
- anemia that has not been diagnosed by a doctor and confirmed with laboratory testing;
- an infection; or
- if you are an alcoholic.

Folic acid side effects

Get emergency medical help if you have any of these signs of an allergic reaction to folic acid: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Less serious side effects are more likely, but may include:

- nausea, loss of appetite;
- bloating, gas;
- bitter or unpleasant taste in your mouth;
- sleep problems;
- depression; or
- feeling excited or irritable.

For the Consumer

Applies to folic acid: capsule, injectable, solution, tablet

In addition to its needed effects, some unwanted effects may be caused by folic acid. In the event that any of these side effects do occur, they may require medical attention.

If any of the following side effects occur while taking folic acid, check with your doctor or nurse as soon as possible:

Rare

- Fever
- general weakness or discomfort
- reddened skin
- shortness of breath
- skin rash or itching
- tightness in chest
- troubled breathing
- wheezing

For Healthcare Professionals

Applies to folic acid: compounding powder, injectable solution, oral tablet

Gastrointestinal

Gastrointestinal side effects have been reported rarely. They have included anorexia, nausea, abdominal distention, flatulence, and bitter taste.[Ref]

Gastrointestinal side effects have been reported among patients with doses of 15 mg/day.[Ref]

Nervous system

Nervous system side effects have included sleep disturbances, concentration problems, irritability, anxiety, depression, confusion, and impaired judgment.

Parenteral administration of high doses of folic acid have been associated with increased seizure activity in patients with epilepsy.[Ref]

Nervous system side effects have been reported in some patients who were taking 15 mg/day.

Daily doses of folic acid > 100 mcg/day can obscure pernicious anemia in that hematologic remission can occur while neurologic signs and symptoms progress.[Ref]

Hypersensitivity

Hypersensitivity side effects have been reported rarely. They have included erythema, rash, pruritus, malaise, dyspnea with bronchospasm, and a single case of apparent anaphylaxis.[Ref]

Metabolic

Metabolic side effects have included impaired gastrointestinal absorption of zinc.[Ref]

A measurable decline in plasma zinc has been associated with folic acid dosages as low as 400 mcg/day.

Zinc is an intrinsic part of at least 70 metalloenzymes and other cellular components, and is essential for the synthesis of protein, DNA, and RNA. While zinc deficiency is rare, it may become a problem during pregnancy or with patients who have inflammatory bowel disease, malabsorption, liver cirrhosis, and high alcohol intake. Zinc deficiency usually presents as diarrhea; mental irritability; depression; skin lesions of the face, perineum, limbs, and skin folds; alopecia; loss of taste; and defects in the immunologic system.[Ref]

References

1. "Product Information. Renal Multivitamin Formula Rx (folic acid)." Vitaline Corporation, Ashland, OR.

2. Prakash R, Petrie WM "Psychiatric changes associated with an excess of folic acid." Am J Psychiatry 139 (1982): 1192-3

3. Dhar M, Bellevue R, Carmel R "Pernicious anemia with neuropsychiatric dysfunction in a patient with sickle cell anemia treated with folate supplementation." N Engl J Med 348 (2003): 2204-7

4. Butterworth CE Jr, Tamura T "Folic acid safety and toxicity: a brief review." Am J Clin Nutr 50 (1989): 353-8

5. Berg MJ, Rivey MP, Vern BA, Fischer LJ, Schottelius DD "Phenytoin and folic acid: individualized drug-drug interaction." Ther Drug Monit 5 (1983): 395-9

6. Berg MJ, Fischer LJ, Rivey MP, Vern BA, Lantz RK, Schottelius DD "Phenytoin and folic acid interaction: a preliminary report." Ther Drug Monit 5 (1983): 389-94

7. Alhadeff L, Gualtieri CT, Lipton M "Toxic effects of water-soluble vitamins." Nutr Rev 42 (1984): 33-40

8. Ch'ien LT, Krumdieck CL, Scott CW Jr, Butterworth CE Jr "Harmful effect of megadoses of vitamins: electroencephalogram abnormalities and seizures induced by intravenous folate in drug- treated epileptics." Am J Clin Nutr 28 (1975): 51-8

9. Katz M "Potential danger of self-medication with folic acid." N Engl J Med 289 (1973): 1095

10. Woodliff HJ, Davis RE "Allergy to folic acid." Med J Aust 1 (1966): 351-2

11. Tamura T, Goldenberg RL, Freeberg LE, Cliver SP, Cutter GR, Hoffman HJ "Maternal serum folate and zinc concentrations and their relationships to pregnancy outcome." Am J Clin Nutr 56 (1992): 365-70

12. Simmer K, Iles CA, James C, Thompson RP "Are iron-folate supplements harmful?" Am J Clin Nutr 45 (1987): 122-5

13. Kakar F, Henderson MM "Potential toxic side effects of folic acid." J Natl Cancer Inst 74 (1985): 263

14. Swinhoe DJ, Maclean AB, Gibson BE "Iron and folate supplements during pregnancy." BMJ 298 (1989): 118-9

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"Excessive doses of Folic Acid are not recommended for persons with compromised kidney function, due to Creatinine = 0.85 mg/dL (against an optimum level of 0.8 mg/dL) and Cystatin C = 0.85 mg/L (against an optimum level of 0.7 mg/L) coupled with higher levels of BUN and Uric Acid (5.2 mg/dL)which are well above the desirable levels."

The second point worth mentioning is the side effect of high Folic Acid.

Folic Acid interferes with the absorption of zinc. When taken for a long period, folic acid can lower the serum zinc levels of individuals. This is again reflected the poor value of TSH and the symptoms of Hypothyroidism which are presently seen

Another important effect of low zinc levels is the poor level of testosterone and consequently low libido.

Zinc plays a very important role in maintaining the immunity to fight infections of all sorts and in the functioning of the entire Endocrine System of the body including the production of insulin in the pancreas. This may be the cause of the pre-diabetic condition as fasting blood sugar levels are 98.6 mg/dL against an optimum level of 80.0 mg/dL.

I call B12 and Folic Acid as "drugs" even though they are dietary supplements, as the doses administered were way too high and a cause of serious concern and under these circumstances must be treated as "drugs".

Blessings,
Pramod Vora
Medical Scientist